

Currently Cleared CBER 510(k)s by Applicant As of 31-MAY-2026

BK980025-0 5D Information Management  
Suite 500, 10025 - 102A Avenue  
Edmonton, Alberta CANADA T5J 2Z2  
Trade Name: Plasma Center Module - 1.0  
Cleared Date: 18-MAY-1999  
Cleared Under Fifth Dimension Information Systems

BK990022-0 5D Information Management  
Suite 500, 10025 - 102A Avenue  
Edmonton, Alberta CANADA T5J 2Z2  
Trade Name: Donor Management System - 1.0.0  
Cleared Date: 10-SEP-1999  
Cleared Under Fifth Dimension Information Systems

BK000026-0 5D Information Management  
Suite 500, 10025 - 102A Avenue  
Edmonton, Alberta CANADA T5J 2Z2  
Trade Name: P2K Plasma Center Module 2000 -  
1.0  
Cleared Date: 22-JUN-2000  
Cleared Under Fifth Dimension Information Systems

BK020058-0 5D Information Management  
Suite 500, 10025 - 102A Avenue  
Edmonton, Alberta CANADA T5J 2Z2  
Trade Name: LOGIC - 1.0  
Cleared Date: 03-FEB-2003  
Cleared Under Fifth Dimension Information Systems

BK040040-0 5D Information Management  
Suite 500, 10025 - 102A Avenue  
Edmonton, Alberta CANADA T5J 2Z2  
Trade Name: LOGIC - 2.0  
Cleared Date: 06-OCT-2004  
Cleared Under Fifth Dimension Information Systems

BK050060-0 5D Information Management  
Suite 500, 10025 - 102A Avenue  
Edmonton, Alberta CANADA T5J 2Z2  
Trade Name: E-Interview (eQue) - 1.0.0  
Cleared Date: 24-MAY-2006  
Cleared Under Fifth Dimension Information Systems

BK060051-0 5D Information Management

Suite 500, 10025 - 102A Avenue  
Edmonton, Alberta CANADA T5J 2Z2  
Trade Name: HaemoConnect (eLynx) - 1.0.0  
Cleared Date: 06-MAR-2008

BK070011-0 ABSORBER AB  
Drottninggatan 33  
Stockholm, SWEDEN SE-103 95  
Trade Name: XM-ONE Transplantation Cross Match  
Cleared Date: 29-JUL-2008

BK960027-0 ADAC HealthCare Information System  
5 Greenway Plaza  
Suite 1900  
Houston, TX 77046  
Trade Name: ADAC Blood Bank System  
Cleared Date: 12-AUG-1998

BK180252-0 APEX Biologix  
5650 South Green St  
Murray, UT 84123  
Trade Name: XCELL PRP Platelet Concentrating  
System 60ml  
Cleared Date: 05-APR-2019

BK200512-0 ARC-One Solutions, LLC  
7901 Riviera Blvd  
Miramar, FL 33023  
Trade Name: Regulated Software Application  
(RSA) - Version 2.0  
Cleared Date: 15-OCT-2020

BK870009-0 ARK-Bio-Medical Canada Corp.  
#671 Rustico Road  
Winsloe, CANADA CIE 1Z2  
Trade Name: WesLabs Model 601  
Cleared Date: 15-NOV-1989  
Cleared Under Rush Enterprises, Inc.

BK130020-0 Abbott Laboratories  
Dept 09VA, Bldg AP8-1  
100 Abbott Park Road  
Abbott Park, IL 60064-3500  
Trade Name: ABBOTT PRISM Director  
Cleared Date: 14-MAY-2013

BK251234-0 Abbott Molecular  
1300 E Touhy Ave  
Des Plaines, IL 60018  
Trade Name: Alinity m HIV-1 AMP Kit

Alinity m HIV-1 Application  
Specification File  
Alinity m HIV-1 CAL Kit  
Alinity m HIV-1 CTRL Kit  
Cleared Date: 27-AUG-2025

BK810599-0 Accugenics, Inc.

Costa Mesa, CA 92626  
Trade Name: Dade Rh Control Reagent  
Cleared Date: 31-MAR-1981

BK820004-0 Accugenics, Inc.

Costa Mesa, CA 92626  
Trade Name: Trans-Type Reagents  
Cleared Date: 29-OCT-1982

BK830001-0 Accugenics, Inc.

Costa Mesa, CA 92626  
Trade Name: Polycation Potentiator System  
Cleared Date: 06-MAY-1983

BK860038-0 Accugenics, Inc.

Costa Mesa, CA 92626  
Trade Name: Data-Fi Thrombin Reagent  
Cleared Date: 16-JAN-1987

BK890018-0 Ackrad Laboratories

70 Jackson Dr.  
Cranford, NJ 07016  
Trade Name: Ackrad Blood Warming Assembly  
Cleared Date: 21-SEP-1990

BK960071-0 AcroMetrix Corporation

6058 Egret Court  
Benicia, CA 94510  
Trade Name: ViroSure Multi-Marker  
Cleared Date: 11-FEB-1998

BK040060-0 AcroMetrix Corporation

6058 Egret Court  
Benicia, CA 94510  
Trade Name: VeriSure Pro External Quality  
Controls  
Cleared Date: 03-MAY-2005

BK050061-0 AcroMetrix Corporation

6058 Egret Court  
Benicia, CA 94510

Trade Name: VeriSure Pro WNV RNA Negative  
External Quality Control  
VeriSure Pro WNV RNA Positive  
External Quality Control  
VeriSure Pro West Nile Virus (WNV)  
RNA External Quality Controls:  
Cleared Date: 21-DEC-2005

BK060064-0 AcroMetrix Corporation  
6058 Egret Court  
Benicia, CA 94510  
Trade Name: VeriSure Pro HBV DNA External  
Quality Control  
Cleared Date: 08-FEB-2007

BK960002-0 Activated Cell Therapy Inc.  
291 North Bernardo Avenue  
Mountain View, CA 94043  
Trade Name: ACT Buoyant Density Solution  
Cleared Date: 12-AUG-1996

BK190393-0 Aeon Biotherapeutics Corp.  
12F., No.58, Ruihu St.  
Taipei City, Neihu Dist TAIWAN 11494  
Trade Name: Aeon CPKit  
Autologous CellPrep Kit  
Cleared Date: 05-JUN-2020

BK231016-0 Aeon Biotherapeutics Corp.  
12F., No.58, Ruihu St.  
Taipei City, Neihu Dist TAIWAN 11494  
Trade Name: Aeon ACKit  
Cleared Date: 16-FEB-2024

BK150217-0 Alba Bioscience Limited  
5 James Hamilton Way  
Milton Bridge  
Penicuik, Midlothian UNITED KINGDOM EH26 0BF  
Trade Name: ALBAsure QC Kit  
Cleared Date: 01-APR-2015  
Cleared Under ALBA Bioscience Limited (doing business as Quotient)

BK170013-0 Alba Bioscience Limited  
21 Ellen's Glen Rd  
Edinburgh,  
Trade Name: AlbaQ-Chek (R) Simulated Whole  
Blood Controls, Model Z498  
Cleared Date: 09-MAY-2017

BK170086-0 Alba Bioscience Limited  
21 Ellen's Glen Rd  
Edinburgh,  
Trade Name: AlbaQ-Chek Simulated Whole Blood  
Controls  
Cleared Date: 20-OCT-2017

BK180286-0 Alba Bioscience Limited  
James Hamilton Way  
Penicuik, Midlothian UNITED KINGDOM EH26 0BF  
Trade Name: ALBAcyte IgG Sensitized Red Blood  
Cells II  
Cleared Date: 05-FEB-2019

BK190389-0 Alba Bioscience Limited  
James Hamilton Way  
Penicuik, Midlothian UNITED KINGDOM EH26 0BF  
Trade Name: ALBAcheck BGS Monoclonal Control  
ALBAcheck BGS Monoclonal Control  
Cleared Date: 26-NOV-2019

BK251265-0 Alba Bioscience Limited  
5 James Hamilton Way  
Milton Bridge  
Penicuik, Midlothian UNITED KINGDOM EH26 0BF  
Trade Name: ORTHO Elution Kit  
ORTHO Elution Kit (6324444)  
Cleared Date: 12-NOV-2025

BK251272-0 Alba Bioscience Limited  
5 James Hamilton Way  
Milton Bridge  
Penicuik, Midlothian UNITED KINGDOM EH26 0BF  
Trade Name: Alba Elution Kit  
Alba Elution Kit (FD313M)  
Cleared Date: 14-NOV-2025

BK160045-0 Alliance Partners LLC  
14206 Northbrook Drive  
San Antonio, TX 78232  
Trade Name: Cyclone Platelet Rich Plasma (PRP)  
Concentrating System  
Cleared Date: 04-NOV-2016

BK170108-0 Alliance Partners LLC  
14206 Northbrook Drive  
San Antonio, TX 78232  
Trade Name: Cyclone Blood & Bone Marrow  
Concentration (BBMC) System

Cleared Date: 02-JAN-2018

BK190361-0 Alliance Technologies, LLC  
1552 West Griswold Rd  
Phoenix,, AZ 85021  
Trade Name: BloodRelay 1.0.0  
Cleared Date: 17-SEP-2019

BK210620-0 Alliance Technologies, LLC  
1552 West Griswold Rd  
Phoenix,, AZ 85021  
Trade Name: BloodRelay - 1.0.0  
BloodRelay 1.1.0  
Cleared Date: 04-OCT-2021

BK220668-0 Alma Lasers, Inc  
485 Half Day Rd  
Suite 100  
Buffalo Grove, IL 60089  
Trade Name: LipoFlow System with VorFat Kit  
VorFat System  
Cleared Date: 12-JUN-2023

BK220713-0 Alma Lasers, Inc  
485 Half Day Rd  
Suite 100  
Buffalo Grove, IL 60089  
Trade Name: Alma LipoFlow System (K171242)  
Cleared Date: 14-JUL-2017

BK940054-0 Alpha Scientific Corporation  
P.O. Box 725  
Southeastern, PA 19399  
Trade Name: SEG-Safe (TM)  
Cleared Date: 15-MAR-1995

BK950014-0 Alpha Scientific Corporation  
P.O. Box 725  
Southeastern, PA 19399  
Trade Name: SEG-SAFE  
Cleared Date: 31-MAR-1995

BK860014-0 Alpha Therapeutic Corporation  
5555 Valley Boulevard  
Los Angeles, CA 90032  
Trade Name: JMS Double Blood Collection Pack  
Cleared Date: 04-JUN-1986

BK870004-0 Alpha Therapeutic Corporation  
5555 Valley Boulevard

Los Angeles, CA 90032  
Trade Name: Plasma Transfer Pack  
Cleared Date: 11-MAR-1987

BK950044-0 Alpha Therapeutic Corporation  
13111 Temple Avenue  
City of Industry, CA 91746  
Trade Name: Transfer Device  
Cleared Date: 18-OCT-1995

BK950021-0 Alton Dean Medical, Inc.  
1547 West 2290 South  
Woods Cross, UT 84087  
Trade Name: Alton Dean Model FW-437  
Cleared Date: 15-MAY-1995

BK960030-0 American Blood Resources Association  
PO Box 669  
Annapolis, MD 21404  
Trade Name: National Donor Deferral Registry  
Cleared Date: 20-MAR-1997

BK010012-0 American Blood Resources Association  
147 Old Solomons Island Rd.  
Annapolis, MD 21401  
Trade Name: National Donor Deferral Registry  
(NDDR) - 1.0  
Cleared Date: 06-SEP-2001

BK960040-0 American Red Cross  
Diagnostic Manufacturing Division  
2025 E Street NW  
Washington, DC 20006  
Trade Name: NBCS 1.1  
Cleared Date: 28-FEB-1997

BK090021-0 American Red Cross  
Diagnostic Manufacturing Division  
2025 E Street NW  
Washington, DC 20006  
Trade Name: Control Cells  
Cleared Date: 24-JUN-2009

BK120042-0 American Red Cross  
Diagnostic Manufacturing Division  
2025 E Street NW  
Washington, DC 20006  
Trade Name: DailyChek QC Kit  
Cleared Date: 06-OCT-2012

BK820016-0 American Red Cross Blood Services  
15601 Crabbs Branch Way  
Rockville, MD 20855  
Trade Name: ARC HLA Extended Trays  
ARC HLA Trays  
Cleared Date: 01-JUN-1983

BK840015-0 American Red Cross Blood Services  
15601 Crabbs Branch Way  
Rockville, MD 20855  
Trade Name: Bovine Albumin 3%  
Cleared Date: 25-OCT-1984

BK880021-0 American Red Cross Blood Services  
15601 Crabbs Branch Way  
Rockville, MD 20855  
Trade Name: Frozen-Dried Bromelain  
Cleared Date: 21-DEC-1988

BK020032-0 American Red Cross Blood Services  
Quality and Regulatory Affairs  
1616 Fort Myer Drive  
Arlington, VA 22209  
Trade Name: NGTL Automation System (NAS) -  
5.2.0  
Cleared Date: 20-MAR-2003

BK850010-0 Amtec Diagnostics International Inc.  
1107 IH-45 South  
Conroe, TX 77305  
Trade Name: Rh-Hr Control  
Cleared Date: 27-DEC-1985

BK850023-0 Amtec Diagnostics International Inc.  
1107 IH-45 South  
Conroe, TX 77305  
Trade Name: Amtec CM-Tec Control  
Cleared Date: 30-DEC-1985

BK860002-0 Amtec Diagnostics International Inc.  
1107 IH-45 South  
Conroe, TX 77305  
Trade Name: Bovine Albumin 22%  
Cleared Date: 03-MAR-1986

BK860003-0 Amtec Diagnostics International Inc.  
1107 IH-45 South  
Conroe, TX 77305  
Trade Name: Bovine Albumin 30%  
Cleared Date: 03-MAR-1986

BK860008-0 Amtec Diagnostics International Inc.  
1107 IH-45 South  
Conroe, TX 77305  
Trade Name: Amtec Anti-A1 Lectin  
Cleared Date: 16-JUN-1986

BK860009-0 Amtec Diagnostics International Inc.  
1107 IH-45 South  
Conroe, TX 77305  
Trade Name: Amtec Anti-N Lectin  
Cleared Date: 18-SEP-1987

BK860010-0 Amtec Diagnostics International Inc.  
1107 IH-45 South  
Conroe, TX 77305  
Trade Name: Amtec PS  
Cleared Date: 16-DEC-1986

BK860020-0 Amtec Diagnostics International Inc.  
1107 IH-45 South  
Conroe, TX 77305  
Trade Name: Amtec R-E-S System  
Cleared Date: 25-FEB-1987

BK860021-0 Amtec Diagnostics International Inc.  
1107 IH-45 South  
Conroe, TX 77305  
Trade Name: Amtec Coombs Control Cells  
Cleared Date: 26-AUG-1986

BK860026-0 Amtec Diagnostics International Inc.  
1107 IH-45 South  
Conroe, TX 77305  
Trade Name: Amtec Anti-H Lectin  
Cleared Date: 27-JAN-1987

BK860036-0 Amtec Diagnostics International Inc.  
1107 IH-45 South  
Conroe, TX 77305  
Trade Name: Model Series, Mini & BB  
Cleared Date: 24-FEB-1987

BK870020-0 Amtec Diagnostics International Inc.  
1107 IH-45 South  
Conroe, TX 77305  
Trade Name: Amtec Ficin System  
Cleared Date: 02-FEB-1988

BK220698-0 Andrew Technologies LLC

3 Haddon Ave  
Haddonfield, NJ 08033  
Trade Name: HYDRASOLVE LIPOPLASTY SYSTEM  
(K130152)  
Cleared Date: 18-APR-2013

BK010024-0 Applied Biosystems  
850 Lincoln Centre Drive  
Foster City, CA 94404  
Trade Name: ViroSeq HIV-1 Genotyping System  
Cleared Date: 10-DEC-2002

BK030005-0 Applied Biosystems  
1401 Harbor Bay Parkway  
Alameda, CA 94502  
Trade Name: ViroSeq HIV-1 Genotyping System  
Cleared Date: 29-JAN-2003

BK010031-0 Applied Science, Inc.  
964-B Golden Gate Terrace  
Grass Valley, CA 95945  
Trade Name: Hemoflow Model 400 with Data  
Scanner  
Cleared Date: 23-JAN-2002

BK990011-0 Applied Sciences, Inc.  
964-B Golden Gate Terrace  
Grass Valley, CA 95945  
Trade Name: HemoFlow Donor Monitor  
Cleared Date: 16-JUL-1999

BK990019-0 Applied Sciences, Inc.  
964-B Golden Gate Terrace  
Grass Valley, CA 95945  
Trade Name: HemoFlow Donor Monitor and Mixer  
Cleared Date: 05-OCT-1999

BK020031-0 Arlington Scientific, Inc.  
1840 North Technology Dr.  
Springville, UT 84663  
Trade Name: ASI TPHA Test  
Cleared Date: 30-JAN-2003

BK130001-0 Arlington Scientific, Inc.  
1840 North Technology Dr.  
Springville, UT 84663  
Trade Name: ASiManager-AT  
Cleared Date: 24-FEB-2014

BK140192-0 Arlington Scientific, Inc.

1840 North Technology Dr.  
Springville, UT 84663  
Trade Name: ASi Manager-AT  
Cleared Date: 19-FEB-2015

BK170114-0 Arlington Scientific, Inc.  
1840 North Technology Dr.  
Springville, UT 84663  
Trade Name: ASI Evolution - 2800-000  
Cleared Date: 28-DEC-2017

BK200488-0 Arlington Scientific, Inc.  
1840 North Technology Dr.  
Springville, UT 84663  
Trade Name: ASI Automated RPR test for  
Syphilis for use on the ASI  
Evolution  
ASI Evolution  
Cleared Date: 30-SEP-2020

BK200539-0 Arlington Scientific, Inc.  
1840 North Technology Dr.  
Springville, UT 84663  
Trade Name: ASI Automated RPR test for  
Syphilis for use on the ASI  
Evolution  
ASI Evolution  
Cleared Date: 02-FEB-2021

BK940022-0 Arrow International, Inc.  
P.O.Box 12888 3000 Bernville Road  
Reading, PA 19612  
Trade Name: Arrow Qwik-1 TM Blood and Fluid  
Administration Set  
Cleared Date: 14-JUL-1994

BK950036-0 Arrow International, Inc.  
P.O.Box 12888 3000 Bernville Road  
Reading, PA 19612  
Trade Name: Arrow High Flow Fluid Adm. Set  
with Blood Filter &  
Cleared Date: 02-AUG-1995

BK200540-0 Arteriocyte Medical Systems, Inc  
45 South Street, Suite 3  
Hopkinton, MA 01748  
Trade Name: Precise Cell Concentration System  
Cleared Date: 17-MAR-2022

BK251168-0 Arteriocyte Medical Systems, Inc.

45 South St.  
Hopkinton, MA 01748  
Trade Name: Precise Cell Concentration System  
Cleared Date: 03-FEB-2026

BK070069-0 Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, FL 34108  
Trade Name: Arthrex Double Syringe (ACP,  
Autologous Conditioned Plasma)  
System  
Cleared Date: 12-DEC-2008

BK170144-0 Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, FL 34108  
Trade Name: Arthrex Thrombinator System  
Thrombinator System for use with  
the Arthrex Angel concentrated  
Platelet Rich Plasma (PRP) System  
Cleared Date: 10-MAY-2018

BK180180-0 Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, FL 34108  
Trade Name: Arthrex Angel System Kits  
Cleared Date: 05-JUL-2018

BK180299-0 Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, FL 34108  
Trade Name: Arthrex Thrombinator System  
Cleared Date: 07-MAR-2019

BK190383-0 Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, FL 34108  
Trade Name: Arthrex Angel System  
Cleared Date: 18-SEP-2019

BK190406-0 Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, FL 34108  
Trade Name: Arthrex Double Syringe (ACP)  
System  
Cleared Date: 06-NOV-2019

BK200442-0 Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, FL 34108

Trade Name: Arthrex Double Syringe (ACP)  
System

Cleared Date: 09-JUL-2020

BK210655-0 Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, FL 34108  
Trade Name: Arthrex Autologous Conditioned  
Plasma (ACP) Max System  
Cleared Date: 22-SEP-2022

BK241060-0 Arthrex, Inc.  
1370 Creekside Boulevard  
Naples, FL 34108  
Trade Name: Arthrex Thrombinator System  
(ABS-10080)  
Cleared Date: 24-APR-2024

BK910017-0 Assoc. of Cape Cod  
P.O. Box 224  
Woods Hole, MA 02543  
Trade Name: Control Standard  
Endotoxin/Pepyrogeneration Valid.  
Cleared Date: 21-OCT-1991

BK940032-0 Augustine Medical, Inc.  
10393 West 70 th Street  
Eden Prairie, MN 55344  
Trade Name: Bair Hugger Patient Warming Device  
Cleared Date: 29-SEP-1994

BK130049-0 B.T.I Biotechnology Institute, S.L.  
Leonardo DaVinci 14  
Parque Tecnologico De Alava  
Minano, Alava SPAIN 01510  
Trade Name: BTI Biotechnology Institute S.L.  
Endoret Kit for Platelet and  
Plasma Separator  
Cleared Date: 16-JAN-2014

BK150294-0 B.T.I Biotechnology Institute, S.L.  
Leonardo DaVinci 14  
Parque Tecnologico De Alava  
Minano, Alava SPAIN 01510  
Trade Name: ENDORET Kit  
Cleared Date: 09-DEC-2015

BK251157-0 B.T.I Biotechnology Institute, S.L.  
Leonardo DaVinci 14  
Parque Tecnologico De Alava

Minano, Alava SPAIN 01510  
Trade Name: ENDORET Kit  
Cleared Date: 03-OCT-2025

BK930027-0 BBI Diagnostics, A SeraCare Company  
375 West Street  
West Bridgewater, MA 02379  
Trade Name: Accurun 1  
Cleared Date: 25-OCT-1994  
Cleared Under Boston Biomedica, Inc.

BK970004-0 BBI Diagnostics, A SeraCare Company  
375 West Street  
West Bridgewater, MA 02379  
Trade Name: ACCURUN155  
Cleared Date: 23-APR-1999  
Cleared Under Boston Biomedica, Inc.

BK990032-0 BBI Diagnostics, A SeraCare Company  
375 West Street  
West Bridgewater, MA 02379  
Trade Name: Accurun 106 HIV-1 Antigen  
Cleared Date: 20-JAN-2000  
Cleared Under Boston Biomedica, Inc.

BK010038-0 BBI Diagnostics, A SeraCare Company  
375 West Street  
West Bridgewater, MA 02379  
Trade Name: Accurun 1 Multimarker Negative  
Control  
Cleared Date: 18-DEC-2001  
Cleared Under Boston Biomedica, Inc.

BK040006-0 BBI Diagnostics, A SeraCare Company  
375 West Street  
West Bridgewater, MA 02379  
Trade Name: ACCURUN 315 HIV-1 RNA Positive  
Control  
Cleared Date: 12-OCT-2004  
Cleared Under Boston Biomedica, Inc.

BK040016-0 BBI Diagnostics, A SeraCare Company  
375 West Street  
West Bridgewater, MA 02379  
Trade Name: ACCURUN 305 HCV RNA Positive  
Quality Control  
Cleared Date: 17-DEC-2004  
Cleared Under Boston Biomedica, Inc.

BK040064-0 BBI Diagnostics, A SeraCare Company

375 West Street  
West Bridgewater, MA 02379  
Trade Name: ACCURUN 345 HIV-1 RNA, HCV RNA,  
HBV DNA Positive Quality Control  
Series 150  
Cleared Date: 29-OCT-2004  
Cleared Under Boston Biomedica, Inc.

BK040067-0 BBI Diagnostics, A SeraCare Company  
375 West Street  
West Bridgewater, MA 02379  
Trade Name: ACCURUN 803 Nucleic Acid Negative  
Quality Control (HIV, HCV, HBV)  
Cleared Date: 19-NOV-2004  
Cleared Under Boston Biomedica, Inc.

BK060022-0 BBI Diagnostics, A SeraCare Company  
375 West Street  
West Bridgewater, MA 02379  
Trade Name: ACCURUN 365 West Nile Virus RNA  
Positive Quality Control  
Cleared Date: 12-JUN-2006

BK060030-0 BBI Diagnostics, A SeraCare Company  
375 West Street  
West Bridgewater, MA 02379  
Trade Name: ACCURUN 804 Nucleic Acid Negative  
Quality Control (HIV, HCV, HBV,  
WNV)  
Cleared Date: 18-AUG-2006

BK100037-0 BBK Technology LLC  
2910 E Highland Ave  
Phoenix, AZ 85016  
Trade Name: RC-AID  
Cleared Date: 13-SEP-2010

BK030027-0 BD Biosciences  
2350 Qume Drive  
San Jose, CA 95131-1807  
Trade Name: BD IMAGN Microvolume Fluorimeter  
and BD IMAGN rWBC Assay Kit  
Cleared Date: 10-JUL-2003

BK050062-0 BD Biosciences  
2350 Qume Drive  
San Jose, CA 95131-1807  
Trade Name: BD HLA-B27 kit  
Cleared Date: 27-OCT-2005

BK050073-0 BD Biosciences  
2350 Qume Drive  
San Jose, CA 95131-1807  
Trade Name: BD HLA-B27 System  
Cleared Date: 16-FEB-2006

BK110037-0 BD Biosciences  
2350 Qume Drive  
San Jose, CA 95131-1807  
Trade Name: BD Stem Cell Enumeration Kit  
Cleared Date: 19-OCT-2011

BK150307-0 BD Biosciences  
2350 Qume Drive  
San Jose, CA 95131-1807  
Trade Name: BD FACSVia System with the BD  
Leucocount reagent Assay  
Cleared Date: 16-SEP-2016

BK970024-0 BECTON DICKINSON VACUTAINER Systems  
1 Becton Drive  
Franklin Lakes, NJ 07417  
Trade Name: Plasma Preparation Tube - PPT  
Cleared Date: 10-AUG-1998

BK980011-0 BECTON DICKINSON VACUTAINER Systems  
1 Becton Drive  
Franklin Lakes, NJ 07417  
Trade Name: VACUTAINER Brand PLUS (Plastic)  
Blood Collection Tube with EDTA  
Anticoagulant  
Cleared Date: 07-JUN-1999

BK210625-0 BIO RAD MEDICAL DIAGNOSTICS GMBH  
Industriestrasse 1  
, Dreieich GERMANY 63303  
Trade Name: IH-500  
Cleared Date: 28-FEB-2022

BK230971-0 BIO RAD MEDICAL DIAGNOSTICS GMBH  
Industriestrasse 1  
, Dreieich GERMANY 63303  
Trade Name: IH-500  
Cleared Date: 09-AUG-2023

BK210593-0 BIQ-Health Solutions, Lda  
Rua ferreira de Castro, 20C  
Barcarena, Lisbon PORTUGAL 2730-081  
Trade Name: BTrac  
Cleared Date: 13-AUG-2021

BK820008-0 BMT Incorporated  
7315 Hazeltine Boulevard  
Excelsior, MN 55331  
Trade Name: BMT Model 24 Bloodmixer  
Cleared Date: 22-OCT-1982

BK220715-0 BSL Co.  
6-13, Chilsan-ro 237beon-gil  
, Gimhae-si, Gyeongsangnam-do KOREA, SOUTH 51006  
Trade Name: Automatic Tissue Processing Unit  
(K172717)  
Cleared Date: 25-MAY-2018

BK220722-0 BSL Co.  
6-13, Chilsan-ro 237beon-gil  
, Gimhae-si, Gyeongsangnam-do KOREA, SOUTH 51006  
Trade Name: Smart Kit Basic, Smart Kit Pro  
(K202443)  
Cleared Date: 11-MAR-2021

BK251248-0 Bahia Medical  
7250 Dallas Parkway  
Suite 400  
Plano, TX 75024  
Trade Name: PRiSM PRP, 10 mL (PRP10)  
PRiSM PRP, 20 mL (PRP20)  
PRiSM PRP, 30 mL (PRP30)  
PRiSM PRP, 40 mL (PRP40)  
Cleared Date: 23-DEC-2025

BK940031-0 Bard Radiology  
10115 Highway 142  
Covington, GA 30209  
Trade Name: True-Pulse Infusion Catheter  
Cleared Date: 27-APR-1995

BK100063-0 Barkey GmbH & Co KG  
Gewerbestrasse 8  
D-33818 Leopoldshoehe  
, Leopoldshoehe GERMANY 33818  
Trade Name: plasmatherm  
Cleared Date: 14-SEP-2017

BK170028-0 Baxalta US Inc.  
One Baxter Way  
Westlake Village, CA 91362  
Trade Name: myPKFiT for ADVATE Version 2.0  
Cleared Date: 14-DEC-2017

BK900010-0 Baxter Healthcare Corporation  
1851 Delaware Parkway  
Miami, FL 33152  
Trade Name: Dade Chemically Modified Control  
Reagent  
Cleared Date: 21-SEP-1990

BK920025-0 Baxter Healthcare Corporation  
1 Baxter Pkwy.  
Deerfield, IL 60015  
Trade Name: Dade Fetal-Cyte Screening Kit  
Cleared Date: 05-AUG-1993

BK940062-0 Baxter Healthcare Corporation  
1 Baxter Pkwy.  
Deerfield, IL 60015  
Trade Name: Cryocyte TM  
Cleared Date: 27-DEC-1994

BK950049-0 Baxter Healthcare Corporation  
9 Parker  
Irvine, CA 92618  
Trade Name: Cryocyte Freezing Container  
Cleared Date: 14-FEB-1996

BK960010-0 Baxter Healthcare Corporation  
9 Parker  
Irvine, CA 92618  
Trade Name: Cell Wash Set  
Cleared Date: 22-MAY-1996

BK980001-0 Baxter Healthcare Corporation  
1 Baxter Pkwy.  
Deerfield, IL 60015  
Trade Name: CulturePro Tissue Culture Flask  
Cleared Date: 19-FEB-1998

BK980012-0 Baxter Healthcare Corporation  
1 Baxter Pkwy.  
Deerfield, IL 60015  
Trade Name: N/A  
Cleared Date: 18-MAY-1998

BK020002-0 Baxter Healthcare Corporation  
550 North Brand Blvd.  
Glendale, CA 91203  
Trade Name: Serology SQL LIMS - 1.0  
Cleared Date: 07-AUG-2002

BK020059-0 Baxter Healthcare Corporation

25212 West ILL Route 120  
RoundLake, IL 60073  
Trade Name: ALYX Component Collection System  
Cleared Date: 23-JAN-2003

BK170033-0 Baxter Healthcare Corporation  
32650 North Wilson Rd  
Round Lake, IL 60073  
Trade Name: DUO Set  
DUO Set A  
DUPLOCATH Application Catheter  
DUPLOJECT  
Cleared Date: 24-JUL-2017

BK030052-0 Bayer HealthCare Diagnostics Division  
700 BAY Street, Suite 1000  
Toronto, Ontario M5G 1Z6 CANADA  
Trade Name: TRUGENE HIV-1 Genotyping Kit and  
OpenGene DNA Sequencing System  
Cleared Date: 08-OCT-2003

BK040052-0 Bayer HealthCare Diagnostics Division  
700 BAY Street, Suite 1000  
Toronto, Ontario M5G 1Z6 CANADA  
Trade Name: TRUGENE HIV-1 Genotyping Kit and  
OpenGene DNA Sequencing System  
Cleared Date: 15-OCT-2004

BK050035-0 Bayer HealthCare Diagnostics Division  
P.O. Box 2466  
Berkeley, CA 94702-5828  
Trade Name: TRUGENE HIV-1 Genotyping Kit and  
OpenGene DNA Sequencing System  
Cleared Date: 20-SEP-2005

BK010044-0 Beckman Coulter, Inc.  
11800 SW 147 Avenue  
(M/C: 31-B06)  
Miami, FL 33196-2500  
Trade Name: stemONE System for EPICS XL/  
XL-MCL Flow Cytometry Systems  
Cleared Date: 20-MAY-2002

BK020063-0 Beckman Coulter, Inc.  
11800 SW 147 Avenue  
(M/C: 31-B06)  
Miami, FL 33196-2500  
Trade Name: LeukoSure Enumeration Kit with  
Leuko-Trol RBC Control Cells and  
Leuko Trol Platelet Control Cells

Cleared Date: 03-FEB-2003

BK040032-0 Beckman Coulter, Inc.  
11800 SW 147 Avenue  
(M/C: 31-B06)  
Miami, FL 33196-2500  
Trade Name: Stem-Kit Reagents  
Cleared Date: 05-MAY-2004

BK040055-0 Beckman Coulter, Inc.  
11800 SW 147 Avenue  
(M/C: 31-B06)  
Miami, FL 33196-2500  
Trade Name: stemCXP System for the FC 500 with  
CXP Software  
Cleared Date: 16-SEP-2004

BK180292-0 Beckman Coulter, Inc.  
250 South Kraemer Blvd  
Brea, CA 92821  
Trade Name: PK7400 Automated Microplate System  
Cleared Date: 07-MAY-2020

BK210639-0 Beckman Coulter, Inc.  
11800 SW 147 Avenue  
(M/C: 31-B06)  
Miami, FL 33196-2500  
Trade Name: Stem-Kit Reagents, stemCXP System  
Cleared Date: 15-DEC-2021

BK230833-0 Beckman Coulter, Inc.  
1000 Lake Hazeltine Dr  
Chaska, MN 55318  
Trade Name: Access HIV Ag/Ab combo  
Access HIV Ag/Ab combo Calibrators  
Access HIV Ag/Ab combo QC  
Cleared Date: 27-JUL-2023

BK230961-0 Beckman Coulter, Inc.  
11800 SW 147 Avenue  
(M/C: 31-B06)  
Miami, FL 33196-2500  
Trade Name: AQUIOS CL Flow Cytometer  
AQUIOS STEM Kit  
Cleared Date: 01-SEP-2023

BK930010-0 Becton Dickinson Immunocytometry Systems  
2350 Qume Drive  
San Jose, CA 95131  
Trade Name: HLA-B27 Screening Systems

Cleared Date: 09-SEP-1993

BK940015-0 Becton Dickinson Immunocytometry Systems  
2350 Qume Drive  
San Jose, CA 95131  
Trade Name: The HLA-B27 System  
Cleared Date: 24-OCT-1994

BK960087-0 Becton Dickinson Immunocytometry Systems  
2350 Qume Drive  
San Jose, CA 95131  
Trade Name: ProCount Progenitor Cell  
Enumeration Kit  
Cleared Date: 04-JUN-1998

BK970038-0 Becton Dickinson Immunocytometry Systems  
2350 Qume Drive  
San Jose, CA 95131  
Trade Name: Procount Software  
Cleared Date: 04-FEB-1999

BK970046-0 Becton Dickinson Immunocytometry Systems  
2350 Qume Drive  
San Jose, CA 95131  
Trade Name: LeucoCOUNT Reagent  
Cleared Date: 14-AUG-1998

BK950068-0 Becton, Dickinson & Company  
1 Becton Drive  
Franklin Lakes, NJ 07417-1885  
Trade Name: CMV Scan Card Test  
Cleared Date: 22-DEC-1995

BK040030-0 Becton, Dickinson & Company  
1 Becton Drive  
Franklin Lakes, NJ 07417-1885  
Trade Name: BD Vacutainer Plus Plastic Serum  
Tubes with Clot Activator  
Cleared Date: 05-MAY-2004

BK050036-0 Becton, Dickinson & Company  
1 Becton Drive  
Franklin Lakes, NJ 07417-1885  
Trade Name: BD Vacutainer Plus K2EDTA Tubes  
BD Vacutainer Plus Serum Tubes  
BD Vacutainer SST Glass Tubes  
BD Vacutainer SST II Advance Tubes  
BD Vacutainer SST Plus Tubes  
Cleared Date: 24-FEB-2006

BK060046-0 Becton, Dickinson & Company  
1 Becton Drive  
Franklin Lakes, NJ 07417-1885  
Trade Name: Bd.id Patient Identification  
System for Transfusion Management  
- V7.00  
Cleared Date: 13-FEB-2007

BK180211-0 Becton, Dickinson & Company  
7 Loveton Circle, MC 694  
Sparks, MD 21152-0999  
Trade Name: BD BACTEC Platelet Aerobic/F  
Culture vials  
BD BACTEC Platelet Anaerobic/F  
Culture Vials  
Cleared Date: 08-AUG-2018

BK200530-0 Becton, Dickinson & Company  
7 Loveton Circle, MC 694  
Sparks, MD 21152-0999  
Trade Name: BD BACTEC Platelet Aerobic/F  
Culture Vials  
BD BACTEC Platelet Anaerobic/F  
Culture Vials  
Cleared Date: 23-DEC-2020

BK210649-0 Becton, Dickinson & Company  
1 Becton Drive  
Franklin Lakes, NJ 07417-1885  
Trade Name: BD Vacutainer ACD A Blood  
Collection Tube  
BD Vacutainer ACD B Blood  
Collection Tube  
Cleared Date: 21-JAN-2022

BK210652-0 Becton, Dickinson & Company  
2350 Qume Dr  
San Jose, CA 95131  
Trade Name: BD Stem Cell Enumeration Kit  
Cleared Date: 27-JAN-2022

BK230835-0 Becton, Dickinson & Company  
2350 Qume Dr  
San Jose, CA 95131  
Trade Name: BD FACSLyric Flow Cytometer  
(662875, 662876, 662877, 662878,  
663518)  
BD FACSuite Clinical BD  
Leucocount Assay Module (665732)  
BD Leucocount Kit

BD Leucocount Kit (662415)  
Cleared Date: 24-JUL-2023

BK230980-0 Becton, Dickinson & Company  
7 Loveton Circle, MC 694  
Sparks, MD 21152-0999  
Trade Name: BD Vacutainer K2 EDTA (K2E)  
BD Vacutainer K2EDTA Blood  
Collection Tubes  
BD Vacutainer Plus K2EDTA Blood  
Collection Tubes  
BD Vacutainer Plus K2EDTA Tubes  
Cleared Date: 17-APR-2024

BK960001-0 Behring Diagnostics  
175 University Avenue  
Westwood, MA 02090  
Trade Name: OPUS CMV  
Cleared Date: 09-OCT-1996

BK850022-0 Bellhouse Medical Products Ltd.  
Larkhill House; Abingdon  
Oxford, OX 14 1AS,  
Trade Name: Platelet Screening Test  
Cleared Date: 12-NOV-1985

BK150301-0 Belmont Instrument Corporation  
780 Boston Road  
Billerica, MA 01821  
Trade Name: The Belmont buddy(TM) 2  
Blood/Fluid Warmer  
Cleared Date: 02-SEP-2015

BK251296-0 Bimini Health Tech  
8400 Belleview Drive  
Suite 125  
Plano, TX 75024  
Trade Name: PUREGRAFT SYNC Adipose Filtration  
System  
Cleared Date: 12-FEB-2026

BK140112-0 Bio-Rad Laboratories  
6565 185th Ave NE  
Clinical Diagnostics Group  
Redmond, WA 98052-5039  
Trade Name: BioPlex? 2200 System  
Cleared Date: 23-JUL-2015

BK251254-0 Bio-Rad Laboratories, Inc.  
14620 NE North Woodinville Way

Woodinville, WA 98072  
Trade Name: Geenius HIV 1/2 Supplemental Assay  
Cleared Date: 26-AUG-2025

BK130070-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: MLB 2 10 x 10 mL  
Cleared Date: 27-NOV-2013

BK140106-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: IH-1000  
Cleared Date: 20-OCT-2016

BK140107-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: IH-COM  
Cleared Date: 20-OCT-2016

BK140138-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: IH-Card Neutral  
Cleared Date: 20-OCT-2016

BK140139-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: IH-Card Control  
Cleared Date: 20-OCT-2016

BK150327-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: Tango Infinity TM  
Cleared Date: 16-DEC-2015

BK170019-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: IH-1000 (Model# 001100)  
Cleared Date: 05-MAY-2017

BK170021-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: IH-Com V5.0

Cleared Date: 05-MAY-2017

BK170064-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: IH-Internal QC  
Cleared Date: 18-DEC-2017

BK170065-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: IH-Centtrifuge L  
Cleared Date: 18-DEC-2017

BK170066-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: IH-Incubator L  
Cleared Date: 18-DEC-2017

BK170071-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: IH-Com V5.0  
Cleared Date: 26-SEP-2017

BK170075-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: IH-Basic QC  
IH-QC System  
Cleared Date: 20-DEC-2017

BK180174-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: IH-Com V5.0  
Cleared Date: 01-MAY-2018

BK180175-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: TANGO Infinity  
Cleared Date: 01-MAY-2018

BK180225-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: IH-Reader 24  
Cleared Date: 28-SEP-2018

BK180226-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: IH-Com V5.0  
Cleared Date: 28-SEP-2018

BK180274-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: IH-500 Analyzer  
Cleared Date: 21-MAR-2019

BK180275-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: IH-Com - 5.0  
Cleared Date: 21-MAR-2019

BK190312-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: TANGO infinity  
Cleared Date: 25-APR-2019

BK190388-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: TANGO Infinity  
Cleared Date: 13-DEC-2019

BK190424-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: IH-COM V5.2 - 12010236  
Cleared Date: 20-DEC-2019

BK200548-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: IH-1000  
Cleared Date: 12-JAN-2021

BK220769-0 Bio-Rad Medical Diagnostics GmbH  
Industriestrasse 1  
Dreieich, GERMANY 63303  
Trade Name: IH-AbID  
Cleared Date: 07-DEC-2022

BK970035-0 BioAccess, Inc.

8400 Cedar Street  
Silver Spring, MD 20910  
Trade Name: Bioaccess Marrow Collection System  
Cleared Date: 23-DEC-1998

BK130050-0 BioArray Solutions, Ltd.  
35 Technology Drive  
Suite 100  
Warren, NJ 07059  
Trade Name: BeadCheck HEA Positive Control  
Cleared Date: 21-MAY-2014

BK130051-0 BioArray Solutions, Ltd.  
35 Technology Drive  
Suite 100  
Warren, NJ 07059  
Trade Name: BioArray Imaging System (AIS) 400C  
Cleared Date: 21-MAY-2014

BK150270-0 BioArray Solutions, Ltd.  
35 Technology Drive  
Suite 100  
Warren, NJ 07059  
Trade Name: Array Imaging System AS 400D  
Cleared Date: 15-JUN-2015

BK000046-0 BioE, Inc.  
4280 Centerville Road  
St. Paul, MN 55127  
Trade Name: FluoroTrol Control Kits  
Cleared Date: 02-APR-2001  
Cleared Under BioErgonomics, Inc.

BK070067-0 BioE, Inc.  
4280 Centerville Road  
St. Paul, MN 55127  
Trade Name: PrepaCyte(R)-CB Processing System  
Cleared Date: 17-DEC-2008

BK150347-0 BioLife Plasma Services L.P. - Baxalta US Inc  
440 N. Fairway Drive, 2W - 141  
Vernon Hills, IL 60061  
Trade Name: Lookback Notification System  
(LNS), Version 1.0  
Cleared Date: 12-FEB-2016

BK160103-0 BioLife Plasma Services L.P. - Baxalta US Inc  
440 N. Fairway Drive, 2W - 141  
Vernon Hills, IL 60061  
Trade Name: Automated Plasma Dispositioning

System (APDS) - Version 2.0  
Cleared Date: 15-NOV-2016

BK050029-0 BioLife Plasma Services LP  
One Baxter Parkway  
Deerfield, IL 60015  
Trade Name: Donor Information System (DIS) -  
3.1  
Cleared Date: 07-JUL-2005

BK060017-0 BioLife Plasma Services LP  
One Baxter Parkway  
Deerfield, IL 60015  
Trade Name: Donor Information System (DIS) -  
3.2  
Cleared Date: 09-MAY-2006

BK080016-0 BioLife Plasma Services LP  
One Baxter Parkway  
Deerfield, IL 60015  
Trade Name: Donor Information System - v3.3  
Cleared Date: 02-JUL-2008

BK090001-0 BioLife Plasma Services LP  
One Baxter Parkway  
Deerfield, IL 60015  
Trade Name: Donor Information System (DIS) -  
version 4.0  
Cleared Date: 18-AUG-2009

BK100021-0 BioLife Plasma Services LP  
One Baxter Parkway  
Deerfield, IL 60015  
Trade Name: Donor Information System (DIS)  
Cleared Date: 18-JUN-2010

BK120064-0 BioLife Plasma Services LP  
One Baxter Parkway  
Deerfield, IL 60015  
Trade Name: Donor Information System (DIS) v  
6.0  
Cleared Date: 19-DEC-2012

BK120069-0 BioLife Plasma Services LP  
One Baxter Parkway  
Deerfield, IL 60015  
Trade Name: Automated Plasma DIspositioning  
System (APDS) v1.0  
Cleared Date: 31-MAY-2013

BK140164-0 BioLife Plasma Services LP  
 One Baxter Parkway  
 Deerfield, IL 60015  
 Trade Name: Donor Information System (DIS) -  
 7.0  
 Cleared Date: 20-OCT-2014

BK241136-0 BioLife Plasma Services LP  
 1200 Lakeside Drive  
 Bannockburn, IL 60015  
 Trade Name: Lookback Notification System - 2.0  
 Cleared Date: 20-FEB-2025

BK970017-0 BioMerieux  
 1022 Hingham Street  
 Rockland, MA 02370  
 Trade Name: HLA-DR Oligo Detection Kit  
 Cleared Date: 28-MAY-1998

BK251216-0 BioMonde  
 62 Forest Street  
 Suite 300  
 Marlborough, MA 01752  
 Trade Name: FBioMonde Larval Debridemntl  
 Therapy Products - BioBag  
 50/I100/200/300/400  
 FBioMonde Larval Debridemntl  
 Therapy Products - BioBag  
 50/I100/200/300/400 (K131221)  
 Larval Debridemnt Therapy Products  
 - BioBag 50/I100/200/300/400  
 (K131221)  
 Cleared Date: 28-AUG-2013

BK251219-0 BioMonde  
 62 Forest Street  
 Suite 300  
 Marlborough, MA 01752  
 Trade Name: BIOMONDE LARVAL DEBRIDEMENT  
 THERAPY PRODUCTS, LARVAE  
 100/200/300 AND BIOBAG  
 50/100/200/300/400 (K142020)  
 BioMonde Larval Debridement  
 Therapy Products - BioBag  
 50/100/200/300/400  
 BioMonde Larval Debridement  
 Therapy Products - BioBag  
 50/100/200/300/400 (K142020)  
 Cleared Date: 05-NOV-2014

BK130028-0 Biofortuna LTD  
1 Hawkshead Road  
Croft Business Park  
Wirral  
, Merseyside UNITED KINGDOM CH62 3RJ  
Trade Name: Biofortuna Ltd. SSPGo HLA Typing  
Kit  
Cleared Date: 19-DEC-2013  
Cleared Under Biofortuna LTD

BK090082-0 Biomat USA, Inc.  
1311 Temple Avenue  
City of Industry, CA 91746  
Trade Name: SGP Version 7.0 (Plasma Management  
System)  
Cleared Date: 01-OCT-2010

BK180240-0 Biomat USA, Inc.  
2410 Lillyvale Ave  
Los Angeles, CA 90032  
Trade Name: GDS (Grifols Donation System) -  
1.0  
Cleared Date: 05-NOV-2018

BK200517-0 Biomat USA, Inc.  
2410 Lillyvale Ave  
Los Angeles, CA 90032  
Trade Name: GDS (Grifols Donation System)  
Cleared Date: 05-NOV-2020

BK020019-0 Biomet Biologics, Inc.  
56 East Bell Drive  
PO Box 587  
Warsaw, IN 46581-0587  
Trade Name: PCCS Graft Delivery System  
Cleared Date: 19-JUN-2002

BK040036-0 Biomet Biologics, Inc.  
56 East Bell Drive  
PO Box 587  
Warsaw, IN 46581-0587  
Trade Name: GPS II Platelet Concentrate  
Separation Kit  
Cleared Date: 18-JUN-2004  
Cleared Under Biomet, Inc.

BK050016-0 Biomet Biologics, Inc.  
56 East Bell Drive  
PO Box 587  
Warsaw, IN 46581-0587

Trade Name: Fibrostik Plasma Concentrator  
Cleared Date: 20-JUL-2005  
Cleared Under Biomet, Inc.

BK070003-0 Biomet Biologics, Inc.  
56 East Bell Drive  
PO Box 587  
Warsaw, IN 46581-0587  
Trade Name: GPS II Platelet Concentration  
Separation Kit with ACD-A  
Plasmax Plasma Concentrator with  
GPS Mini Platelet Concentrate  
Separation Kit with ACD-A  
Cleared Date: 22-FEB-2007  
Cleared Under Biomet, Inc.

BK070026-0 Biomet Biologics, Inc.  
56 East Bell Drive  
PO Box 587  
Warsaw, IN 46581-0587  
Trade Name: GPS III Mini Platelet Concentrate  
Separation Kit with ACD-A  
GPS III Platelet Concentrate  
Separation Kit with ACD-A  
GPS III Platelet Concentrate  
Separation Kit with ACD-A Double  
Kit  
Cleared Date: 06-JUN-2007  
Cleared Under Biomet, Inc.

BK070036-0 Biomet Biologics, Inc.  
56 East Bell Drive  
PO Box 587  
Warsaw, IN 46581-0587  
Trade Name: Vortech Concentration System  
Cleared Date: 21-NOV-2007

BK080004-0 Biomet Biologics, Inc.  
56 East Bell Drive  
PO Box 587  
Warsaw, IN 46581-0587  
Trade Name: Clotalyst and GPS III Mini  
Platelet Concentrate Separation  
Kit with ACD-A  
Clotalyst and GPS III Platelet  
Concentrate Separation Kit with  
ACD-A  
Cleared Date: 14-SEP-2017

BK090008-0 Biomet Biologics, Inc.

56 East Bell Drive  
PO Box 587  
Warsaw, IN 46581-0587  
Trade Name: MarrowStim Concentration System  
Cleared Date: 18-DEC-2009

BK090023-0 Biomet Biologics, Inc.  
56 East Bell Drive  
PO Box 587  
Warsaw, IN 46581-0587  
Trade Name: CoAxial Applicator System  
Cleared Date: 07-AUG-2009

BK100027-0 Biomet Biologics, Inc.  
56 East Bell Drive  
PO Box 587  
Warsaw, IN 46581-0587  
Trade Name: BioCUE Platelet Concentration Kit  
Cleared Date: 26-MAY-2010

BK110040-0 Biomet Biologics, Inc.  
56 East Bell Drive  
PO Box 587  
Warsaw, IN 46581-0587  
Trade Name: Clotalyst Kit with GPS(R)III  
Separator  
Cleared Date: 23-DEC-2011

BK220690-0 Biomet Biologics, Inc.  
56 East Bell Drive  
PO Box 587  
Warsaw, IN 46581-0587  
Trade Name: FAT CONCENTRATION SYSTEM (K100114)  
Cleared Date: 29-SEP-2010

BK230844-0 Biomet Biologics, Inc.  
56 East Bell Drive  
PO Box 587  
Warsaw, IN 46581-0587  
Trade Name: nSTRIDE APS PRP Concentration  
System  
nSTRIDE PRP Concentration System  
Cleared Date: 09-AUG-2023

BK970015-0 Biometric Imaging, Inc.  
1025 Terra Bella Avenue  
Mountain View, CA 94043  
Trade Name: CEQer RBC Assay  
Cleared Date: 18-SEP-1998

BK970016-0 Biometric Imaging, Inc.  
1025 Terra Bella Avenue  
Mountain View, CA 94043  
Trade Name: CEQer PRP Assay  
Cleared Date: 18-SEP-1998

BK970018-0 Biometric Imaging, Inc.  
1025 Terra Bella Avenue  
Mountain View, CA 94043  
Trade Name: STELLer CD34 Assay  
Cleared Date: 18-AUG-1998

BK251214-0 Biomonde (A Trading name of Zoobiotic Limited)  
225 Turnpike Road  
Southborough,, MA 01772  
Trade Name: BioMonde Larval Debridement  
Therapy Products-Larvae  
100/200/300  
BioMonde Larval Debridement  
Therapy Products-Larvae  
100/200/300 (K123449)  
Larval Debridement Therapy  
Products-Larvae 100/200/300  
(K123449)  
Cleared Date: 05-MAR-2013

BK251217-0 Biopharm (UK) Ltd.  
2 Bryngwili Road  
Hendy, Carmarthenshire UNITED KINGDOM SA4 OXT  
Trade Name: MEDICINAL LEECHES (K132958)  
Medicinal Leech  
Medicinal Leech (K132958)  
Cleared Date: 19-FEB-2014

BK980035-0 Biopool International, Inc.  
1230 Wilson Drive  
West Chester, PA 19380-4254  
Trade Name: SliDe Chek  
Cleared Date: 11-JUN-1999

BK090037-0 Biosafe SA  
Route du Petit-Eysins  
Eysins, Vaud SWITZERLAND 1262  
Trade Name: CryoSC Freezing Bag  
Cleared Date: 22-MAR-2010

BK110022-0 Biosafe SA  
Route du Petit-Eysins  
Eysins, Vaud SWITZERLAND 1262  
Trade Name: Sepax Cell Separation and single

use kits  
Cleared Date: 28-OCT-2011

BK140203-0 Biosafe SA  
Route du Petit-Eysins  
Eysins, Vaud SWITZERLAND 1262  
Trade Name: Sepax Cell Separation System and  
Single Use Kits  
Cleared Date: 13-FEB-2015

BK840028-0 Biotech Research Laboratories, Inc.  
1600 East Gude Drive  
Rockville, MD 20850  
Trade Name: Run Control for HBsAg Assay  
Cleared Date: 25-JAN-1985

BK090069-0 Biotechnology Institute, SL.  
C/Leonardo Da Vinci 14B, 1B.  
01510 Minano (Alava)  
Alava, SPAIN 01510  
Trade Name: Endoret Kit  
Secondary Product Code: FMI, GKT  
Cleared Date: 01-FEB-2010

BK060066-0 Biotest AG  
Postfach 10 20 40  
D-63266 Dreieich, GERMANY  
Trade Name: TANGO Automated Blood Bank  
Analyzer System, Version 3.0  
Service Pack 4  
Cleared Date: 17-JAN-2007

BK950015-0 Biotest Diagnostics Corporation  
66 Ford Road, Suite 131  
Denville, NJ 07834  
Trade Name: Biotest DRB-SSO Typing Kit  
Cleared Date: 09-JUN-1995

BK960061-0 Biotest Diagnostics Corporation  
66 Ford Road, Suite 131  
Denville, NJ 07834  
Trade Name: Biotest DQB-ELPHA  
Cleared Date: 04-AUG-1997

BK960086-0 Biotest Diagnostics Corporation  
66 Ford Road, Suite 131  
Denville, NJ 07834  
Trade Name: Biotest High Resolution  
Supplementary Kit  
Cleared Date: 03-JUL-1997

BK980007-0 Biotest Diagnostics Corporation  
66 Ford Road, Suite 131  
Denville, NJ 07834  
Trade Name: BIOTEST DRB-ELPHA Low Resolution  
(Enzyme Linked Probe Hybridization  
Assay)  
Cleared Date: 26-JAN-1999

BK980033-0 Biotest Diagnostics Corporation  
66 Ford Road, Suite 131  
Denville, NJ 07834  
Trade Name: LYMPHOSCREEN ABC 60  
Cleared Date: 15-DEC-1999

BK980044-0 Biotest Diagnostics Corporation  
66 Ford Road, Suite 131  
Denville, NJ 07834  
Trade Name: Lymphoscreen DR 30 x 2  
Cleared Date: 15-DEC-1999

BK020004-0 Biotest Diagnostics Corporation  
66 Ford Road, Suite 131  
Denville, NJ 07834  
Trade Name: Biotest HLA SSP Kit  
Cleared Date: 07-AUG-2002

BK080012-0 Biotest Medical Diagnostics GmbH  
P.O. Box 10 21 50  
63267 Dreiech, GERMANY  
Trade Name: (1) Seraclone Control ABO+Rh  
(2) Coombscell-E  
(3) MLB2  
Cleared Date: 23-JUL-2008

BK080013-0 Biotest Medical Diagnostics GmbH  
P.O. Box 10 21 50  
63267 Dreiech, GERMANY  
Trade Name: Alsevers Solution (510(k) exempt  
but part of system)  
Solidscreen II Control B  
Solidscreen Negative Control  
Tango Optimo Automated Blood Bank  
Analyzer System with version 3.1  
Cleared Date: 23-JUL-2008

BK820009-0 Biotest-Serum-Institut GmbH  
Flughafenstrasse 4  
6000 Frankfurt/Main 73, GERMANY  
Trade Name: Anti-HLA Leukocyte Typing Serum

Cleared Date: 20-JAN-1983

BK820011-0 Biotest-Serum-Institut GmbH  
Flughafenstrasse 4  
6000 Frankfurt/Main 73, GERMANY  
Trade Name: Microdroplet Testing Tray  
(Lymphotype ABC-72 Well)  
Cleared Date: 20-JAN-1983

BK830027-0 Biotest-Serum-Institut GmbH  
Flughafenstrasse 4  
6000 Frankfurt/Main 73, GERMANY  
Trade Name: Microtest Testing Tray (HLA-DR  
Wells)  
Cleared Date: 26-APR-1984

BK170150-0 Biowy Corporation  
27031 Vista Terrace  
Lake Forest, CA 92630  
Trade Name: Biowy Freezing Bag FB1000  
Biowy Freezing Bag FB250  
Biowy Freezing Bag FB50  
Biowy Freezing Bag FB500  
Cleared Date: 11-MAY-2018

BK261343-0 Biowy Corporation  
27031 Vista Terrace  
Lake Forest, CA 92630  
Trade Name: Biowy Multi-Chamber Freezing Bag  
Set  
Cleared Date: 29-APR-2026

BK890015-0 Blackhawk BioSystems, Inc.  
12945 Alcosta Blvd.  
San Ramon, CA 94583  
Trade Name: Blood Screening/Diagnostic Serum  
Controls  
Cleared Date: 17-APR-1992

BK890019-0 Blackhawk BioSystems, Inc.  
12945 Alcosta Blvd.  
San Ramon, CA 94583  
Trade Name: Blood Bank Saline  
Cleared Date: 18-JUL-1990

BK920008-0 Blackhawk BioSystems, Inc.  
12945 Alcosta Blvd.  
San Ramon, CA 94583  
Trade Name: VIROTROL  
Cleared Date: 17-SEP-1992

BK920028-0 Blackhawk BioSystems, Inc.  
12945 Alcosta Blvd.  
San Ramon, CA 94583  
Trade Name: Virotrol HIV-2  
Cleared Date: 03-JUN-1993

BK930016-0 Blackhawk BioSystems, Inc.  
12945 Alcosta Blvd.  
San Ramon, CA 94583  
Trade Name: Virotrol I Reagents (CMV)  
Cleared Date: 16-NOV-1993

BK930033-0 Blackhawk BioSystems, Inc.  
12945 Alcosta Blvd.  
San Ramon, CA 94583  
Trade Name: Virotrol HIV-Ag  
Cleared Date: 27-SEP-1995

BK930034-0 Blackhawk BioSystems, Inc.  
12945 Alcosta Blvd.  
San Ramon, CA 94583  
Trade Name: Virotrol III  
Cleared Date: 27-JUL-1994

BK950011-0 Blackhawk BioSystems, Inc.  
12945 Alcosta Blvd.  
San Ramon, CA 94583  
Trade Name: Viroclear  
Cleared Date: 28-AUG-1995

BK960085-0 Blackhawk BioSystems, Inc.  
12945 Alcosta Blvd.  
San Ramon, CA 94583  
Trade Name: VIROTROL II  
Cleared Date: 03-OCT-1997

BK000041-0 Blackhawk BioSystems, Inc.  
12945 Alcosta Blvd.  
San Ramon, CA 94583  
Trade Name: Viroclear  
Cleared Date: 28-DEC-2000

BK060052-0 Blackhawk BioSystems, Inc.  
12945 Alcosta Blvd.  
San Ramon, CA 94583  
Trade Name: AmpliTrol III  
Cleared Date: 07-NOV-2006

BK960044-0 Blood Bank Computer Systems, Inc.

1501 West Valley Highway, North  
Suite 101  
Auburn, WA 98001  
Trade Name: Blood Bank Control System  
Cleared Date: 15-OCT-1997

BK040056-0 Blood Bank Computer Systems, Inc.  
1002 15th St. SW, Suite 120  
Auburn, WA 98001-6502  
Trade Name: Blood Bank Control System (BBCS) -  
5.0  
Cleared Date: 22-OCT-2004

BK040087-0 Blood Bank Computer Systems, Inc.  
1002 15th St. SW, Suite 120  
Auburn, WA 98001-6502  
Trade Name: BBCS Lab Interface Application  
(BBCS Lab) - 5.0L  
Cleared Date: 15-FEB-2005

BK050013-0 Blood Bank Computer Systems, Inc.  
1002 15th St. SW, Suite 120  
Auburn, WA 98001-6502  
Trade Name: BBCS Mobile Application - 5.0M  
Cleared Date: 01-JUN-2005

BK090081-0 Blood Bank Computer Systems, Inc.  
1002 15th St. SW, Suite 120  
Auburn, WA 98001-6502  
Trade Name: BBCS Hospital Interface  
Application (BBCSH), H 1.0.0  
Cleared Date: 20-JAN-2010

BK120028-0 Blood Bank Computer Systems, Inc.  
1002 15th St. SW, Suite 120  
Auburn, WA 98001-6502  
Trade Name: BBCS BloodTrack Interface  
Application (BBCSBT), BT1.0.0  
Blood Bank Control System - V. 5.0  
Cleared Date: 21-JUN-2012

BK140130-0 Blood Bank Computer Systems, Inc.  
1002 15th St. SW, Suite 120  
Auburn, WA 98001-6502  
Trade Name: ABO QuickPass, version 1.0.0  
Cleared Date: 10-OCT-2014

BK140142-0 Blood Bank Computer Systems, Inc.  
1002 15th St. SW, Suite 120  
Auburn, WA 98001-6502

Trade Name: BBCS Primary Application, version  
5.4.3

Cleared Date: 10-OCT-2014

BK140184-0 Blood Bank Computer Systems, Inc.  
1002 15th St. SW, Suite 120  
Auburn, WA 98001-6502

Trade Name: ABO Wheels - 1.0.0

Cleared Date: 30-DEC-2014

BK140198-0 Blood Bank Computer Systems, Inc.  
1002 15th St. SW, Suite 120  
Auburn, WA 98001-6502

Trade Name: ABO QuickPass - 1.0.0

Cleared Date: 04-FEB-2015

BK160011-0 Blood Bank Computer Systems, Inc.  
1002 15th St. SW, Suite 120  
Auburn, WA 98001-6502

Trade Name: ABO Express - Model 2.0.0

Cleared Date: 26-APR-2016

BK220790-0 Blood Bank Computer Systems, Inc.  
7206 Vandermark Rd. E  
Bonney Lake, WA 98391

Trade Name: Blood Bank Control Systems - 6.0

Cleared Date: 17-FEB-2023

BK940048-0 BloodCare  
9000 Harry Hines Blvd.  
Dallas, TX 75235

Trade Name: LifeTrak /Lab (a.k.a. Lab\*Care) -  
V. 2.01

Cleared Date: 01-OCT-1998

BK100051-0 Boekel Scientific, Inc  
855 Pennsylvania Blvd.  
Feasterville, PA 19053

Trade Name: Boekel Plasma Thawer, Model 301000

Cleared Date: 22-APR-2011

BK940025-0 Boston Scientific, Inc.  
1 Boston Scientific Place  
Natick, MA 01760-1537

Trade Name: Katzen Thrombolysis Guideware

Cleared Date: 24-JAN-1996

BK231004-0 Buoy Software, LLC  
55 Post Rd West  
Westport, CT 06880

Trade Name: Blood Product Questionnaire Module  
Cleared Date: 16-NOV-2023

BK890009-0 C-six Diagnostics, Inc.  
9653 N. Granville Rd.  
Meguon, WI 53092  
Trade Name: Frozen Cell Panel Tray (Human)  
Cleared Date: 02-AUG-1989

BK890010-0 C-six Diagnostics, Inc.  
9653 N. Granville Rd.  
Meguon, WI 53092  
Trade Name: Leukocyte Typing Serum Trays  
(Human)  
Cleared Date: 02-AUG-1989

BK890011-0 C-six Diagnostics, Inc.  
9653 N. Granville Rd.  
Meguon, WI 53092  
Trade Name: Leukocyte Typing Serum Trays  
(Human)  
Cleared Date: 02-AUG-1989

BK251218-0 CAROLINA BIOLOGICAL SUPPLY COMPANY  
2700 York Rd  
Burlington, NC 27215  
Trade Name: Medicinal Leech  
Medicinal Leech (K140907)  
Cleared Date: 07-AUG-2015

BK960049-0 CIS-US, Inc.  
10 de Angelo Drive  
Bedford, MA 01730  
Trade Name: DoseWriter  
Cleared Date: 25-MAR-1998

BK950024-0 COBE Cardiovascular, Inc.  
1201 Oak Street  
Lakewood, CO 80215  
Trade Name: COBE Platelet Filtration and  
Storage Set  
Cleared Date: 29-NOV-1995  
Cleared Under COBE BCT

BK950056-0 COBE Cardiovascular, Inc.  
1201 Oak Street  
Lakewood, CO 80215  
Trade Name: Cobe Spectra LRD Leukoreduction  
(System Versions)  
Cleared Date: 31-JAN-1996

Cleared Under COBE BCT

BK950065-0 COBE Cardiovascular, Inc.  
1201 Oak Street  
Lakewood, CO 80215  
Trade Name: Cobe Spectrum Apheresis System  
(stem cell collection)  
Cleared Date: 12-NOV-2002  
Cleared Under COBE BCT

BK960076-0 COBE Cardiovascular, Inc.  
1201 Oak Street  
Lakewood, CO 80215  
Trade Name: COBE Spectra LRS Turbo System  
Cleared Date: 14-JUL-1997  
Cleared Under COBE BCT

BK970005-0 COBE Cardiovascular, Inc.  
1201 Oak Street  
Lakewood, CO 80215  
Trade Name: Focussed System  
Cleared Date: 13-OCT-1998  
Cleared Under COBE BCT

BK970023-0 COBE Cardiovascular, Inc.  
1201 Oak Street  
Lakewood, CO 80215  
Trade Name: Collection of pRBC Using the  
Focussed System  
Cleared Date: 13-OCT-1998  
Cleared Under COBE BCT

BK980004-0 COBE Cardiovascular, Inc.  
1201 Oak Street  
Lakewood, CO 80215  
Trade Name: COBE Spectra Apheresis System  
Anticoagulant Free Flow  
Restriction  
Cleared Date: 09-JUL-1998  
Cleared Under COBE BCT

BK990025-0 COBE Cardiovascular, Inc.  
1201 Oak Street  
Lakewood, CO 80215  
Trade Name: Cobe Trima  
Cleared Date: 07-APR-2000  
Cleared Under COBE BCT

BK990040-0 COBE Cardiovascular, Inc.  
1201 Oak Street

Lakewood, CO 80215  
Trade Name: COBE Trima with the r/LS RBC  
Leukoreduction Filter  
Cleared Date: 03-MAR-2000  
Cleared Under COBE BCT

BK050033-0 COBE Cardiovascular, Inc.  
14401 West 65th Way  
Arvada, CO 80004-3599  
Trade Name: COBE Angel Whole Blood Separation  
System  
Cleared Date: 22-AUG-2005  
Cleared Under COBE BCT

BK060010-0 COBE Cardiovascular, Inc.  
14401 West 65th Way  
Arvada, CO 80004-3599  
Trade Name: COBE Angel Whole Blood Separation  
System  
Cleared Date: 27-FEB-2006

BK130003-0 CPSI  
6600 Wall Street  
Mobile, AL 36695  
Trade Name: Blood Administration - Version  
1800  
Cleared Date: 30-APR-2014

BK020020-0 CSL Behring AG  
Wankdorfstrasse 10  
3014 Bern, SWITZERLAND  
Trade Name: System for Plasma Identification  
(SPI) - 1.0  
Cleared Date: 30-OCT-2002  
Cleared Under ZLB Behring AG

BK050078-0 CSL Behring AG  
Wankdorfstrasse 10  
3014 Bern, SWITZERLAND  
Trade Name: System for Plasma Identification  
(SPI) - 2.0.0  
Cleared Date: 22-DEC-2005

BK110023-0 CSL Behring AG  
Wankdorfstrasse 10  
3014 Bern, SWITZERLAND  
Trade Name: System for Plasma Identification  
(SPI), version - 3.1.0  
Cleared Date: 08-JUN-2011

BK120002-0 CSL Plasma  
900 Broken Sound Parkway  
Suite 400  
Boca Raton, FL 33487  
Trade Name: LOGIC version 3.0.0  
Cleared Date: 24-APR-2012  
Cleared Under Haemonetics Corporation

BK190430-0 CSL Plasma  
900 Broken Sound Parkway  
Suite 400  
Boca Raton, FL 33487  
Trade Name: Anti-D Donor Management and  
Inventory System (ADIMS) - Version  
1.7  
Cleared Date: 11-MAR-2020

BK210650-0 CSL Plasma  
900 Broken Sound Parkway  
Suite 400  
Boca Raton, FL 33487  
Trade Name: LOGIC - 4.0.8  
Cleared Date: 25-JAN-2022

BK090054-0 Calimex USA Corporation  
258 Hollister Avenu  
Alameda, CA 94501  
Trade Name: Picture-ID  
Cleared Date: 11-JAN-2010

BK110070-0 Calimex USA Corporation  
258 Hollister Avenu  
Alameda, CA 94501  
Trade Name: eOrders, Version 1 - 1  
Cleared Date: 17-FEB-2012

BK120035-0 Calimex USA Corporation  
258 Hollister Avenu  
Alameda, CA 94501  
Trade Name: Picture-ID Version 2.0  
Cleared Date: 17-DEC-2012

BK940027-0 Cardiovascular Dynamics, Inc.  
15 Hammond Suite 307  
Irvine, CA 92718  
Trade Name: CVD Bullett Infusion Catheter  
Cleared Date: 27-FEB-1995

BK940028-0 Cardiovascular Dynamics, Inc.  
15 Hammond Suite 307

Irvine, CA 92718  
Trade Name: CVD Bullett Hi-Flo Infusion  
Cleared Date: 27-FEB-1995

BK040002-0 Care Fusion, Inc.  
1430 Spring Hill Road, Suite 510  
McLean, VA 22102  
Trade Name: wBlood Care - 1.0  
Cleared Date: 10-NOV-2004

BK080035-0 CaridianBCT  
10811 W. Collins Avenue  
Lakewood, CO 80215-4498  
Trade Name: COBE Spectra Apheresis System  
Trima Accel Automated Blood  
Component Collection System  
Cleared Date: 29-AUG-2008

BK080043-0 CaridianBCT  
10811 W. Collins Avenue  
Lakewood, CO 80215-4498  
Trade Name: Atreus Whole Blood Processing  
System  
Cleared Date: 29-SEP-2008

BK080058-0 CaridianBCT  
10811 W. Collins Avenue  
Lakewood, CO 80215-4498  
Trade Name: Trima Accel Automated Blood  
Component Collection System  
Cleared Date: 25-NOV-2008

BK090003-0 CaridianBCT  
10811 W. Collins Avenue  
Lakewood, CO 80215-4498  
Trade Name: Trima Accel System  
Cleared Date: 16-FEB-2010

BK100032-0 CaridianBCT  
10811 W. Collins Avenue  
Lakewood, CO 80215-4498  
Trade Name: Trima Accel System Version 6.0  
Cleared Date: 06-AUG-2010

BK110009-0 CaridianBCT  
10811 W. Collins Avenue  
Lakewood, CO 80215-4498  
Trade Name: Trima Accel Automated Blood  
Component Collection System  
Cleared Date: 19-APR-2011

BK110051-0 CaridianBCT  
10811 W. Collins Avenue  
Lakewood, CO 80215-4498  
Trade Name: Trima Accel Automated Blood  
Component Collection System  
version 5.1.8  
Cleared Date: 20-DEC-2011

BK110068-0 CaridianBCT  
10811 W. Collins Avenue  
Lakewood, CO 80215-4498  
Trade Name: Trima Accel Automated Blood  
Component Collection System  
Cleared Date: 23-MAR-2012

BK990015-0 Carter BloodCare  
2205 Highway 121  
Bedford, TX 76021  
Trade Name: LifeTrak/Distribution - 2.03  
Cleared Date: 22-OCT-1999

BK990027-0 Carter BloodCare  
2205 Highway 121  
Bedford, TX 76021  
Trade Name: LifeTrak/Donor - 2.03  
Cleared Date: 15-DEC-1999

BK180246-0 Carter BloodCare  
2205 Highway 121  
Bedford, TX 76021  
Trade Name: Blood Bank Information System -  
v2.06.00  
Cleared Date: 01-NOV-2018

BK200491-0 Carter BloodCare  
2205 Highway 121  
Bedford, TX 76021  
Trade Name: iWeBB electronic Laboratory  
Information System (iWeBB-eLIS)  
Cleared Date: 29-JUL-2020

BK241069-0 Carter BloodCare  
2205 Highway 121  
Bedford, TX 76021  
Trade Name: Blood Bank Information Management  
System (BBIMS) - 3.01  
Blood Bank Information System  
(BBIMS) - 3.01  
Cleared Date: 09-JUL-2024

BK200514-0 Cartiva, Inc.  
6120 Windward Pkwy  
Alpharetta, GA 30005  
Trade Name: Cartiva SCI Disposable  
Instrumentation set  
Cleared Date: 14-AUG-2020

BK020051-0 Cascade Medical Enterprises, LLC  
20 Greenup Court  
Wayne, NJ 07470  
Trade Name: Cascade Medical Fibrinet,  
Autologous Platelet System  
Cleared Date: 20-DEC-2002

BK030024-0 Cascade Medical Enterprises, LLC  
20 Greenup Court  
Wayne, NJ 07470  
Trade Name: Cascade Medical Fibrinet System  
Cleared Date: 02-JUN-2003

BK060006-0 Cascade Medical Enterprises, LLC  
20 Greenup Court  
Wayne, NJ 07470  
Trade Name: Cascade Medical FIBRINET System  
Cleared Date: 16-FEB-2006

BK120009-0 Cascade Medical Enterprises, LLC  
20 Greenup Court  
Wayne, NJ 07470  
Trade Name: FIBRINET (R) Autologous PRP System  
Cleared Date: 01-AUG-2012

BK170096-0 Cascade Medical Enterprises, LLC  
20 Greenup Court  
Wayne, NJ 07470  
Trade Name: Fibrinet? Platelet System  
Fibrinet Platelet System  
Cleared Date: 21-NOV-2017

BK030033-0 Celera Corporation  
1401 Harbor Bay Parkway  
Alameda, CA 94502  
Trade Name: ViroSeq HIV-1 Genotyping System  
Cleared Date: 11-JUN-2003  
Cleared Under Celera Diagnostics, LLC

BK030088-0 Celera Corporation  
1401 Harbor Bay Parkway  
Alameda, CA 94502

Trade Name: ViroSeq HIV-1 Genotyping System  
v2.0  
Cleared Date: 22-JAN-2004  
Cleared Under Celera Diagnostics, LLC

BK060049-0 Celera Corporation  
1401 Harbor Bay Parkway  
Alameda, CA 94502  
Trade Name: ViroSeq HIV-1 Genotyping System  
Cleared Date: 31-AUG-2006  
Cleared Under Celera Diagnostics, LLC

BK080026-0 Celera Corporation  
1401 Harbor Bay Parkway  
Alameda, CA 94502  
Trade Name: ViroSeq HIV-1 Genotyping System  
v2.0  
Cleared Date: 10-JUL-2008  
Cleared Under Celera Diagnostics, LLC

BK130039-0 Celera Corporation  
1401 Harbor Bay Parkway  
Alameda, CA 94502  
Trade Name: ViroSeq HIV-1 Genotyping System  
v2.0  
Cleared Date: 05-SEP-2013

BK150221-0 Celling Biosciences, Inc.  
93 Red River St.  
Austin, TX 78701  
Trade Name: Circle Biologics Autologous  
Platelet Separator (APS) System  
Cleared Date: 09-JUN-2015

BK130079-0 Cellmedix Holdings, LLC.  
19 Park Drive  
Franklin, NJ 07416  
Trade Name: Centrepid Platelet Concentrator  
Cleared Date: 31-JUL-2014

BK880002-0 Cellular Products  
688 Main Street  
Buffalo, NY 14202  
Trade Name: Blood Bank Refrigerator  
Cleared Date: 04-MAY-1988

BK950010-0 Centocor, Inc.  
200 Great Valley Parkway  
Malvern, PA 19355  
Trade Name: CAPTIA CMV-TA EIA

Cleared Date: 22-MAR-1995

BK950051-0 Cerner Corporation  
2800 Rock Creek Parkway  
Kansas City, MO 64117-2551  
Trade Name: Pathnet Blood Center (L-2510)  
Cleared Date: 16-JUL-1997

BK950053-0 Cerner Corporation  
2800 Rock Creek Parkway  
Kansas City, MO 64117-2551  
Trade Name: Pathnet Blood Bank Transfusion  
(L-2300)  
Cleared Date: 16-JUL-1997

BK950055-0 Cerner Corporation  
2800 Rock Creek Parkway  
Kansas City, MO 64117-2551  
Trade Name: Pathnet Blood Bank Donor (L2400)  
Cleared Date: 16-JUL-1997

BK960024-0 Cerner Corporation  
2800 Rock Creek Parkway  
Kansas City, MO 64117-2551  
Trade Name: PathNet Worksystem Blood Bank  
Transfusion (L2812)  
Cleared Date: 16-JUL-1997

BK990007-0 Cerner Corporation  
2800 Rock Creek Parkway  
Kansas City, MO 64117-2551  
Trade Name: HNA Millennium PathNet Blood Bank  
Transfusion  
Cleared Date: 02-NOV-1999

BK030028-0 Cerner Corporation  
2800 Rock Creek Parkway  
Kansas City, MO 64117-2551  
Trade Name: Cerner Millennium PathNet Blood  
Bank Donor (PA-22200) - 2003.01  
Cleared Date: 19-AUG-2003

BK060037-0 Cerner Corporation  
2800 Rock Creek Parkway  
Kansas City, MO 64117-2551  
Trade Name: Cerner Bridge Medical Transfusion  
Administration and Specimen  
Collections - 3.3  
Cleared Date: 24-MAY-2007

BK860025-0 Cetus Corporation  
1400 53rd Street  
Emeryville, CA 94608  
Trade Name: Pro Group System  
Cleared Date: 27-APR-1987

BK050021-0 Charter Medical, Ltd.  
3948-A Westpoint Blvd.  
Winston-Salem, NC 27103  
Trade Name: Charter Medical Transfer Set  
Cleared Date: 22-JUL-2005

BK060042-0 Charter Medical, Ltd.  
3948-A Westpoint Blvd.  
Winston-Salem, NC 27103  
Trade Name: Cell Freeze Liquid Nitrogen  
Freezing Container  
Cleared Date: 03-OCT-2008

BK100049-0 Charter Medical, Ltd.  
3948-A Westpoint Blvd.  
Winston-Salem, NC 27103  
Trade Name: Cell-Freeze Cryogenic Storage  
Container  
Cleared Date: 07-DEC-2010

BK170004-0 Charter Medical, Ltd.  
3948-A Westpoint Blvd.  
Winston-Salem, NC 27103  
Trade Name: Charter Medical Cell Therapy Fluid  
Transfer Set  
Cleared Date: 06-OCT-2017

BK910003-0 CharterMed, Inc.  
3948-A West Point Blvd.  
Winston-Salem, NC 27103  
Trade Name: CharterMed Blood Freezing Bag  
Cleared Date: 11-MAR-1993

BK960043-0 CharterMed, Inc.  
3948-A West Point Blvd.  
Winston-Salem, NC 27103  
Trade Name: Charter Med Transfer Bags  
Cleared Date: 11-SEP-1996

BK000049-0 Chiron Corporation  
4560 Horton Street  
Emeryville, CA 94608-2916  
Trade Name: Chiron CPT Pooling Software,  
Version 2.0.0.2

Cleared Date: 04-DEC-2001

BK010025-0 Chiron Corporation  
4560 Horton Street  
Emeryville, CA 94608-2916  
Trade Name: Chiron Procleix NAT Tracker - 1.0E  
Cleared Date: 03-JAN-2002  
Cleared Under Rubin & Poor

BK030030-0 Chiron Corporation  
4560 Horton Street  
Emeryville, CA 94608-2916  
Trade Name: Procleix NAT Tracker  
Cleared Date: 23-MAY-2003  
Cleared Under Rubin & Poor

BK040058-0 Chiron Corporation  
4560 Horton Street  
Emeryville, CA 94608-2916  
Trade Name: Chiron CPT Pooling Software,  
Version 2.0.0.2  
Cleared Date: 28-JUL-2004

BK040072-0 Chiron Corporation  
4560 Horton Street  
Emeryville, CA 94608-2916  
Trade Name: Procleix NAT Tracker Software  
Version 2.1  
Cleared Date: 04-NOV-2004

BK050004-0 Chiron Corporation  
4560 Horton Street  
Emeryville, CA 94608-2916  
Trade Name: Procleix Optiva RAS  
Cleared Date: 08-APR-2005

BK060005-0 Chiron Corporation  
4560 Horton Street  
Emeryville, CA 94608-2916  
Trade Name: Chiron Procleix NAT Tracker - 3.0  
Cleared Date: 01-MAR-2006

BK070007-0 Chiron Corporation  
4560 Horton Street  
Emeryville, CA 94608-2916  
Trade Name: PROCLEIX NAT TRACKER  
Cleared Date: 06-MAR-2007

BK980043-0 Chrono-Log Corporation  
2 West Park Road

Havertown, PA 19083-4691  
Trade Name: Chrono-log Lumi-Agrregometer  
Cleared Date: 22-DEC-1998

BK100014-0 Circle Biologics, Inc.  
3650 Annapolis Lane, Suite 105  
Minneapolis, MN 55447  
Trade Name: Autologous Fluid Concentrator  
(AFC) System  
Changed with 6/25/10 Submission  
to: "Autologous Platelet  
Concentrator (APC)(TM) System  
Cleared Date: 09-JUL-2010  
Cleared Under Circle Biologic, LLC

BK840008-0 Cobe Laboratories, Inc.  
1185 Oak Street  
Lakewood, CO 80215  
Trade Name: IBM 2991 - Change of Ownership  
Cleared Date: 08-JUN-1984

BK840009-0 Cobe Laboratories, Inc.  
1185 Oak Street  
Lakewood, CO 80215  
Trade Name: IBM 2997 - Change of Ownership  
Cleared Date: 08-JUN-1984

BK870022-0 Cobe Laboratories, Inc.  
1185 Oak Street  
Lakewood, CO 80215  
Trade Name: COBE Spectra Blood Component  
Separator  
Cleared Date: 20-JUN-1988

BK900002-0 Cobe Laboratories, Inc.  
1185 Oak Street  
Lakewood, CO 80215  
Trade Name: COBE Spectra: Simultaneous  
Collection of Platelets and Plasma  
Cleared Date: 21-JUN-1990

BK900003-0 Cobe Laboratories, Inc.  
1185 Oak Street  
Lakewood, CO 80215  
Trade Name: COBE Spectra: Change in  
Anticoagulant Ratio  
Cleared Date: 14-NOV-1990

BK900004-0 Cobe Laboratories, Inc.  
1185 Oak Street

Lakewood, CO 80215  
Trade Name: COBE Spectra: Single Needle  
System  
Cleared Date: 21-JUN-1990

BK910020-0 Cobe Laboratories, Inc.  
1185 Oak Street  
Lakewood, CO 80215  
Trade Name: COBE SPECTRATHERM  
Cleared Date: 02-NOV-1992

BK920011-0 Cobe Laboratories, Inc.  
1185 Oak Street  
Lakewood, CO 80215  
Trade Name: Cobe Spectra with PCM  
Cleared Date: 15-MAY-1995

BK920036-0 Cobe Laboratories, Inc.  
1185 Oak Street  
Lakewood, CO 80215  
Trade Name: COBE Spectra Single-Needle  
Extended Life Platelet (ELP) Set  
Cleared Date: 06-APR-1993

BK930017-0 Cobe Laboratories, Inc.  
1185 Oak Street  
Lakewood, CO 80215  
Trade Name: COBE Spectra Apheresis System  
(Triple Platelet)  
Cleared Date: 27-JUL-1994

BK940016-0 Cobe Laboratories, Inc.  
1185 Oak Street  
Lakewood, CO 80215  
Trade Name: COBE Spectra Version 4  
Cleared Date: 20-SEP-1994

BK950030-0 Cobe Laboratories, Inc.  
1185 Oak Street  
Lakewood, CO 80215  
Trade Name: COBE Spectra Extended Life  
Platelet Set  
Cleared Date: 15-FEB-1996

BK970007-0 Community Bio-Resources, Inc.  
2197 Parkway Lake Drive  
Hoover, AL 35244  
Trade Name: Donor Information System - 1.0  
Cleared Date: 09-APR-1997

BK960060-0 Community Blood Center of Greater Kansas City  
4040 Main Street  
Kansas City, MO 64111  
Trade Name: CBC Blood System, Version 1.2  
Cleared Date: 20-NOV-1997

BK110048-0 Community Blood Centers of South Florida  
1700 North State Road 7  
Lauderhill, FL 33313  
Trade Name: Regulated Software Application  
(RSA) - 1.0  
Cleared Date: 12-JAN-2012

BK920006-0 Connaught Laboratories Limited  
Discovery Drive  
Swiftwater, PA 18370  
Trade Name: CONTINENTAL REFRIG. BLD.BNK. MODEL  
C-BBRA-1S  
Cleared Date: 17-JUL-1992

BK970010-0 Controlled Chemicals, Inc.  
317 S. Division  
Suite 9  
Ann Arbor, MI 48104  
Trade Name: CryoGuard Thermal Exposure  
Indicator  
Cleared Date: 26-AUG-1997

BK940026-0 Cook, Inc.  
925 S. Curry Pike  
Bloomington, IN 47402  
Trade Name: Roubin Infusion Catheter  
Cleared Date: 29-JUN-1995

BK830008-0 Cooper Biomedical  
1230 Wilson Drive  
West Chester, PA 19380  
Trade Name: W.A.R.M.  
Cleared Date: 21-JUN-1983

BK850008-0 Cooper Biomedical  
1 Technology Court  
Malvern, PA 29355  
Trade Name: H.P.C.  
Cleared Date: 09-JAN-1986

BK820007-0 Cry-0-Safe, Inc.  
999 Airport Road  
Lakewood, NJ 08701  
Trade Name: Plasma Safe

Cleared Date: 26-JUL-1982

BK190356-0 Cryo-Cell International, Inc.  
700 Brooker Creek Blvd  
Oldsmar, FL 34677  
Trade Name: PrepaCyte -CB Processing System -  
PCB 2100-270  
Cleared Date: 17-JUN-2020

BK820018-0 Cryosan Inc.  
850 Providence Highway  
Dedham, MA 02026  
Trade Name: Dideco BT Series  
Cleared Date: 16-DEC-1982

BK820021-0 Cryosan Inc.  
850 Providence Highway  
Dedham, MA 02026  
Trade Name: Dideco BT790/A  
Dideco BT792  
Cleared Date: 03-JAN-1983

BK830015-0 Cryosan Inc.  
850 Providence Highway  
Dedham, MA 02026  
Trade Name: Dideco BT 125  
Dideco BT 225  
Dideco BT 375  
Dideco BT 691  
Cleared Date: 31-OCT-1983

BK830016-0 Cryosan Inc.  
850 Providence Highway  
Dedham, MA 02026  
Trade Name: Dideco Progress BT 790/A  
Cleared Date: 07-FEB-1984

BK840011-0 Cryosan Inc.  
850 Providence Highway  
Dedham, MA 02026  
Trade Name: BT 765 Blood Cell Separator  
Equipment  
Cleared Date: 10-APR-1985

BK840012-0 Cryosan Inc.  
850 Providence Highway  
Dedham, MA 02026  
Trade Name: BT 765 Elutriation Pump  
Cleared Date: 06-FEB-1985

BK870003-0 Cryosan Inc.  
850 Providence Highway  
Dedham, MA 02026  
Trade Name: Cryo-Pak™ System  
Cleared Date: 17-APR-1987

BK960012-0 CytoTherm LP  
110 Sewell Avenue  
Trenton, NJ 08610  
Trade Name: Cyto Therm (T-S)  
Cleared Date: 15-APR-1996  
Cleared Under Photo-Therm

BK980042-0 CytoTherm LP  
110 Sewell Avenue  
Trenton, NJ 08610  
Trade Name: CytoTherm J  
Cleared Date: 07-JAN-1999  
Cleared Under Photo-Therm

BK060027-0 CytoTherm LP  
110 Sewell Avenue  
Trenton, NJ 08610  
Trade Name: CytoTherm Plasma Thawing System  
Cleared Date: 01-AUG-2006

BK060063-0 CytoTherm LP  
110 Sewell Avenue  
Trenton, NJ 08610  
Trade Name: CytoTherm Cryoprecipitate Thawer,  
Model CT-4T.6C  
Cleared Date: 04-MAY-2007

BK080019-0 CytoTherm LP  
110 Sewell Avenue  
Trenton, NJ 08610  
Trade Name: CytoTherm Plasma Thawing System  
Cleared Date: 16-JUL-2008

BK060007-0 Cytomedix, Inc  
416 Hungerford Drive  
Rockville, MD 20850  
Trade Name: Autologel System  
Cleared Date: 20-SEP-2007

BK110046-0 Cytomedix, Inc  
416 Hungerford Drive  
Rockville, MD 20850  
Trade Name: Angel(R) Whole Blood Separation  
System

Cleared Date: 07-NOV-2012

BK130060-0 Cytonics Corporation  
555 Heritage Drive, Suite 115  
Jupiter, FL 33458  
Trade Name: Autologous Platelet Integrated  
Concentration ("APIC") System  
Cleared Date: 17-JAN-2014

BK220684-0 Cytori Therapeutics Inc.  
3020 Callan Road  
San Diego, CA 92121  
Trade Name: CYTORI AFT SYSTEM  
CYTORI AFT SYSTEM (K072587)  
Cleared Date: 10-DEC-2007

BK220689-0 Cytori Therapeutics Inc.  
3020 Callan Road  
San Diego, CA 92121  
Trade Name: CYTORI PUREGRAFT 250/PURE SYSTEM  
(K092923)  
FAT CONCENTRATION SYSTEM (K100114)  
Cleared Date: 06-JAN-2010

BK220693-0 Cytori Therapeutics Inc.  
3020 Callan Road  
San Diego, CA 92121  
Trade Name: PUREGRAFT 850/PURE SYSTEM  
(K113255)  
Cleared Date: 07-MAR-2012

BK220699-0 Cytori Therapeutics Inc.  
3020 Callan Road  
San Diego, CA 92121  
Trade Name: PUREGRAFT 50 SYSTEM (K132815)  
Cleared Date: 24-JAN-2014

BK950060-0 Cytosol Laboratories, Inc.  
55 Messina Drive  
Braintree, MA 02184-6783  
Trade Name: Y-Type Rejuvenation Set PN7212  
Cleared Date: 25-NOV-1996

BK000022-0 DENCO, INC.  
P.O.BOX 9600  
Wilmington, DE 19809  
Trade Name: Total Containment Device  
Cleared Date: 18-APR-2000

BK990041-0 DENCO, INC.

P.O.BOX 9600  
Wilmington, DE 19809  
Trade Name: Total Containment Device  
Cleared Date: 21-DEC-1999

BK160084-0   DIAGAST  
    Parc Eurasant  
    251, Avenue Eug ne Avin e  
    BP 9  
    LOOS Cedex, FRANCE 59374  
Trade Name: Neg Control  
Cleared Date: 02-FEB-2018

BK190313-0   DIAGAST  
    Parc Eurasant  
    251, Avenue Eug ne Avin e  
    BP 9  
    LOOS Cedex, FRANCE 59374  
Trade Name: PK SYSTEM CONTROL  
Cleared Date: 07-MAY-2020

BK130053-0   DSM BIOMEDICAL  
    735 Pennsylvania Drive  
    Exton, PA 19341  
Trade Name: DSM Biomedical PRP Device  
Cleared Date: 25-MAR-2014

BK140176-0   DSM BIOMEDICAL  
    735 Pennsylvania Drive  
    Exton, PA 19341  
Trade Name: The JEN Device  
Cleared Date: 06-MAR-2015

BK950019-0   DUPACO  
    2620 TEMPLE HEIGHTS DR.  
    OCEANSIDE, CA 92056  
Trade Name: DUPACO BLOOD/FLUID WARMING SET  
    D25416  
Cleared Date: 27-APR-1995

BK950038-0   DUPACO  
    2620 TEMPLE HEIGHTS DR.  
    OCEANSIDE, CA 92056  
Trade Name: Dupaco Counterflo 300 Blood/Fluid  
    Warmer  
Cleared Date: 01-SEP-1995

BK020057-0   Data Innovations LLC  
    120 Kimball Ave., Suite 100  
    South Burlington, VT 05430

Trade Name: imExpress - 7.2.5  
Cleared Date: 29-JUL-2003  
Cleared Under Data Innovations

BK060053-0 Data Innovations LLC  
120 Kimball Ave., Suite 100  
South Burlington, VT 05430  
Trade Name: Instrument Manager - 8.05.01.10  
Cleared Date: 05-JAN-2007  
Cleared Under Data Innovations Inc.

BK080052-0 Data Innovations LLC  
120 Kimball Ave., Suite 100  
South Burlington, VT 05430  
Trade Name: INSTRUMENT MANAGER - V 8.07  
Cleared Date: 28-OCT-2008  
Cleared Under Data Innovations Inc.

BK100046-0 Data Innovations LLC  
120 Kimball Ave., Suite 100  
South Burlington, VT 05430  
Trade Name: Instrument Manager - 8.10.01  
Cleared Date: 12-AUG-2010  
Cleared Under Data Innovations Inc.

BK120051-0 Data Innovations LLC  
120 Kimball Ave., Suite 100  
South Burlington, VT 05430  
Trade Name: Instrument Manager v8.12  
Cleared Date: 17-OCT-2012  
Cleared Under Data Innovations Inc.

BK180245-0 Data Innovations LLC  
120 Kimball Ave., Suite 100  
South Burlington, VT 05430  
Trade Name: Instrument Manager - 8.16.10  
Cleared Date: 08-NOV-2018

BK070035-0 Defense Blood Standard System  
5205 Leesburg Pike  
Suite 1000  
Falls Church, VA 22041  
Trade Name: Defense Blood Standard System  
(DBSS) - 10.0.0  
Cleared Date: 22-MAY-2008

BK180229-0 Delcon S.r.l.  
Via Zanica  
Grassobbio, BG ITALY 24050  
Trade Name: HEMOMIX 3

HemoMix 3 with DCSX Software  
Cleared Date: 04-OCT-2018

BK190429-0 Delcon S.r.l.  
Via Zanica  
Grassobbio, BG ITALY 24050  
Trade Name: HemoMix 4 (Basic version)  
HemoMix 4 (Internal optional RFID  
installed version)  
Cleared Date: 30-JAN-2020

BK231039-0 Delcon S.r.l.  
Via Zanica  
Grassobbio, BG ITALY 24050  
Trade Name: Giotto Monza (BCS03)  
Macopress Smart Smarter  
Cleared Date: 26-MAR-2025

BK970021-0 Department of Veterans Affairs  
P.O. Box 5000  
VA Hines Medical Center  
Hines, IL 60141  
Trade Name: Vista Blood Bank Software (V5.2)  
Cleared Date: 23-APR-1999

BK060043-0 Department of Veterans Affairs  
P.O. Box 7008  
Hines, IL 60141-7008  
Trade Name: Vista Blood Establishment Computer  
Software (VBECS) - 1.0  
Cleared Date: 19-OCT-2006

BK140172-0 Department of Veterans Affairs  
P.O. Box 7008  
Hines, IL 60141-7008  
Trade Name: Vista Blood Establishment Computer  
Software (VBECS) - 2.0.0  
Cleared Date: 20-NOV-2014

BK180227-0 Department of Veterans Affairs  
P.O. Box 7008  
5th Ave and Roosevelt Rd  
Bldg 37  
Hines, IL 60141  
Trade Name: Vista Blood Establishment Computer  
Software (VBECS)  
Cleared Date: 01-OCT-2018

BK830025-0 Dia Tech  
2525 Shader Road

Orlando, FL 328  
Trade Name: DiaCent 2 Automated Cell  
Washer/Centrifuge  
Cleared Date: 10-JAN-1984

BK840001-0 Dia Tech  
2525 Shader Road  
Orlando, FL 328  
Trade Name: DIACENT 1, Automated Cell  
Washer/Centrifuge  
Cleared Date: 19-MAR-1984

BK870007-0 DiaClin Laboratories, Inc.  
450 10th Circle North  
Nashville, TN 37203  
Trade Name: SEOPF ROP Tray  
Cleared Date: 04-APR-1990

BK241116-0 DiaSorin Inc.  
1951 Northwestern Avenue  
Stillwater, MN 55082  
Trade Name: LIAISON MUREX Control HIV Ab-Ag  
HT (318291)  
LIAISON MUREX HIV Ab/Ag HT  
(318290)  
Cleared Date: 10-JUN-2025

BK261335-0 DiaSorin Inc.  
1951 Northwestern Avenue  
Stillwater, MN 55082  
Trade Name: LIAISON MUREX HIV Ab/Ag HT  
LIAISON XL  
LIAISON diluteX  
Cleared Date: 29-MAY-2026

BK120043-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: DG Gel 8 Neutral Gel  
Cleared Date: 19-JUL-2013

BK120044-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: Grifols Diluent  
Cleared Date: 19-JUL-2013

BK120045-0 Diagnostic Grifols, S. A.

Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: DG Spin  
Cleared Date: 19-JUL-2013

BK120046-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: DG THERM  
Cleared Date: 19-JUL-2013

BK130025-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: WADiana(R) Compact  
Cleared Date: 30-AUG-2013

BK130067-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: Erytra(R)  
Cleared Date: 17-JAN-2014

BK140101-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: DG Reader  
Cleared Date: 21-MAY-2014

BK150266-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: DG Gel(R) 8 Neutral  
Cleared Date: 28-JUL-2015

BK160100-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: DG Gel 8 Neutral  
Cleared Date: 09-NOV-2016

BK170130-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24

Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: Erytra  
Erytra  
Cleared Date: 01-NOV-2017

BK180260-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: Erytra Eflexis  
Cleared Date: 20-DEC-2018

BK180262-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: DG Gel 8 Neutral  
Cleared Date: 20-DEC-2018

BK190318-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: Erytra  
Cleared Date: 10-DEC-2019

BK190320-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: DG Reader  
Cleared Date: 10-DEC-2019

BK190321-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: WADiana Compact  
Cleared Date: 10-DEC-2019

BK190379-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: DG Reader Net  
Cleared Date: 11-OCT-2019

BK200467-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24

Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: Erytra Eflexis  
Cleared Date: 23-APR-2020

BK220738-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: DG Reader Net  
Cleared Date: 07-DEC-2022

BK220744-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: Blood Typing Manager  
Cleared Date: 04-OCT-2022

BK220751-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: Erytra  
Cleared Date: 01-NOV-2022

BK220752-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: Erytra Eflexis  
Cleared Date: 01-NOV-2022

BK220753-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: DG Reader Net  
Cleared Date: 01-NOV-2022

BK220754-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: DG Gel 8 Neutral  
Cleared Date: 01-NOV-2022

BK230811-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona

Parets Del Valles, SPAIN 08150  
Trade Name: Blood Typing Manager - 3.0  
Cleared Date: 24-JUL-2023

BK230820-0 Diagnostic Grifols, S. A.  
Passeig Fluvial, 24  
Barcelona  
Parets Del Valles, SPAIN 08150  
Trade Name: Erytra Eflexis - 3.0.0  
Cleared Date: 22-JUN-2023

BK251182-0 Diagnostic Grifols, S.A.  
Passeig Fluvial, 24  
Parets del Valles, Barcelona SPAIN 08150  
Trade Name: Erytra Eflexis (210600)  
Cleared Date: 17-JUN-2025

BK251183-0 Diagnostic Grifols, S.A.  
Passeig Fluvial, 24  
Parets del Valles, Barcelona SPAIN 08150  
Trade Name: Erytra (210400)  
Cleared Date: 17-JUN-2025

BK251184-0 Diagnostic Grifols, S.A.  
Passeig Fluvial, 24  
Parets del Valles, Barcelona SPAIN 08150  
Trade Name: DG Gel 8 Neutral (210393)  
Cleared Date: 17-JUN-2025

BK261329-0 Diagnostic Grifols, S.A.  
Passeig Fluvial, 24  
Parets del Valles, Barcelona SPAIN 08150  
Trade Name: Erytra Eflexis  
Cleared Date: 21-MAY-2026

BK110036-0 Diaspect Medical GMBH  
800 E. Leigh Street  
Suite 206-5  
Richmond, VA 23219  
Trade Name: DiaSpect Hemoglobin T and DiaSpect  
Hemoglobin Cuvettes  
Cleared Date: 01-NOV-2011

BK120052-0 Diaspect Medical GMBH  
800 E. Leigh Street  
Suite 206-5  
Richmond, VA 23219  
Trade Name: DiaSpect Control HBT (-L, -M. -H)  
Cleared Date: 14-NOV-2012

BK970013-0 Digi-Trax Corporation  
1550 Barclay Boulevard  
Buffalo Grove, IL 60089  
Trade Name: Donor-ID  
Cleared Date: 27-FEB-1998

BK000020-0 Digi-Trax Corporation  
1550 Barclay Boulevard  
Buffalo Grove, IL 60089  
Trade Name: Digi-Trax Donor-ID - 2.0  
Cleared Date: 20-APR-2000

BK010049-0 Digi-Trax Corporation  
1550 Barclay Boulevard  
Buffalo Grove, IL 60089  
Trade Name: Donor-ID - 2.2  
Cleared Date: 26-APR-2002

BK850006-0 Division of Immunologic Oncology  
3900 Reservoir Rd.,NW,Box 63,Med-Den Bld  
Washington, DC 20007  
Trade Name: GTU DR/DQ Typing Tray  
Cleared Date: 25-APR-1985

BK980009-0 Dominion Biologicals Limited  
5 Isnor Drive  
Dartmouth, Nova Scotia CANADA B3B1M1  
Trade Name: Coombs Control Cells (IgG Coated)  
Cleared Date: 30-OCT-1998

BK070065-0 Duley Hopkins and Associates  
1200 Mountain Creek Road  
# 215  
Chattanooga, TN 37405  
Trade Name: Blood Bank Information Management  
System (BBIMS) - V2.05.01  
Cleared Date: 25-APR-2008

BK090079-0 Duley Hopkins and Associates  
1200 Mountain Creek Road  
# 215  
Chattanooga, TN 37405  
Trade Name: Blood Bank Information Management  
System (BBIMS V2.05.01)  
Cleared Date: 13-JAN-2010

BK030056-0 Dynal Biotech Ltd  
11 Bassendale Road  
Croft Busines Park  
Bromborough, Wirral, CH62 3QL, UNITED KINGDOM

Trade Name: Dynal Reli SSO HLA-A Typing Kit  
Cleared Date: 29-JAN-2004

BK030057-0 Dynal Biotech Ltd  
11 Bassendale Road  
Croft Busines Park  
Bromborough, Wirral, CH62 3QL, UNITED KINGDOM  
Trade Name: Dynal Reli SSO HLA-B Typing Kit  
Cleared Date: 29-JAN-2004

BK030058-0 Dynal Biotech Ltd  
11 Bassendale Road  
Croft Busines Park  
Bromborough, Wirral, CH62 3QL, UNITED KINGDOM  
Trade Name: DYNAL RELI SSO HLA-Cw Typing Kit  
Cleared Date: 29-JAN-2004

BK030059-0 Dynal Biotech Ltd  
11 Bassendale Road  
Croft Busines Park  
Bromborough, Wirral, CH62 3QL, UNITED KINGDOM  
Trade Name: Dynal RELI SSO HLA-DQB1 Typing Kit  
Cleared Date: 29-JAN-2004

BK030060-0 Dynal Biotech Ltd  
11 Bassendale Road  
Croft Busines Park  
Bromborough, Wirral, CH62 3QL, UNITED KINGDOM  
Trade Name: DYNAL RELI SSO HLA-DRB Typing  
System.  
Cleared Date: 29-JAN-2004

BK050012-0 Dynal Biotech Ltd  
11 Bassendale Road  
Croft Busines Park  
Bromborough, Wirral, CH62 3QL, UNITED KINGDOM  
Trade Name: Dynal RELI SSO HLA-DRB1 Typing Kit  
-  
For Use as a manual asssay or with  
the AutoRELI Instrument  
Cleared Date: 18-MAY-2005

BK960041-0 Dynamic Healthcare Technologies, Inc.  
101 Southhall Lane, Suite 210  
Maitland, FL 32751  
Trade Name: Transfusion Service Mgr.  
Cleared Date: 16-DEC-1997

BK840004-0 Dynatech Laboratories, Inc.  
900 Slaters Lane

Alexandria, VA 22314  
Trade Name: MicroBBank 220 Automated  
Microplate Reader  
Cleared Date: 18-MAY-1984

BK850013-0 Dynatech Laboratories, Inc.  
900 Slaters Lane  
Alexandria, VA 22314  
Trade Name: MicroBank System  
Cleared Date: 08-OCT-1985

BK840003-0 E.I. duPont de Nemours & Company  
Medical Products Department  
Wilmington, DE 19898  
Trade Name: DuPont SCD  
Cleared Date: 07-NOV-1984

BK910022-0 E.I. duPont de Nemours & Company  
Medical Products Department  
Wilmington, DE 19898  
Trade Name: Du Pont Sorvall RC 3B Plus  
Du Pont Sorvall RC 3C Plus  
Centrifuge  
Cleared Date: 21-JAN-1992

BK230958-0 EDONORSOFT LLC  
1619 Whitfield Street  
Sugarland, TX 77479  
Trade Name: HemDonER 1.0.1  
Cleared Date: 31-MAY-2024

BK840018-0 EK Industries, Inc.  
411 Kay Avenue  
Addison, IL 60101  
Trade Name: Copper Sulfate Solution ( for  
women)  
Cleared Date: 11-DEC-1984

BK840019-0 EK Industries, Inc.  
411 Kay Avenue  
Addison, IL 60101  
Trade Name: Copper Sulfate Solution (for men)  
Cleared Date: 11-DEC-1984

BK200520-0 EKF-diagnostic GmbH  
Ebendorfer Chaussee 3  
, Barleben GERMANY 39179  
Trade Name: DiaSpect TM System  
DiaSpect Tm  
DiaSpect Tm Cuvettes

DiaSpect™ system  
Cleared Date: 24-NOV-2020

BK170138-0 ETHICON Inc.  
Route 22 West  
P.O. Box 151  
Somerville, NJ 08876  
Trade Name: EVICEL Laparoscopic Airless Spray  
Accessory (35 cm Rigid)  
Cleared Date: 26-JAN-2018

BK180287-0 ETHICON Inc.  
Route 22 West  
P.O. Box 151  
Somerville, NJ 08876  
Trade Name: VISTASEAL Airless Spray Accessory  
Cleared Date: 10-APR-2019

BK190324-0 ETHICON Inc.  
Route 22 West  
P.O. Box 151  
Somerville, NJ 08876  
Trade Name: VISTASEAL Laparoscopic Dual  
Applicator (35 cm Rigid or 45 cm  
Flexible)  
VISTASEAL Laparoscopic Dual  
Applicator (35 em Rigid or 45 em  
Flexible)  
Cleared Date: 05-JUN-2019

BK251199-0 EUROMI S.A  
11 rue des Nouvelles Technologies  
ANDRIMONT, Belgium BELGIUM 4821  
Trade Name: NLF system kit 2 (EUROMI)  
Cleared Date: 10-NOV-2025

BK090044-0 Eclypsis Corporation  
450 Lapp Road  
Malvern, PA 19355  
Trade Name: Sunrise Blood Bank version 2.0 SP2  
Cleared Date: 13-NOV-2009

BK900006-0 Electrolux SARL  
1317 F St. NW, suite 150  
Washington, DC 20004  
Trade Name: Blood Chain Thermostabilizer  
RCB42P  
Cleared Date: 18-JUL-1990

BK190317-0 EmCyte Corporation

4331 Veronica South Shoemaker Blvd  
For Myers, FL 33916  
Trade Name: PurePRP SupraPhysiologic  
Concentrating System  
Cleared Date: 12-FEB-2020

BK220719-0 EmCyte Corporation  
4331 Veronica South Shoemaker Blvd  
For Myers, FL 33916  
Trade Name: Progenikine Concentrating Sytem 25  
M System (K191564)  
Cleared Date: 07-NOV-2019

BK860018-0 Engineering & Research Associates, Inc.  
500 North Tucson Boulevard (ERA Plaza)  
Tucson, AZ 85716  
Trade Name: SEBRA Model 1150 (Blood Weigth  
Monitor)  
Cleared Date: 11-JUL-1986

BK860019-0 Engineering & Research Associates, Inc.  
500 North Tucson Boulevard (ERA Plaza)  
Tucson, AZ 85716  
Trade Name: SEBRA Model 1300 (Tube Stripper)  
Cleared Date: 29-SEP-1986

BK870023-0 Engineering & Research Associates, Inc.  
500 North Tucson Boulevard (ERA Plaza)  
Tucson, AZ 85716  
Trade Name: Sebra Model #1500 Centrifuge Cup  
Blood Bag Holder  
Cleared Date: 25-SEP-1986

BK900025-0 Engineering & Research Associates, Inc.  
500 North Tucson Boulevard (ERA Plaza)  
Tucson, AZ 85716  
Trade Name: SEBRA Model #2470, Mobile Tube  
Sealer  
Cleared Date: 26-JUN-1991

BK900026-0 Engineering & Research Associates, Inc.  
500 North Tucson Boulevard (ERA Plaza)  
Tucson, AZ 85716  
Trade Name: SEBRA MODEL #1040, DIGITAL BLOOD  
SHAKER/WEIGHT MONITOR  
Cleared Date: 26-JUN-1991

BK900029-0 Engineering & Research Associates, Inc.  
500 North Tucson Boulevard (ERA Plaza)  
Tucson, AZ 85716

Trade Name: Sebra Model #2390, Mobile Tube  
Sealer

Cleared Date: 26-JUN-1991

BK910015-0 Engineering & Research Associates, Inc.  
500 North Tucson Boulevard (ERA Plaza)  
Tucson, AZ 85716  
Trade Name: Sebra Model #1290, Blood/Platelet  
Coolant  
Cleared Date: 11-SEP-1991

BK910024-0 Engineering & Research Associates, Inc.  
500 North Tucson Boulevard (ERA Plaza)  
Tucson, AZ 85716  
Trade Name: SEBRA/MODEL #2100 TUBE SEALER  
Cleared Date: 05-NOV-1992

BK910025-0 Engineering & Research Associates, Inc.  
500 North Tucson Boulevard (ERA Plaza)  
Tucson, AZ 85716  
Trade Name: SEBRA MODEL 1440 BLD.  
SHAKER/WT.MONITOR  
Cleared Date: 05-NOV-1992

BK910026-0 Engineering & Research Associates, Inc.  
500 North Tucson Boulevard (ERA Plaza)  
Tucson, AZ 85716  
Trade Name: SEBRA/MODEL 2590 HAND HELD TUBE  
SEALER  
Cleared Date: 05-NOV-1992

BK130037-0 Epic Systems Corporation  
1979 Milky Way  
Verona, WI 53593  
Trade Name: Blood Product Administration  
Module version 0.9  
Cleared Date: 06-MAR-2014

BK170032-0 Epic Systems Corporation  
1979 Milky Way  
Verona, WI 53593  
Trade Name: Blood Product Administration  
Module, Version 2-2017  
Cleared Date: 28-JUN-2017

BK200482-0 Epic Systems Corporation  
1979 Milky Way  
Verona, WI 53593  
Trade Name: Blood Product Administration  
Module

Cleared Date: 10-JUN-2020

BK241081-0 Epic Systems Corporation  
1979 Milky Way  
Verona, WI 53593  
Trade Name: Blood Product Administration  
Module (BPAM 4-2023)  
Cleared Date: 21-AUG-2024

BK110035-0 Estar Technologies LTD  
420 Lexington Avenue  
Suite 2400  
New York, NY 10170  
Trade Name: TropoCells Autologous Platelet  
Preparation Kit  
Cleared Date: 28-MAR-2012

BK920002-0 Ethox Corp.  
251 Seneca St,  
Buffalo, NY 14204  
Trade Name: Ethox Transfer Pack  
Cleared Date: 17-SEP-1992

BK830010-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Transfer Pack Unit(s) with  
Sterile Connector  
Cleared Date: 23-AUG-1988  
Cleared Under Travenol Laboratories

BK830011-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Closed Apheresis Kit for Extended  
Platelet Storage  
Cleared Date: 27-MAY-1983  
Cleared Under Travenol Laboratories

BK830009-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Plasma-Gard  
Cleared Date: 25-JAN-1984  
Cleared Under Travenol Laboratories

BK860015-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Apheresis Kit/Extended Plate.

Stor. & Plas. Coll.

Cleared Date: 03-JUL-1986

Cleared Under Travenol Laboratories

BK860029-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Isoradial Separation Chamber  
Cleared Date: 28-NOV-1986  
Cleared Under Travenol Laboratories

BK860035-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: CS-3000 Bld Cell Separator Bld  
Sample Containers  
Cleared Date: 26-FEB-1987  
Cleared Under Travenol Laboratories

BK870017-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Fenwal LS-300 Centrifuge  
Cleared Date: 16-NOV-1987  
Cleared Under Fenwal Laboratories

BK880023-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Fenual CS3000 Blood Cell Separator  
Cleared Date: 13-JUN-1989  
Cleared Under Travenol Laboratories

BK900005-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Closed System Apheresis Kit-  
CS3000 Blood Cell Separator  
Cleared Date: 05-JUN-1990  
Cleared Under Baxter Healthcare Corporation

BK900016-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Closed System Apheresis Kit  
CS-3000 Blood Cell Separator  
(single venous access for platelet  
collection)  
Cleared Date: 07-JUN-1991  
Cleared Under Baxter Healthcare Corporation

BK900020-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Optum Platelet Separation Chamber  
Cleared Date: 07-NOV-1990  
Cleared Under Baxter Healthcare Corporation

BK910014-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Sepacell R-200; Pre-Storage  
Leukocyte Depletion Set for Red  
Blood  
Cleared Date: 18-SEP-1991  
Cleared Under Baxter Healthcare Corporation

BK910032-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: OptiPress  
Cleared Date: 03-JUN-1993  
Cleared Under Baxter Healthcare Corporation

BK920003-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Fenwal Needle/Tube Sampling  
Protector/Safety Cover  
Cleared Date: 12-MAR-1992  
Cleared Under Baxter Healthcare Corporation

BK920029-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: 30-mL Collection Chamber for  
CS-3000 Plus Blood Cell Separator  
Cleared Date: 06-MAY-1994  
Cleared Under Baxter Healthcare Corporation

BK920032-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Sepacell Pre-storage Leukocyte  
Depletion Set for Red Cell  
Cleared Date: 07-JUN-1993  
Cleared Under Baxter Healthcare Corporation

BK920038-0 Fenwal Inc  
Three Corporate Drive

Lake Zurich, IL 60047  
Trade Name: Closed System Apheresis Kit with  
Integral Leukocyte Removal Filter  
Cleared Date: 27-JUL-1994  
Cleared Under Baxter Healthcare Corporation

BK930029-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Access™ Management System (AMS)  
Cleared Date: 20-JUN-1994  
Cleared Under Baxter Healthcare Corporation

BK940005-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Fenwal Bone Marrow Collection Kit  
w/ Flexible Pre-filter and Inline  
Filters and Fenwal Bone Marrow  
Collection Stand  
Cleared Date: 18-MAY-1994  
Cleared Under Baxter Healthcare Corporation

BK940009-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Optipress™ Automated Blood  
Component  
Cleared Date: 18-MAY-1994  
Cleared Under Baxter Healthcare Corporation

BK940013-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Ex Storage PL 732 Containers w/  
Sepacell Filter for Leukocytes  
Reduced Platelets  
Cleared Date: 27-JUL-1994  
Cleared Under Baxter Healthcare Corporation

BK940023-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Accessory Weight Scale for Medical  
Purposes  
Cleared Date: 05-JUL-1994  
Cleared Under Baxter Healthcare Corporation

BK940036-0 Fenwal Inc  
Three Corporate Drive

Lake Zurich, IL 60047  
Trade Name: Storage Containers for CS-3000  
Apheresis Kit  
Cleared Date: 27-DEC-1994  
Cleared Under Baxter Healthcare Corporation

BK940040-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Sepacell PLS-10A,5A Leukocyte  
Reduction Filter Platelet Products  
Cleared Date: 28-FEB-1995  
Cleared Under Baxter Healthcare Corporation

BK940041-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Sepacell R-2000 Prestorage  
Leukocyte Reduction Set for Red  
Blood Cells  
Cleared Date: 14-FEB-1995  
Cleared Under Baxter Healthcare Corporation

BK950013-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: CS-3000 Plus (mononeuclear cells)  
Cleared Date: 12-NOV-2002  
Cleared Under Baxter Healthcare Corporation

BK950016-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Pall BPF4 Leukocyte Reduction Set  
for RBC  
Cleared Date: 20-SEP-1995  
Cleared Under Baxter Healthcare Corporation

BK950023-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: CS-3000 Blood Cell Separator  
Apheresis Kit  
Cleared Date: 29-JUN-1995  
Cleared Under Baxter Healthcare Corporation

BK960005-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Amicus Separator

Cleared Date: 19-DEC-1996  
Cleared Under Baxter Healthcare Corporation

BK960083-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Hematype Segment Device  
Cleared Date: 28-FEB-1997  
Cleared Under Medical Safety Products, Inc.

BK980041-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Sepacell Pre-Storage Leukocyte  
Reduction Set for Red Cells  
Cleared Date: 16-JUL-1999  
Cleared Under Baxter Healthcare Corporation

BK990009-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Fenwal Amicus Separator Collection  
of Three Platelet Products  
Cleared Date: 03-MAR-2000  
Cleared Under Baxter Healthcare Corporation

BK000039-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Amicus Separator, Concurrent  
Collection of Red Blood Cells  
Cleared Date: 26-AUG-2002  
Cleared Under Baxter Healthcare Corporation

BK000047-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Amicus Separator, Mononuclear Cell  
Collection  
Cleared Date: 31-JUL-2002  
Cleared Under Baxter Healthcare Corporation

BK010016-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Apheresis Data Integration System  
(ADIS)  
Cleared Date: 04-DEC-2001  
Cleared Under Baxter Healthcare Corporation

BK010033-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Cygnet System  
Cleared Date: 27-AUG-2002  
Cleared Under Baxter Healthcare Corporation

BK020008-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: LeukoConnect - Pre-Storage Sterile  
Connect Leukoreduction Set with  
Sepacell Filter for Red Blood  
Cells  
Cleared Date: 10-DEC-2002  
Cleared Under Baxter Healthcare Corporation - I.V. Systems Division

BK020056-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: ALYX System  
Cleared Date: 20-DEC-2002  
Cleared Under Baxter Healthcare Corporation

BK030085-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: ALYX Component Collection System  
and Amicus Separator System  
Cleared Date: 15-MAR-2004  
Cleared Under Baxter Healthcare Corporation

BK040059-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Amicus Separator System  
Cleared Date: 24-SEP-2004  
Cleared Under Baxter Healthcare Corporation - Transfusion Therapies  
Division

BK040084-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: ALYX Component Collection System  
Cleared Date: 15-MAR-2005  
Cleared Under Baxter Healthcare Corporation

BK050020-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047

Trade Name: LeukoConnect - Pre-Storage Sterile  
Connect Leukoreduction Set with  
Sepacell Filter for Red Blood  
Cells in additive solution  
Cleared Date: 17-MAY-2005  
Cleared Under Baxter Healthcare Corporation

BK050038-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: AMICUS Separator System  
Cleared Date: 03-NOV-2005  
Cleared Under Baxter Healthcare Corporation

BK060061-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: ALYX Component Collection System:  
ALYX 2RBC-NLR Kit  
Cleared Date: 09-FEB-2007  
Cleared Under Baxter Healthcare Corporation

BK080024-0 Fenwal Inc  
Three Corporate Drive  
2nd Floor  
Lake Zurich, IL 60047  
Trade Name: ALYX Component Collection System  
Cleared Date: 24-JUN-2008

BK080048-0 Fenwal Inc  
Three Corporate Drive  
2nd Floor  
Lake Zurich, IL 60047  
Trade Name: AMICUS Separator  
Cleared Date: 02-OCT-2008

BK080053-0 Fenwal Inc  
Three Corporate Drive  
2nd Floor  
Lake Zurich, IL 60047  
Trade Name: ALYX Component Collection System  
Cleared Date: 22-DEC-2008

BK090031-0 Fenwal Inc  
Three Corporate Drive  
2nd Floor  
Lake Zurich, IL 60047  
Trade Name: Bone Marrow Collection Kit and  
Accessories  
Cleared Date: 23-JUL-2009

BK090058-0 Fenwal Inc  
Three Corporate Drive  
2nd Floor  
Lake Zurich, IL 60047  
Trade Name: AMICUS Separator System  
Cleared Date: 18-FEB-2010

BK090065-0 Fenwal Inc  
Three Corporate Drive  
2nd Floor  
Lake Zurich, IL 60047  
Trade Name: AMICUS Separator System  
Cleared Date: 04-MAR-2010

BK100041-0 Fenwal Inc  
Three Corporate Drive  
2nd Floor  
Lake Zurich, IL 60047  
Trade Name: Autopheresis - C Plasmapheresis  
System  
Cleared Date: 14-SEP-2017

BK100050-0 Fenwal Inc  
Three Corporate Drive  
2nd Floor  
Lake Zurich, IL 60047  
Trade Name: Autopheresis-C Plasmapheresis  
system  
Cleared Date: 16-NOV-2010

BK100056-0 Fenwal Inc  
Three Corporate Drive  
2nd Floor  
Lake Zurich, IL 60047  
Trade Name: ALYX Component Collection System  
Cleared Date: 07-DEC-2010

BK110025-0 Fenwal Inc  
Three Corporate Drive  
2nd Floor  
Lake Zurich, IL 60047  
Trade Name: Software, Blood Ban, Stand Alone  
Cleared Date: 22-AUG-2011

BK110030-0 Fenwal Inc  
Three Corporate Drive  
2nd Floor  
Lake Zurich, IL 60047  
Trade Name: AMICUS Separator System with

Software Version 4.3

Cleared Date: 23-DEC-2011

BK110066-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Product Sample Pack  
Cleared Date: 27-FEB-2012

BK110072-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Aurora Plasmapheresis System  
Plasmacell-C Disposable Set  
Cleared Date: 29-MAR-2012

BK120082-0 Fenwal Inc  
Three Corporate Drive  
2nd Floor  
Lake Zurich, IL 60047  
Trade Name: AMICUS Apheresis Kits  
AMICUS Separator System  
Cleared Date: 08-JAN-2013

BK130004-0 Fenwal Inc  
Three Corporate Dr  
Lake Zurich, IL 60047  
Trade Name: Alyx Component Collection System  
Cleared Date: 11-SEP-2013

BK150236-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Alyx 2RBC Closed Disposable  
Apheresis Kit  
Alyx Component Collection System  
(Alyx Classic)  
Alyx Component Collection System  
(Alyx by Fenwal)  
Cleared Date: 22-APR-2015

BK170001-0 Fenwal Inc  
Three Corporate Dr  
Lake Zurich, IL 60047  
Trade Name: Alyx Component Collection System  
(Alyx Classic)  
Alyx Component Collection System  
(Alyx by Fenwal)  
Alyx Component Collection System  
(Fresenius Kabi)

Cleared Date: 03-APR-2017

BK200475-0 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: ALYX Component Collection System  
Cleared Date: 10-JUN-2020

BK920026-0 Fenwal, Inc.  
25212 W. Illinois Route 120, RLP-34  
Round Lake, IL 60073  
Round Lake, IL 60073  
Trade Name: SDP Microplate Assay Management  
Software  
Cleared Date: 30-JUL-1993  
Cleared Under Genetic Systems Corporation

BK080018-0 Fenwal, Inc.  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Amicus Separator System  
Cleared Date: 26-AUG-2008  
Cleared Under Fenwal Blood Technologies

BK080033-0 Fenwal, Inc.  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: PLASMALINK  
Cleared Date: 22-AUG-2008  
Cleared Under Fenwal Blood Technologies

BK100044-0 Fenwal, Inc.  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Amicus Separator System  
Cleared Date: 30-JUL-2010  
Cleared Under Fenwal Blood Technologies

BK120018-0 Fenwal, Inc.  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: AMICUS Apheresis Kits  
AMICUS Separator System  
Cleared Date: 20-JUL-2012

BK120041-0 Fenwal, Inc.  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: ALYX Component Collection System  
AMICUS Separator System

Cleared Date: 03-OCT-2012

BK120047-0 Fenwal, Inc.  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Autopheresis-C Plasmapheresis  
System  
Plasmacell-C Set  
Cleared Date: 18-DEC-2012

BK130030-0 Fenwal, Inc.  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Alyx Component Collection System (  
Alyx Classic)  
Alyx Component Collection System (  
Alyx by Fenwal)  
Alyx Plasma Kit  
Cleared Date: 01-NOV-2013

BK180296-0 Fidia Farmaceutici S.p.A.  
Via Ponte della Fabbrica 3/A  
, Abano Terme, Padua ITALY 35031  
Trade Name: Fidia PRP Kit  
Fidia PRP Kit - 20mL  
Fidia PRP Kit - 50mL  
Cleared Date: 05-NOV-2019

BK251299-0 Forever Labs, Inc  
600 S Wagner Rd  
Ann Arbor, MI 48103  
Trade Name: PlateletQuick PRP  
Cleared Date: 11-MAR-2026

BK190401-0 Fremon Scientific Inc  
5726 La Jolla Blvd  
La Jolla, CA 92037  
Trade Name: ZipThaw 202  
Cleared Date: 18-DEC-2019

BK160042-0 Fresenius Kabi  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Bone Marrow Collection Kit and  
Stand  
Cleared Date: 09-JUN-2016

BK170030-0 Fresenius Kabi  
Three Corporate Drive  
Lake Zurich, IL 60047

Trade Name: Bone Marrow Collection Kit with  
Flexible Pre-Filter and Inline  
Filters  
Bone Marrow Collection Stand  
Cleared Date: 24-JUL-2017

BK160012-0 Fresenius Kabi AG  
Else-Kroner-Strasse 1  
Bad Homburg, GERMANY 61346  
Trade Name: Aurora Plasmapheresis System,  
Software Version 1.3  
Cleared Date: 19-MAY-2016

BK160028-0 Fresenius Kabi AG  
Three Corporate Dr  
Lake Zurich, IL 60047  
Trade Name: Aurora Xi Plasmapheresis System  
Cleared Date: 21-SEP-2016

BK170057-0 Fresenius Kabi AG  
Three Corporate Dr  
Lake Zurich, IL 60047  
Trade Name: Aurora Xi Plasmapheresis  
System/Aurora Xi/Aurora Xi  
system/Aurora Xi Software Version  
1.1  
Cleared Date: 25-AUG-2017

BK170072-0 Fresenius Kabi AG  
Three Corporate Dr  
Lake Zurich, IL 60047  
Trade Name: DXT Data Management System  
Cleared Date: 26-SEP-2017

BK180230-0 Fresenius Kabi AG  
Three Corporate Dr  
Lake Zurich, IL 60047  
Trade Name: DXT Data Management System - 3.1  
Cleared Date: 14-AUG-2018

BK180254-0 Fresenius Kabi AG  
Three Corporate Dr  
Lake Zurich, IL 60047  
Trade Name: Glycerolyte 57 Solution, 400 mL  
Glycerolyte 57 Solution, 500 mL  
Cleared Date: 03-DEC-2018

BK180268-0 Fresenius Kabi AG  
Three Corporate Dr  
Lake Zurich, IL 60047

Trade Name: Aurora XI Plasmapheresis  
System/Aurora XI System/Aurora XI  
- 1.2  
Cleared Date: 02-NOV-2018

BK180293-0 Fresenius Kabi AG  
Three Corporate Dr  
Lake Zurich, IL 60047  
Trade Name: Plasmalink Bottle with Locking  
Luer Adapter  
Cleared Date: 21-DEC-2018

BK190362-0 Fresenius Kabi AG  
Three Corporate Dr  
Lake Zurich, IL 60047  
Trade Name: Plasmalink Bottle with Locking  
Luer Adapter  
Cleared Date: 19-JUL-2019

BK190368-0 Fresenius Kabi AG  
Else-Kroner-Strasse 1  
Bad Homburg, GERMANY 61346  
Trade Name: Aurora Plasmapheresis  
System/Aurora /Aurora  
system/Aurora Software Version  
2.1/Aurora 2.1 - 2.1  
Aurora Software Version 2.1  
Upgrade Kit/Aurora Upgrade Kit -  
2.1  
Cleared Date: 26-JUL-2019

BK190413-0 Fresenius Kabi AG  
Else-Kroner-Strasse 1  
, Bad Homburg GERMANY 61352  
Trade Name: CompoMaster Net G5 Plus - 9026551  
CompoMat G5 Plus - 9026561  
Cleared Date: 06-FEB-2020

BK190421-0 Fresenius Kabi AG  
Else-Kroner-Strasse 1  
Bad Homburg, GERMANY 61346  
Trade Name: Fenwal Plasmalink Transfer Pack  
Container with Luer Adapter and No  
Outlet  
Fenwal Plasmalink Transfer Pack  
Container with Luer Adapter and No  
Outlet Ports - 4R2088P  
Cleared Date: 11-MAR-2020

BK200478-0 Fresenius Kabi AG

Else-Kroner-Strasse 1  
Bad Homburg, GERMANY 61346  
Trade Name: Aurora Xi Plasmapheresis  
System/Aurora Xi/Aurora Xi  
system/Aurora Xi - 1.2  
Cleared Date: 07-MAY-2020

BK220785-0 Fresenius Kabi AG  
Else-Kroner-Strasse 1  
, Bad Homburg GERMANY 61352  
Trade Name: Transfer Packs  
Cleared Date: 20-DEC-2022

BK220788-0 Fresenius Kabi AG  
Else-Kroner-Strasse 1  
Bad Homburg, GERMANY 61346  
Trade Name: Aurora Xi Plasmapheresis System  
Cleared Date: 23-DEC-2022

BK230824-0 Fresenius Kabi AG  
Else-Kroner-Strasse 1  
Bad Homburg, GERMANY 61346  
Trade Name: AMICUS Separator System  
Cleared Date: 21-APR-2023

BK230825-0 Fresenius Kabi AG  
Else-Kroner-Strasse 1  
Bad Homburg, GERMANY 61346  
Trade Name: ALYX 2RBC-LR Kit  
ALYX Component Collection System  
Cleared Date: 05-APR-2024

BK241135-0 Fresenius Kabi AG  
Else-Kroner-Strasse 1  
, Bad Homburg GERMANY 61352  
Trade Name: Aurora Xi Plasmapheresis System  
(6R4612, 6R4612R)  
Cleared Date: 24-JAN-2025

BK251160-0 Fresenius Kabi AG  
Else-Kroner-Strasse 1  
Bad Homburg, GERMANY 61346  
Trade Name: Adaptive Nomogram Bottle  
Cleared Date: 21-FEB-2025

BK251289-0 Fresenius Kabi AG  
Else-Kr ner-Str. 1  
Bad Homburg, Hesse GERMANY 61352  
Trade Name: Plasmacell-C Disposable Set  
Cleared Date: 31-MAR-2026

BK110012-0 Fresenius Kabi USA LLC.  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: CompoMat G5 and CompoMaster Net G5  
System  
Cleared Date: 02-AUG-2012  
Cleared Under fresenius Kabi, LLC.

BK150242-0 Fresenius Kabi USA LLC.  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: Amicus Separator System  
Cleared Date: 22-JUL-2015

BK150288-0 Fresenius Kabi USA LLC.  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: AMICUS Apheresis Kits  
AMICUS Apheresis System  
Cleared Date: 28-AUG-2015

BK150357-0 Fresenius Kabi USA LLC.  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: AMICUS Apheresis Kits (Model#  
4R4580, 4R4580R)  
AMICUS Separator System (Model#  
4R2353, 4R2354)  
Cleared Date: 20-APR-2016

BK160112-0 Fresenius Kabi USA LLC.  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: AMICUS Separator System  
Cleared Date: 07-APR-2017

BK170099-0 Fresenius Kabi USA LLC.  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: AMICUS Separator System  
AMICUS Separator System;  
Refurbished  
Cleared Date: 10-OCT-2017

BK190351-0 Fresenius Kabi USA LLC.  
Three Corporate Drive  
Lake Zurich, IL 60047  
Trade Name: ALYX 2RBC LR Kit  
ALYX Component Collection System

ALYX RBC/Plasma Kit  
ALYX Red Kit  
Cleared Date: 06-JUN-2019

BK030022-0 Fresenius Medical Care North America  
6675 185th Avenue NE  
Suite 100  
Redmond, WA 98052  
Trade Name: Fresenius Compomat G4 &  
Compomaster NT  
Cleared Date: 11-JUL-2003  
Cleared Under Fresenius Hemocare Inc.

BK040005-0 Fresenius Medical Care North America  
95 Hayden Avenue  
Lexington, MA 02420-9192  
Trade Name: Fresenius Compoguard &  
Donationmaster NT  
Cleared Date: 26-MAR-2004  
Cleared Under Fresenius Hemocare Inc.

BK040076-0 Fresenius Medical Care North America  
95 Hayden Avenue  
Lexington, MA 02420-9192  
Trade Name: Compodock  
Cleared Date: 17-DEC-2004  
Cleared Under Fresenius Hemocare Inc.

BK880007-0 Fresenius USA/Seratronics Inc.  
2637 Shadelands Drive  
Walnut Creek, CA 94598  
Trade Name: Fresenius AS104 Cell Separator  
Cleared Date: 22-JUL-1996

BK880018-0 Fresenius USA/Seratronics Inc.  
4090 Pike Lane  
Concord, CA 94502  
Trade Name: Astotherm IFT 200; IFT 220  
Cleared Date: 25-AUG-1988

BK960066-0 Frigidaire Commercial Products Company  
707 Robins St  
Conway, AR 72032  
Trade Name: Eagle Series Blood Storage  
Refrigerator # ST30RGG and ST50  
Cleared Date: 30-AUG-1996

BK960092-0 Fujirebio America Inc.  
30 Two Bridges Road  
Suite 250

Fairfield, NJ 07004  
Trade Name: Olympus PK CMV-PA System &  
Controls  
Cleared Date: 28-OCT-1998

BK960070-0 Fujirebio Diagnostics, Inc  
201 Great Valley Parkway  
Malvern, PA 19355  
Trade Name: Olympus PK-TP System Control Set  
Cleared Date: 19-JUN-1997  
Cleared Under SCIMEDX Corporation

BK200476-0 Fujirebio Diagnostics, Inc  
201 Great Valley Parkway  
Malvern, PA 19355  
Trade Name: PK CMV-PA System  
PK CMV-PA System Control Set  
Cleared Date: 19-OCT-2020

BK030007-0 Fujirebio Diagnostics, Inc.  
201 Great Valley Parkway  
Malvern, PA 19355  
Trade Name: Olympus PK TP System  
Cleared Date: 21-FEB-2003

BK060062-0 Fujirebio Diagnostics, Inc.  
201 Great Valley Parkway  
Malvern, PA 19355  
Trade Name: Olympus PK TP Reagent System  
Cleared Date: 25-JUN-2007

BK070030-0 Fujirebio Diagnostics, Inc.  
201 Great Valley Parkway  
Malvern, PA 19355  
Trade Name: Olympus PK CMV-PA Test System and  
Controls  
Olympus PK7300 Automated Blood  
Bank Analyzer  
Cleared Date: 20-SEP-2007

BK940047-0 Fujirebio, Inc.  
1129 Bloomfield Ave,  
West Caldwell, NJ 07006  
Trade Name: Olympus PK TP System Reactive  
Control  
Cleared Date: 29-NOV-1995

BK920005-0 Futuremed  
2076 Deer Park Avenue  
Deer Park, NY 11729

Trade Name: AM-4  
Cleared Date: 29-SEP-1994

BK940055-0 Futuremed  
2076 Deer Park Avenue  
Deer Park, NY 11729  
Trade Name: L Fusion Bags for Warming  
Blood/Plasma w/ ANIMEC4  
Cleared Date: 27-DEC-1994

BK050018-0 GE Medical Information Technologies  
540 Northwest Highway  
Barrington, IL 60010  
Trade Name: Centricity Ultra Laboratory  
Transfusion Medicine (Ultra TM) -  
4.0  
Cleared Date: 13-JUN-2005

BK230807-0 GENESIS BIOLOGICS, INC.  
16782 Von Karman Ave  
Irvine, CA 92606  
Trade Name: Adaptive Autologous Processing  
System  
Cleared Date: 10-MAY-2023

BK220791-0 GPI USA, Inc.  
4900 Woodway Dr, Suite 680  
Houston, TX 77056  
Trade Name: e-Delphyn Donor  
Cleared Date: 26-JUN-2023

BK241042-0 Gale Force Aesthetics, LLC.  
1644 Ramona Way  
Alamo, CA 94507  
Trade Name: Illuminate PRP  
Cleared Date: 27-AUG-2024

BK870024-0 Gambro Inc.  
23872 Kelsey Road  
Barrington, IL 60010  
Trade Name: Gambro Welding Device WD2  
Cleared Date: 02-NOV-1987

BK820017-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Omni-Series Control  
Cleared Date: 21-JAN-1983

BK830012-0 Gamma Biologicals, Inc.

3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma Omni Coombs Control Cells  
Cleared Date: 13-JUN-1983

BK830014-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Elu-Kit II  
Cleared Date: 13-JUN-2025

BK830019-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma Microtear System  
Cleared Date: 21-SEP-1983

BK830026-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma Micro-U Plate  
Cleared Date: 08-DEC-1983

BK850001-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma STS-M  
Cleared Date: 05-APR-1985

BK850002-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma STS Red Cell Diluent  
Cleared Date: 05-APR-1985

BK850005-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma STS-A  
Cleared Date: 03-OCT-1986

BK850019-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma Micro-U Accessory Equipment  
(Timer Device)  
Cleared Date: 20-MAR-1986

BK850020-0 Gamma Biologicals, Inc.  
3700 Mangum Road

Houston, TX 77092  
Trade Name: Gamma Micro-U Accessory Equipment  
Cleared Date: 20-MAR-1986

BK850021-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma Micro-U Accessory Equipment  
Cleared Date: 20-MAR-1986

BK850024-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma Micro-U Coombs Wash Solution  
Cleared Date: 20-MAR-1986

BK850025-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma Micro-U Enhancement Reagent  
Cleared Date: 20-MAR-1986

BK860024-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma N-HANCE  
Cleared Date: 26-AUG-1986

BK880016-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: GammaZyme-B  
Cleared Date: 25-AUG-1988

BK900021-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma-clone Control  
Cleared Date: 26-OCT-1990

BK910001-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma Peg  
Cleared Date: 24-MAR-1992

BK930026-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma RQC-Kit

Cleared Date: 16-NOV-1993

BK960055-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Coombs Control Cells (EIgG) Strong  
Cleared Date: 23-OCT-1996

BK960056-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Coombs Control Cells (EIgG) Weak  
Cleared Date: 23-OCT-1996

BK960077-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma Re-ACT Centrifuge  
Cleared Date: 18-SEP-1997

BK960078-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma ReACT Incubator  
Cleared Date: 18-SEP-1997

BK960079-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma ReACT Antibody Detection  
Strips  
Cleared Date: 18-SEP-1997

BK960080-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma ReACT Diluent  
Cleared Date: 18-SEP-1997

BK960081-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma ReACT Control Cells (EIgG)  
Cleared Date: 18-SEP-1997

BK960090-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma EGA Kit  
Cleared Date: 19-MAY-2025

BK970002-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma-ReACT workstation  
Cleared Date: 30-MAY-1997

BK970003-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Gamma-ReACT Reader  
Cleared Date: 30-MAY-1997

BK970047-0 Gamma Biologicals, Inc.  
3700 Mangum Road  
Houston, TX 77092  
Trade Name: Olympus System Control Reagent  
Cleared Date: 11-DEC-1998

BK060050-0 Gaymar Industries, Inc.  
1700 Pennsylvania Avenue, N.W.  
Washington, DC 20006-4706  
Trade Name: Medi-Temp III, Model FW600  
Blood/Fluid Warmer  
Cleared Date: 07-NOV-2006

BK950002-0 Gen Trak, Inc.  
5100 Campus Dr.  
Plymouth Meeting, NJ 19462  
Trade Name: CQuantials DR DNA Typing Kit  
Cleared Date: 15-MAY-1995

BK000051-0 Gen-Probe  
10210 Genetic Center Drive  
San Diego, CA 92121-4362  
Trade Name: The Chiron Procleix System  
Cleared Date: 08-FEB-2002

BK010003-0 Gen-Probe  
10210 Genetic Center Drive  
San Diego, CA 92121-4362  
Trade Name: ChironProcleix HIV-1/HCV Controls  
Cleared Date: 22-FEB-2002

BK010005-0 Gen-Probe  
10210 Genetic Center Drive  
San Diego, CA 92121-4362  
Trade Name: Chiron Procleix HIV/HCV  
Proficiency Panel  
Cleared Date: 01-OCT-2001

BK020045-0 Gen-Probe  
10210 Genetic Center Drive  
San Diego, CA 92121-4362  
Trade Name: Chiron Procleix System  
Cleared Date: 21-NOV-2002

BK050007-0 Gen-Probe  
10210 Genetic Center Drive  
San Diego, CA 92121-4362  
Trade Name: Procleix System  
Cleared Date: 29-APR-2005

BK050042-0 Gen-Probe  
10210 Genetic Center Drive  
San Diego, CA 92121-4362  
Trade Name: Procleix System for the Procleix  
WNV Assay  
Cleared Date: 15-NOV-2005

BK060012-0 Gen-Probe  
10210 Genetic Center Drive  
San Diego, CA 92121-4362  
Trade Name: Procleix System  
Cleared Date: 15-MAR-2006

BK060021-0 Gen-Probe  
10210 Genetic Center Drive  
San Diego, CA 92121-4362  
Trade Name: Procleix TIGRIS System for use  
with the Procleix WNV Assay  
Cleared Date: 20-FEB-2007

BK110002-0 Gen-Probe  
550 West Avenue  
Stanford, CT 06902  
Trade Name: LIFECODES HLA-A eRES Typing Kit  
for use with Luminex  
LIFECODES HLA-B eRES Typing Kit  
for use with Luminex  
LIFECODES HLA-DRB 3, 4, 5 Typing  
Kit for use with Luminex  
LIFECODES HLA-DRB1 eRES Typing Kit  
for use with Luminex  
Cleared Date: 02-DEC-2011

BK120063-0 Gen-Probe  
550 West Avenue  
Stanford, CT 06902  
Trade Name: LIFECODES HLA-C eRES Typing Kit

for use with Luminex  
Cleared Date: 21-NOV-2012

BK040019-0 Gen-Probe GTI Diagnostics  
20925 Crossroads Circle  
Waukesha, WI 53186  
Trade Name: Antibody Monitoring System Class I  
and Class II (AMS1 and AMS1+2)  
Cleared Date: 06-JUL-2004  
Cleared Under GTI, INC

BK040034-0 Gen-Probe GTI Diagnostics  
20925 Crossroads Circle  
Waukesha, WI 53186  
Trade Name: Lifecodes LifeScreen: A Luminex  
100 Screening Assay for the  
Detection of IgG Antibodies to HLA  
Class I and Class II Molecules of  
Human Origin  
Cleared Date: 16-JUL-2004  
Cleared Under GTI, INC

BK040035-0 Gen-Probe GTI Diagnostics  
20925 Crossroads Circle  
Waukesha, WI 53186  
Trade Name: Lifecodes ID Class I: A Luminex  
100 screening assay for the  
qualitative detection of IgG panel  
reactive antibodies (PRA) to HLA  
Class I molecules  
Lifecodes ID Class II: A Luminex  
100 screening assay for the  
qualitative detection of IgG panel  
reactive antibodies (PRA) to HLA  
Class II molecules  
Cleared Date: 16-JUL-2004  
Cleared Under GTI, INC

BK050040-0 Gen-Probe GTI Diagnostics  
20925 Crossroads Circle  
Waukesha, WI 53186  
Trade Name: ThromboType (HPA 1-6, 15) and  
ThromboType 1 (HPA 1)  
Cleared Date: 20-JAN-2006  
Cleared Under GTI, INC

BK050054-0 Gen-Probe GTI Diagnostics  
20925 Crossroads Circle  
Waukesha, WI 53186  
Trade Name: GranType(TM)

Cleared Date: 02-MAR-2006  
Cleared Under GTI, INC

BK060038-0 Gen-Probe GTI Diagnostics  
20925 Crossroads Circle  
Waukesha, WI 53186  
Trade Name: MICROAMS  
Cleared Date: 28-JUL-2006  
Cleared Under GTI, INC

BK070034-0 Gen-Probe GTI Diagnostics  
20925 Crossroads Circle  
Waukesha, WI 53186  
Trade Name: HLA EZ Type  
Cleared Date: 10-JUL-2008  
Cleared Under GTI, INC

BK070045-0 Gen-Probe GTI Diagnostics  
20925 Crossroads Circle  
Waukesha, WI 53186  
Trade Name: Donor Screen HLA Class I and Class  
II  
Cleared Date: 30-JUL-2008  
Cleared Under GTI, INC

BK110011-0 Gen-Probe GTI Diagnostics  
20925 Crossroads Circle  
Waukesha, WI 53186  
Trade Name: Lifecodes Class II ID v2  
Cleared Date: 04-JUN-2012

BK220714-0 Genesis Biosystems Inc.  
1500 Eagle Court  
Lewisville, TX 75057  
Trade Name: LipiVage (K172714)  
Cleared Date: 08-DEC-2017

BK850003-0 GenesisBPS, LLC  
65 Commerce Way  
Hackensack, NJ 07601  
Trade Name: Cryosan Pediatric Pack  
Cleared Date: 05-APR-1985  
Cleared Under Cryosan Inc.

BK950018-0 GenesisBPS, LLC  
65 Commerce Way  
Hackensack, NJ 07601  
Trade Name: TOTAL CONTAINMENT DEVICE (TCD)  
Cleared Date: 14-NOV-1995  
Cleared Under Denco, INC.

BK140187-0 GenesisBPS, LLC  
465 State Route 17  
Ramsey, NJ 07446  
Trade Name: Blade Arm Module  
Genesis Rapid Weld STW  
Weld Blade Module Replacement Kits  
Cleared Date: 06-MAR-2015  
Cleared Under Genesis BPS, LLC

BK210584-0 GenesisBPS, LLC  
465 State Route 17  
Ramsey, NJ 07446  
Trade Name: 1000 Weld Blade Module Replacement  
Kit  
250 Weld Blade Module Replacement  
Kit  
500 Weld Blade Module Replacement  
Kit  
Blade Arm Module  
Genesis RapidWeld II STW (Sterile  
Tube Welder), model GRW-430-02  
Genesis RapidWeld II STW, model  
GRW-430-02  
Power Supply  
Cleared Date: 15-JUL-2022

BK880025-0 Genetic Design Inc.  
7019 Albert Pick Rd.; Suite H  
Greensboro, NC 27409  
Trade Name: HLA-DR Typing Trays  
Cleared Date: 30-DEC-1988

BK870006-0 Genetic Systems Corporation  
3005 First Avenue  
Seattle, WA 98121  
Trade Name: HLA-B27 Antigen Typing Kit  
Cleared Date: 20-JUL-1987

BK900011-0 Genetic Systems Corporation  
3005 First Avenue  
Seattle, WA 98121  
Trade Name: Genetic Systems Blood Virus  
Software  
Cleared Date: 15-MAR-1991

BK930031-0 Genetic Systems Corporation  
3005 First Avenue  
Seattle, WA 98121  
Trade Name: Espresso Cartridge Software for

Blood Virus Applications

Cleared Date: 24-FEB-1994

BK860022-0 Genetic Testing Institute  
1701 W. Wisconsin Avenue, Suite 429  
Milwaukee, WI 53233  
Trade Name: GTI-60 HLA Typing Trays  
GTI-72 HLA Typing Trays  
GTI-96 HLA Typing Trays  
Cleared Date: 24-FEB-1987

BK910013-0 Genetic Testing Institute  
1701 W. Wisconsin Avenue, Suite 429  
Milwaukee, WI 53233  
Trade Name: GTI Pep Antibody Enhancement  
Solution  
Cleared Date: 23-JUN-1992

BK930014-0 Genetic Testing Institute  
1701 W. Wisconsin Avenue, Suite 429  
Milwaukee, WI 53233  
Trade Name: GTI Reduced Wash Elution Kit  
Cleared Date: 28-OCT-1993

BK930032-0 Genetic Testing Institute  
1701 W. Wisconsin Avenue, Suite 429  
Milwaukee, WI 53233  
Trade Name: GTI ACE Antigen Capture ELISA for  
Detection of IgG Antibodies to  
Platelet Specific Antibodies  
Cleared Date: 20-JUN-1994

BK950004-0 Genetic Testing Institute  
1701 W. Wisconsin Avenue, Suite 429  
Milwaukee, WI 53233  
Trade Name: GTI-PAK 2 Platelet Antibody  
Screening Kit  
Cleared Date: 15-MAY-1995

BK950005-0 Genetic Testing Institute  
1701 W. Wisconsin Avenue, Suite 429  
Milwaukee, WI 53233  
Trade Name: GTI-HLA 1, Class I Antibody  
Screening Kit  
Cleared Date: 19-MAY-1995

BK970006-0 Genetic Testing Institute  
1701 W. Wisconsin Avenue, Suite 429  
Milwaukee, WI 53233  
Trade Name: GTI-HAT, Heparin-Associated

Antibody Screening Kit

Cleared Date: 14-APR-1997

- BK980005-0 Genetic Testing Institute  
150 N. Patrick Blvd.  
Brookfield, WI 53045  
Trade Name: GTI PAT HPA-1 (PI) Genotyping Kit  
Cleared Date: 23-APR-1999
- BK000015-0 Genetic Testing Institute  
150 N. Patrick Blvd.  
Brookfield, WI 53045  
Trade Name: Quick ID Solid Phase ELISA for  
detection of Panel Reactive HLA  
Class I IgG Antibodies (PRA)  
Cleared Date: 17-OCT-2000
- BK000031-0 Genetic Testing Institute  
150 N. Patrick Blvd.  
Brookfield, WI 53045  
Trade Name: GTI-MACE (Modified Capture Elisa)  
Cleared Date: 29-JAN-2001
- BK990043-0 Genetic Testing Institute  
150 N. Patrick Blvd.  
Brookfield, WI 53045  
Trade Name: B-Screen Solid Phase ELISA Assay  
for Detection of IgG Antibodies to  
HLA Class II Antigens  
Cleared Date: 02-OCT-2000
- BK010010-0 Genetic Testing Institute  
150 N. Patrick Blvd.  
Brookfield, WI 53045  
Trade Name: Quik-ID Class II  
Cleared Date: 01-OCT-2001
- BK960059-0 Genetic Testing Institute, Inc. (GTI)  
20925 Crossroads Circle  
Sutie 200  
Waukesha, WI 53186  
Trade Name: PAKAUTO Platelet Antibody  
Screening Kit  
Cleared Date: 22-OCT-1998  
Cleared Under Genetic Testing Institute
- BK090002-0 Genetic Testing Institute, Inc. (GTI)  
20925 Crossroads Circle  
Sutie 200  
Waukesha, WI 53186

Trade Name: Lifecodes LifeScreen Deluxe  
Cleared Date: 17-APR-2009

BK150354-0 Genteel LLC  
4011 Livingston St  
Midland, TX 79709  
Trade Name: Genteel Lancing Device (Genteel)  
Cleared Date: 18-DEC-2015

BK940057-0 George-King Bio-Medical, Inc.  
11771 W 112th St,  
Overland Park, KS 66210  
Trade Name: B-Fact, Borderline Factor Assay  
Control  
Cleared Date: 14-NOV-1994

BK940058-0 George-King Bio-Medical, Inc.  
11771 W 112th St,  
Overland Park, KS 66210  
Trade Name: A-Fact, Abnormal Factor Assay  
Control  
Cleared Date: 14-NOV-1994

BK940059-0 George-King Bio-Medical, Inc.  
11771 W 112th St,  
Overland Park, KS 66210  
Trade Name: Positive Lupus Anticoagulant  
Plasma  
Cleared Date: 14-NOV-1994

BK940060-0 George-King Bio-Medical, Inc.  
11771 W 112th St,  
Overland Park, KS 66210  
Trade Name: Protein C Deficient Plasma  
Cleared Date: 14-NOV-1994

BK050026-0 Greiner Bio One North America, Inc.  
4238 Capital Drive  
Monroe, NC 28110  
Trade Name: Greiner Vacuette No Additive Tubes  
Cleared Date: 07-JUL-2005

BK050028-0 Greiner Bio One North America, Inc.  
4238 Capital Drive  
Monroe, NC 28110  
Trade Name: Greiner Vacuette Clot Activator  
Tube  
Cleared Date: 07-JUL-2005

BK030001-0 Greiner Bio-One GmbH

4238 Capital Drive  
Monroe, NC 28112  
Trade Name: Greiner Vacuette EDTA K3 Tube  
Cleared Date: 26-FEB-2003

BK030032-0 Greiner Bio-One GmbH  
4238 Capital Drive  
Monroe, NC 28112  
Trade Name: Vacuette EDTA K2 Tube  
Cleared Date: 18-JUL-2003

BK040066-0 Greiner Vacuette North America, Inc.  
4238 Capital Dr  
Monroe, NC 28110  
Trade Name: Greiner VACUETTE No Additive  
Evacuated Blood Collection Tubes  
and Serum Clot Activator Blood  
Collection Tubes  
Cleared Date: 10-SEP-2004  
Cleared Under sienna partners

BK251245-0 Grifols Diagnostic Solutions Inc.  
10808 Willow Court  
San Diego, CA 92127  
Trade Name: Procleix WNV/Babesia Quality  
Control  
Cleared Date: 02-JAN-2026

BK251246-0 Grifols Diagnostic Solutions Inc.  
10808 Willow Court  
San Diego, CA 92127  
Trade Name: Procleix HIV-1/HCV/HBV Quality  
Control (N/A)  
Cleared Date: 02-JAN-2026

BK251300-0 Grifols Diagnostic Solutions Inc.  
10808 Willow Court  
San Diego, CA 92127  
Trade Name: Procleix Plasmodium Quality  
Control  
Cleared Date: 26-MAR-2026

BK231025-0 HOLOGIC INC  
10210 Genetic Center Dr  
San Diego, CA 92121  
Trade Name: Aptima HIV-1 Quant Dx Assay  
Cleared Date: 06-AUG-2024

BK220691-0 HUMAN MED AG  
Wilhelm-Hennemann-Strasse 9

, Schwerin GERMANY D-19061  
Trade Name: LIPCOLLECTOR II (K101713)  
Cleared Date: 29-JUN-2010

BK200449-0 Haeleon Medical, Inc.  
1090 Lawrence Dr  
Newbury Park, CA 91320  
Trade Name: Healeon Duet  
Cleared Date: 06-AUG-2020

BK840002-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Alpha Plasma Pooling Bottle II  
Cleared Date: 13-JUL-1984

BK840007-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Alpha Plasma Pooling Bottle  
Cleared Date: 21-SEP-1984

BK840014-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics V50 Surge Procedure  
Cleared Date: 06-JUL-1984

BK840021-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics PCS Plasma Collection  
System  
Cleared Date: 03-JAN-1985

BK840022-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics 115 Cell Washer  
Cleared Date: 24-OCT-1984

BK840025-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics 16 Programmed Pump  
Cleared Date: 14-NOV-1984

BK860013-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114

Trade Name: 603-EX Extended Storage  
Plateletpheresis Set  
Cleared Date: 06-NOV-1987

BK870026-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics Ultralite Plasma  
Collection System  
Cleared Date: 17-MAR-1988

BK890007-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics 705 Time Saver  
Platelet Pack  
Cleared Date: 13-AUG-1990

BK900019-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Alpha Plasma Pooling Bottle II  
(Significant Rev.)  
Cleared Date: 14-AUG-1990

BK900022-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Plasma Pooling Bottle II  
(Significant Revision)  
Cleared Date: 11-OCT-1990

BK900027-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: 790 ESP Collection Set  
Cleared Date: 19-APR-1991

BK910009-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Alpha Plasma Pooling Bottle II  
(Significant Rev.)  
Cleared Date: 08-SEP-1991

BK920012-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: 705FTSPP/790F  
Cleared Date: 16-SEP-1992

BK920039-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Plasma Collection System PCS2  
Cleared Date: 02-SEP-1993

BK930007-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: 790 Extended Storage Platelet  
Collection Set  
Cleared Date: 16-NOV-1993

BK930008-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: 791 A Fresh Frozen Plasma  
Collection Set (Latham Bowl)  
Cleared Date: 16-NOV-1993

BK930009-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: 791 Fresh Frozen Plasma Collection  
Set (Blow Molded Bowl)  
Cleared Date: 16-NOV-1993

BK930013-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: MCS Plus & Disp.Sets, List No.  
890,790,791A,791  
Cleared Date: 12-JAN-1994

BK940064-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Red Cell and Plasma Apheresis  
Set/FOR USE WITH MCP PLUS  
Cleared Date: 23-OCT-1995

BK950001-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics RBC Apheresis Set for  
MCS+(NO.831)  
Cleared Date: 22-APR-1996

BK950006-0 Haemonetics Corporation

400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: List #890F Extended Storage Plt  
Collection Set  
Cleared Date: 09-JUN-1995

BK950007-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: ESP White Cell Filter (No. 790F)  
Cleared Date: 28-JUN-1995

BK950033-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics PCS2  
Cleared Date: 16-APR-1996

BK950034-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Double Product Collection (SDP-3)  
Cleared Date: 15-FEB-1996

BK950063-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Red Blood Cell and Plasma  
Collection Set for the MCS Plus  
#823  
Cleared Date: 22-JUL-1996

BK960006-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Double Unit Red Blood Cell  
Apheresis Set MCS #833  
Cleared Date: 15-OCT-1996

BK960022-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: MCS+Double Unit RBC Apheresis  
Set-Dry(LN832)  
Cleared Date: 16-APR-1997

BK960023-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: MCS+Red Cell & Plasma Apheresis

Set - Dry(LN822)  
Cleared Date: 16-APR-1997

BK960095-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: MCS+Apheresis System (LN8150)  
Cleared Date: 11-APR-1997

BK970029-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Alpha Plasma Pooling Bottle II  
(60-2227S)  
Cleared Date: 07-JAN-1998  
Cleared Under Alpha Therapeutic Corporation

BK970034-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: LN994CF  
Cleared Date: 15-SEP-1998

BK970041-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics Corp. Extended Storage  
Platelet & Plasma Apheresis Set  
with Saline Compensation & Pall  
LRF-XL (LN994C)  
Cleared Date: 16-NOV-1998

BK980040-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Citroflex Plasticized PVC  
Extended Storage Platelet Bag  
Cleared Date: 07-JAN-1999

BK000002-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Model 215 Automated  
Glycerolization and  
Deglycerolization System  
Cleared Date: 04-MAY-2001

BK990033-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114

Trade Name: MCS+ LN8150  
Cleared Date: 20-JAN-2000

BK990044-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics LN832F  
Two Unit Red Cells Disposable Set  
with Leukocyte reduction Filter  
Cleared Date: 27-OCT-2000

BK000048-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics LN832F  
Cleared Date: 09-APR-2001

BK010035-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: MCS+ Mobile Collection System  
Cleared Date: 20-DEC-2002

BK020001-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Plasma Pooling Bottle II  
Cleared Date: 29-MAR-2002

BK030031-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics Model 215 Automated  
Glycerolization /  
Deglycerolizationand Cell Washing  
System  
Cleared Date: 10-SEP-2003

BK030062-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics Model 215 Automated  
Glycerolization/deglycerolization  
System  
Cleared Date: 10-DEC-2003

BK030084-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics LN994CF-CPP-BA

Extended Storage Platelet and  
Plasma Apheresis Set

Cleared Date: 09-JAN-2004

- BK040001-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics 4mL Sampling System  
Cleared Date: 27-FEB-2004
- BK040020-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics LN994CF-BA Extended  
Storage Platelet and Plasma  
Apheresis Set with Leukocyte  
Reduction Filter, and 4 mL  
Sampling System.  
Cleared Date: 29-MAR-2004
- BK040025-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: PCS2 Plasma Collection System  
Cleared Date: 02-JUN-2004
- BK040041-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics MCS+8150 Apheresis  
System  
Cleared Date: 12-JUL-2004
- BK040077-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics Model 215 Automated  
Glycerolization/Deglycerolization  
System  
Cleared Date: 21-DEC-2004
- BK050006-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: ACP 215  
Glycerolization/Deglycerolization  
System  
Cleared Date: 14-APR-2005
- BK050047-0 Haemonetics Corporation

400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: MCS+9000, SDP revision E software,  
994CF-CPP series disposable sets  
Cleared Date: 21-NOV-2005

BK050048-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics MCS+ 8150 Apheresis  
System  
Cleared Date: 27-SEP-2005

BK060008-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics ACP 215  
Glycerolization/Deglycerolization  
System  
Cleared Date: 23-MAY-2006

BK060023-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics MCS+ 8150 Apheresis  
System  
Cleared Date: 23-MAY-2006

BK060033-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics PCS 2 Plasma  
Collection System, Wireless (W)  
Capable Modification-  
Cleared Date: 27-MAR-2008

BK060057-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Cymbal Automated Blood Collection  
System  
Cleared Date: 28-FEB-2007

BK070019-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics PCS2 Plasma Collection  
System  
Cleared Date: 23-MAY-2007

BK080025-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Cymbal Automated Blood Collection  
System  
Cleared Date: 15-AUG-2008

BK090041-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Symphony System  
Cleared Date: 28-SEP-2009

BK090083-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Cymbal Automated Blood Collection  
System  
Cleared Date: 27-JAN-2010

BK110015-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Nextgen - 1.0.0  
Cleared Date: 13-JUN-2011

BK120065-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: PCS2 Plasma Collection System  
Cleared Date: 26-NOV-2012

BK120083-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: MCS+ 8150 System - Wireless  
Cleared Date: 20-MAR-2013

BK120084-0 Haemonetics Corporation  
4925 Robert J Mathews Parkway  
Suite 100  
El Dorado Hills, CA 95762  
Trade Name: Phlebotomy System  
Cleared Date: 30-APR-2013

BK130056-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics PCS2 Plasma Collection  
System

Cleared Date: 29-AUG-2014

BK130081-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Cymbal Automated Blood Collection  
System  
Cleared Date: 23-JAN-2014

BK130082-0 Haemonetics Corporation  
4925 Robert J Mathews Parkway  
Suite 100  
El Dorado Hills, CA 95762  
Trade Name: NextGen  
Cleared Date: 08-AUG-2014

BK140108-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: MCS+ 8150  
Cleared Date: 26-AUG-2014

BK140199-0 Haemonetics Corporation  
4925 Robert J Mathews Parkway  
Suite 100  
El Dorado Hills, CA 95762  
Trade Name: Surround 5.1  
Cleared Date: 05-FEB-2015

BK150287-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics MCS+ 8150 Apheresis  
System  
Cleared Date: 28-JUL-2015

BK150292-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Haemonetics PCS2 Plasma Collection  
System  
Cleared Date: 28-JUL-2015

BK150360-0 Haemonetics Corporation  
4925 Robert J Mathews Parkway  
Suite 100  
El Dorado Hills, CA 95762  
Trade Name: SafeTrace Tx 3.12.0 Device  
Cleared Date: 11-MAR-2016

BK160019-0 Haemonetics Corporation  
4925 Robert J Mathews Parkway  
Suite 100  
El Dorado Hills, CA 95762  
Trade Name: ElDorado Donor 4 Next Generation  
Donor Management Solution 1.0.0  
Cleared Date: 17-MAY-2016

BK160052-0 Haemonetics Corporation  
4925 Robert J Mathews Parkway  
Suite 100  
El Dorado Hills, CA 95762  
Trade Name: InstaMatch 1.0.0  
Cleared Date: 25-AUG-2016

BK170045-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: PCS 300 Plasma Collection System  
Cleared Date: 25-JUL-2017

BK180185-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: PCS 300 Plasma Collection System  
Cleared Date: 27-MAR-2018

BK180209-0 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Trade Name: Safe Trace Tx - 4.0.0  
SafeTrace Tx  
Cleared Date: 07-AUG-2018

BK200498-0 Haemonetics Corporation  
125 Summer St  
Boston, MA 02110  
Trade Name: NexSys PCS Plasma Collection  
System with Persona Technology  
Cleared Date: 02-OCT-2020

BK220798-0 Haemonetics Corporation  
125 Summer St  
Boston, MA 02110  
Trade Name: NexSys PCS Plasma Collection  
System with ExpressPlus Technology  
Cleared Date: 20-JUN-2023

BK231036-0 Haemonetics Corporation  
125 Summer St

Boston, MA 02110  
Trade Name: NexLynk DMS Donor Management  
System - 4.10.0  
Cleared Date: 15-MAR-2024

BK241062-0 Haemonetics Corporation  
125 Summer St  
Boston, MA 02110  
Trade Name: BloodTrack Software - 4.16.0  
Cleared Date: 21-JUN-2024

BK251241-0 Haemonetics Corporation  
125 Summer St  
Boston, MA 02110  
Trade Name: SafeTrace Tx - 5.0.0  
Cleared Date: 10-SEP-2025

BK251292-0 Haemonetics Corporation  
125 Summer St  
Boston, MA 02110  
Trade Name: NexSys PCS Plasma Collection  
System with Persona Plus  
Technology  
Cleared Date: 20-FEB-2026

BK080001-0 Haemonetics Corporation Software Solutions  
1630 Industrial Park Street  
Covina, CA 91722-9144  
Trade Name: PCS2 Plasma Collection  
System\_Revision K software  
Cleared Date: 28-MAY-2008  
Cleared Under Haemonetics Corporation

BK080038-0 Haemonetics Corporation Software Solutions  
1630 Industrial Park Street  
Covina, CA 91722-9144  
Trade Name: MCS+ 9000 System  
Cleared Date: 04-SEP-2008  
Cleared Under Haemonetics Corporation

BK090004-0 Haemonetics Corporation Software Solutions  
1630 Industrial Park Street  
Covina, CA 91722-9144  
Trade Name: MCS+8150 System - Wireless  
Cleared Date: 20-FEB-2009  
Cleared Under Haemonetics Corporation

BK140133-0 Haemonetics Corporation Software Solutions  
4925 Robert J. Matthews Parkway  
Suite 100

El Dorado Hills, CA 95762  
Trade Name: BloodTrack - 4.7.0  
Cleared Date: 29-AUG-2014

BK140166-0 Haemonetics Corporation Software Solutions  
4925 Robert J. Matthews Parkway  
Suite 100  
El Dorado Hills, CA 95762  
Trade Name: Cross Donation Check System (CDCS)  
- 1.0.0  
Cleared Date: 10-OCT-2014

BK140183-0 Haemonetics Corporation Software Solutions  
4925 Robert J. Matthews Parkway  
Suite 100  
El Dorado Hills, CA 95762  
Trade Name: Donor Doc 3.0.0  
Cleared Date: 10-DEC-2014

BK150308-0 Haemonetics Corporation Software Solutions  
4925 Robert J. Matthews Parkway  
Suite 100  
El Dorado Hills, CA 95762  
Trade Name: ElDorado Donor - 3.0.0  
Cleared Date: 20-NOV-2015

BK150330-0 Haemonetics Corporation Software Solutions  
4925 Robert J. Matthews Parkway  
Suite 100  
El Dorado Hills, CA 95762  
Trade Name: NextGen 3.0.0  
Cleared Date: 03-MAR-2016

BK820014-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Plasma Pooling Bags  
Cleared Date: 13-JUN-2025  
Cleared Under Cutter Biological

BK840010-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: CLX Transfer Bag  
Cleared Date: 15-AUG-1984  
Cleared Under Cutter Biological

BK850026-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184

Trade Name: Neocel System  
Cleared Date: 22-MAY-1986  
Cleared Under Miles, Inc.

BK860001-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Leukotrap System  
Cleared Date: 05-AUG-1986  
Cleared Under Cutter Biological

BK860006-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Cutter PPP Harness  
Cleared Date: 17-SEP-1986  
Cleared Under Miles, Inc.

BK860028-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Component Aliquot System  
Cleared Date: 07-DEC-1987  
Cleared Under Miles, Inc.

BK860040-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Blood Collection Unit w/o  
Anticoagulant  
Cleared Date: 24-JUN-1987  
Cleared Under Cutter Biological

BK900034-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Phlebotomist Protection Device  
Cleared Date: 27-JAN-1992  
Cleared Under Miles, Inc.

BK920027-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Plasma Pooling Bag  
Cleared Date: 13-APR-1993  
Cleared Under Miles, Inc.

BK930001-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184

Trade Name: Plasma Sample Vial  
Cleared Date: 20-SEP-1993  
Cleared Under Miles, Inc.

BK970040-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Medsep Plasma Bag  
Cleared Date: 23-JAN-1998  
Cleared Under MEDSEP Corp.

BK000032-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Modified Plasma Bag  
Cleared Date: 27-SEP-2000  
Cleared Under MEDSEP Corp.

BK020014-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall Bacterial Detection System  
(BDS)  
Cleared Date: 22-OCT-2002  
Cleared Under Medsep Corporation

BK030082-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall eBDS  
Cleared Date: 04-FEB-2004  
Cleared Under Medsep Corporation

BK050015-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Leukotrap SC RC Filtration System  
Cleared Date: 14-APR-2005  
Cleared Under MEDSEP Corp.

BK050034-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall Acrodose PL System, Platelet  
Pool and Store Set with eBDS  
Pall Platelet Pool and Store Set  
with Pall eBDS  
Cleared Date: 28-SEP-2005  
Cleared Under Medsep Corporation

BK050074-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall Acrodose PL System  
Cleared Date: 26-JAN-2006  
Cleared Under Medsep Corporation

BK050075-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall eBDS  
Cleared Date: 20-DEC-2005  
Cleared Under Medsep Corporation

BK060040-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall Acrodose PL System, Platelet  
Pool and Store Set with in-line  
Leukocyte Reduction Filter  
Cleared Date: 12-APR-2007  
Cleared Under Medsep Corporation

BK060044-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall Acrodose PL System, Platelet  
Pool and Store Set with eBDS  
Cleared Date: 01-SEP-2006  
Cleared Under Medsep Corporation

BK060045-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall Acrodose PL System, Platelet  
Pool and Store Set  
Cleared Date: 01-SEP-2006  
Cleared Under Medsep Corporation

BK060047-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall eBDS  
Cleared Date: 04-APR-2007  
Cleared Under Medsep Corporation

BK070004-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall eBDS

Cleared Date: 26-JUN-2007  
Cleared Under Medsep Corporation

BK070056-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall Acrodose Plus System Platelet  
Pool and Store Set with in-line  
Leukocyte Reduction Filter and  
eBDS  
Cleared Date: 27-SEP-2007  
Cleared Under Medsep Corporation

BK070057-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall Acrodose Plus System Platelet  
Pool and Store Set with in-line  
Leukocyte Reduction Filter  
Cleared Date: 27-SEP-2007  
Cleared Under Medsep Corporation

BK070063-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall eBDS  
Cleared Date: 26-JAN-2008  
Cleared Under Medsep Corporation

BK080003-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall Acrodose Plus System,  
Platelet Pool and Store Set with  
in-Line Leukocyte Reduction Filter  
Cleared Date: 18-APR-2008  
Cleared Under MEDSEP Corporation

BK090007-0 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Trade Name: Pall Acrodose PL System  
Cleared Date: 25-FEB-2009  
Cleared Under Medsep Corporation

BK160027-0 Haemonetics Manufacturing Inc.  
1630 Industrial Park Street  
Covina, CA 91722  
Trade Name: Acrodose PL System  
Cleared Date: 16-MAY-2016

BK000037-0 Harvest Technologies Corp  
40 Grissom Road  
Plymouth, MA 02360  
Trade Name: Harvest PRP Separation System  
Cleared Date: 05-FEB-2001  
Cleared Under Harvest Technologies

BK100059-0 Harvest Technologies Corp  
40 Grissom Road  
Plymouth, MA 02360  
Trade Name: Harvest PRP Separation System  
Cleared Date: 18-NOV-2010  
Cleared Under Harvest Technologies

BK120038-0 Harvest Technologies Corp  
40 Grissom Road  
Plymouth, MA 02360  
Trade Name: Harvest PRP Separation System with  
ACDA(30mL)  
  
Cleared Date: 28-SEP-2012  
Cleared Under Harvest Technologies

BK130068-0 Harvest Technologies Corp  
40 Grissom Road  
Plymouth, MA 02360  
Trade Name: SmartPrep2 System  
Cleared Date: 24-MAR-2014  
Cleared Under Harvest Technologies

BK220696-0 Harvest Technologies Corp  
40 Grissom Road  
Plymouth, MA 02360  
Trade Name: ADIPREP ADIPOSE TRANSFER SYSTEM  
(K121005)  
Cleared Date: 21-SEP-2012

BK200526-0 Headspring Healthcare, Inc  
10415 Morado Circle  
Austin, TX 78759  
Trade Name: NDDR and CDCS  
Cleared Date: 18-NOV-2020

BK170136-0 Healeon Medical, Inc.  
1111 Rancho Conejo Blvd #204  
Newbury Park, CA 91320  
Trade Name: Healeon PRP Platelet Preparation  
System  
Cleared Date: 20-NOV-2018

BK050001-0 Healthcare Management Systems, Inc.  
3102 West End Avenue, Suite 400  
Nashville, TN 37203  
Trade Name: Monitor Blood Administration  
Module - Release 24.0  
Cleared Date: 28-SEP-2005

BK090025-0 Healthcare Management Systems, Inc.  
3102 West End Avenue, Suite 400  
Nashville, TN 37203  
Trade Name: HMS Blood Administration Module,  
Release 8.0  
Cleared Date: 04-MAR-2010

BK030049-0 Healthcare-ID, Inc.  
1635 Barclay Blvd.  
Buffalo Grove, IL 60089  
Trade Name: Donor-ID - version 2.5  
Cleared Date: 31-OCT-2003  
Cleared Under Healthcare-ID

BK060058-0 Healthcare-ID, Inc.  
1635 Barclay Blvd.  
Buffalo Grove, IL 60089  
Trade Name: Donor-ID - 3.0  
Cleared Date: 08-FEB-2007  
Cleared Under Healthcare-ID

BK080044-0 Healthcare-ID, Inc.  
1635 Barclay Blvd.  
Buffalo Grove, IL 60089  
Trade Name: Donor-ID Web - 3.1.4  
Cleared Date: 10-JUN-2009  
Cleared Under Healthcare-ID

BK120030-0 Healthcare-ID, Inc.  
1635 Barclay Blvd.  
Buffalo Grove, IL 60089  
Trade Name: Donor-ID Web (TM) 3.2  
Cleared Date: 25-JUN-2012  
Cleared Under Healthcare-ID

BK140149-0 Healthcare-ID, Inc.  
1635 Barclay Blvd.  
Buffalo Grove, IL 60089  
Trade Name: Donor-ID TM version 3.2.6  
Cleared Date: 23-JAN-2015

BK150279-0 Healthcare-ID, Inc.

1635 Barclay Blvd.  
Buffalo Grove, IL 60089  
Trade Name: Donor-ID 3.2 integrated with iCASI  
App iOS  
Cleared Date: 12-NOV-2015

BK160039-0 Healthcare-ID, Inc.  
1635 Barclay Blvd.  
Buffalo Grove, IL 60089  
Trade Name: Donor-ID 3.2 integrated with iCASI  
App Android  
Cleared Date: 29-JUL-2016

BK170141-0 Helmer Inc.  
14400 Bergen Blvd  
Noblesville, IN 46060  
Trade Name: UltraCW  
UltraCW II Automatic Cell Washing  
System  
Cleared Date: 22-JAN-2018

BK820013-0 Helmer Labs., Inc.  
5415 Distribution Drive  
Fort Wayne, IN 46825  
Trade Name: Platelet Agitator  
Cleared Date: 29-OCT-1982

BK820022-0 Helmer Labs., Inc.  
5415 Distribution Drive  
Fort Wayne, IN 46825  
Trade Name: Helmer Incubator-Agitator  
Cleared Date: 03-JAN-1983

BK840027-0 Helmer Labs., Inc.  
5415 Distribution Drive  
Fort Wayne, IN 46825  
Trade Name: Helmer Platelet Agitator PF108  
Helmer Platelet Agitator PF54  
Cleared Date: 16-APR-1985

BK850014-0 Helmer Labs., Inc.  
5415 Distribution Drive  
Fort Wayne, IN 46825  
Trade Name: PLATELET FLATBED AGITATOR MODEL  
PF456  
Cleared Date: 30-AUG-1985

BK850015-0 Helmer Labs., Inc.  
5415 Distribution Drive  
Fort Wayne, IN 46825

Trade Name: Helmer Incubator Models PC1000  
Helmer Incubator Models PC2000  
Helmer Incubator Models PC3000  
Cleared Date: 20-SEP-1985

BK850018-0 Helmer Labs., Inc.  
5415 Distribution Drive  
Fort Wayne, IN 46825  
Trade Name: Tube Stripper  
Cleared Date: 21-OCT-1985

BK940051-0 Helmer Labs., Inc.  
5415 Distribution Drive  
Fort Wayne, IN 46825  
Trade Name: Helmer Water Plasma Thawer  
Cleared Date: 03-MAR-1995

BK020029-0 Helmer Labs., Inc.  
15425 Herriman Boulevard  
Noblesville, IN 46060  
Trade Name: UltraCW (with Software version  
3.13)  
Cleared Date: 04-OCT-2002

BK890028-0 Hemagen Diagnostics, Inc.  
9033 Red Branch Road  
Columbia, MD 21045  
Trade Name: Olypmus PK CMV System  
Cleared Date: 11-DEC-1989

BK940035-0 Hemagen Diagnostics, Inc.  
9033 Red Branch Road  
Columbia, MD 21045  
Trade Name: Olympus PK TM CMV System & System  
Controls  
Cleared Date: 15-JUL-1996

BK251294-0 Hemanext Inc.  
99 Hayden Avenue  
Building B, Suite 620  
Lexington, MA 02421  
Trade Name: Hemanext ONE  
Cleared Date: 06-MAR-2026

BK150300-0 Hemasoft Software SL  
Antonio Lopez 249, 4 3A  
Madrid, SPAIN 28041  
Trade Name: e- Delphyn Blood management  
Software version 7.1.0.0  
Cleared Date: 24-OCT-2015

BK200513-0 Hemasoft Software SL  
Calle Antonio Lopez, 249 4  
, Madrid SPAIN 28041  
Trade Name: e-Delphyn LIS Donor - 11.0.0.1  
Cleared Date: 09-NOV-2020

BK200515-0 Hemasoft Software SL  
Calle Antonio Lopez, 249 4  
, Madrid SPAIN 28041  
Trade Name: e-Delphyn Donor - 11.0.0.1  
Cleared Date: 05-NOV-2020

BK950008-0 HemaSure, Inc.  
140 Locke Drive  
Marlborough, MA 01752  
Trade Name: LeukoNet Pre Storage  
Leukodepletion Filtration System  
Cleared Date: 28-JUN-1995

BK980014-0 HemaSure, Inc.  
140 Locke Drive  
Marlborough, MA 01752  
Trade Name: HemaSure r|LS Pre-Storage  
Leukoreduction Filtration System  
for Red Blood Cells  
HemaSure r|LS Pre-Storage  
Leukoreduction Filtration System  
with spike for Red Blood Cells  
Cleared Date: 27-MAY-1999

BK070024-0 Hemerus Medical, LLC  
5000 Township Parkway  
Saint Paul, MN 55110  
Trade Name: LEUKOSEP HRC-600-C Leukocyte  
Reduction Filtration System for  
Red Blood Cells  
Cleared Date: 23-AUG-2007

BK080031-0 Hemerus Medical, LLC  
5000 Township Parkway  
Saint Paul, MN 55110  
Trade Name: HEMERUS LEUKOSEP HRC-600-C  
Leukocyte Reduction Filtration  
System for Red Blood Cells  
Cleared Date: 11-SEP-2008

BK120022-0 Hemo bioscience  
801 Capitola Drive, Suite 9  
Research Triangle Park

Durham, NC 27713  
Trade Name: C3 Control Cells  
Cleared Date: 24-OCT-2012

BK140161-0 Hemo bioscience  
801 Capitola Drive, Suite 9  
Research Triangle Park  
Durham, NC 27713  
Trade Name: Hemo QC  
Cleared Date: 08-SEP-2014

BK160079-0 Hemo bioscience  
633 Davis Drive  
Suite 100  
Morrisville, NC 27560  
Trade Name: MQC  
Cleared Date: 27-FEB-2017

BK160081-0 Hemo bioscience  
633 Davis Drive  
Suite 100  
Morrisville, NC 27560  
Trade Name: MQC-CAT  
Cleared Date: 30-MAR-2017

BK060020-0 HemoCue AB  
40 Empire Drive  
Lake Forest, CA 92630  
Trade Name: HemoCue Hb 301 System  
Cleared Date: 14-APR-2006

BK060048-0 HemoCue AB  
Kuvettgatan 1  
Angelholm, SWEDEN SE-262 71  
Trade Name: HemoCue Hb 301 System  
Cleared Date: 05-OCT-2006

BK000043-0 HemoCue, Incorporated  
9229 Cranford Drive  
Potomac, MD 20854  
Trade Name: HemoCue Low Hemoglobin Analyzing  
System  
Cleared Date: 09-APR-2001

BK030020-0 HemoCue, Incorporated  
9229 Cranford Drive  
Potomac, MD 20854  
Trade Name: Donor Hemoglobin Checker System  
Cleared Date: 17-APR-2003

BK030067-0 HemoCue, Incorporated  
9229 Cranford Drive  
Potomac, MD 20854  
Trade Name: HemoCue Donor Hb Checker Control  
Cleared Date: 19-DEC-2003

BK040031-0 Hemosystem, S.A.  
45, Cours Gouffe  
13006 Marseille, FRANCE  
Trade Name: Scansytem bacterial detection  
device  
Cleared Date: 23-SEP-2004

BK900024-0 Heraeus Inc.  
111A Corporate Blvd, S.  
Plainfield, NJ 07080  
Trade Name: Cryofuge 6000  
Cleared Date: 05-NOV-1992

BK200519-0 Holding Technologies  
600-A Royal Commerce Rd  
Suite A  
Royal Palm Beach, FL 33411  
Trade Name: Maximus Blood PRP Kit  
Cleared Date: 19-NOV-2020

BK251197-0 HsingChi Medical Ltd.  
No. 10, Ln. 82, Shijian St.  
Taipei City, Beitou Dist TAIWAN 11276  
Trade Name: HsingChi LipoSelector Disposable  
Fat Collection System (LS-1200)  
Cleared Date: 23-DEC-2025

BK220775-0 Hydra Srl  
Via Savonarola n 4  
, Modena ITALY 41037  
Trade Name: Procedure Tray - Lipoaspirate fat  
harvest and injection kit  
Cleared Date: 04-JAN-2023

BK900015-0 I. B. G. Systems Inc.  
P.O. Box 5306  
Laytonsville, MD 20882  
Trade Name: Inverness Blood Grouping System  
Cleared Date: 20-SEP-1990

BK920019-0 I. B. G. Systems Inc.  
P.O. Box 5306  
Laytonsville, MD 20882  
Trade Name: Inverness Automated Antibody

Screening System

Cleared Date: 26-MAR-1993

BK930025-0 ICU MEDICAL INC  
142 TECHNOLOGY DRIVE  
IRVINE, CA 92718  
Trade Name: Kelsea Clamp Needle Cover & Guide  
Cleared Date: 28-OCT-1993

BK110064-0 IT Synergistics, LLC  
115 Tree Street  
Flowood, MS 39232  
Trade Name: DoVac Elite 1.0  
Cleared Date: 06-SEP-2012

BK140091-0 IT Synergistics, LLC  
115 Tree Street  
Flowood, MS 39232  
Trade Name: DVac Elite v 2.0  
Cleared Date: 09-APR-2014

BK241061-0 IT Synergistics, LLC  
115 Tree Street  
Flowood, MS 39232  
Trade Name: bexWISE API - 1.0  
Cleared Date: 25-OCT-2024

BK030087-0 ITL Corporation Pty, Ltd  
41-45 Tennant Street  
Canberra ACT 2609, AUSTRALIA  
Trade Name: ITL SampLok Sampling Kit  
Cleared Date: 18-FEB-2004

BK170102-0 ITL Corporation Pty, Ltd  
41-45 Tennant Street  
Canberra ACT 2609, AUSTRALIA  
Trade Name: Samplok Segment Sampler  
Cleared Date: 28-NOV-2017

BK980008-0 ITL Corporation, LTD.  
22 Molonglo Mall  
Fyshwick, Canberra AUSTRALIA 2609  
Trade Name: Bloodpack Needle Protector (BNP)  
Cleared Date: 07-APR-1998

BK820010-0 Idas America Ltd.  
Lockview Plaza  
Lockport, NY 14094  
Trade Name: Animec  
Cleared Date: 14-SEP-1982

BK130046-0 Immucor GTI Diagnostics, Inc.  
20925 Crossroads Circle  
Waukesha, WI 53186  
Trade Name: LIFECODES(R) LifeScreen Deluxe  
(LMX)  
Cleared Date: 23-SEP-2013

BK140163-0 Immucor GTI Diagnostics, Inc.  
20925 Crossroads Circle  
Waukesha, WI 53186  
Trade Name: PakPlus  
Cleared Date: 27-APR-2015

BK160035-0 Immucor GTI Diagnostics, Inc.  
20925 Crossroads Circle  
Waukesha, WI 53186  
Trade Name: LIFECODES LifeScreen Deluxe (LMX)  
Cleared Date: 21-APR-2016

BK180181-0 Immucor GTI Diagnostics, Inc.  
20925 Crossroads Circle  
Waukesha, WI 53186  
Trade Name: DonorScreen-HLA Class I and Class  
II  
Cleared Date: 14-JUN-2018

BK190439-0 Immucor GTI Diagnostics, Inc.  
20925 Crossroads Circle  
Waukesha, WI 53186  
Trade Name: MATCH IT! DNA  
Cleared Date: 21-JAN-2020

BK210572-0 Immucor GTI Diagnostics, Inc.  
20925 Crossroads Circle  
Waukesha, WI 53186  
Trade Name: MATCH IT! Antibody  
MATCHI IT! Antibody  
Cleared Date: 19-NOV-2021

BK210573-0 Immucor GTI Diagnostics, Inc.  
20925 Crossroads Circle  
Waukesha, WI 53186  
Trade Name: LIFECODES LSA Class I  
LIFECODES LSA Class II  
Cleared Date: 22-NOV-2021

BK210574-0 Immucor GTI Diagnostics, Inc.  
20925 Crossroads Circle  
Waukesha, WI 53186

Trade Name: LIFECODES LSA Class II  
Cleared Date: 19-NOV-2021

BK220762-0 Immucor GTI Diagnostics, Inc.  
20925 Crossroads Circle  
Waukesha, WI 53186  
Trade Name: MATCH IT! Antibody  
Cleared Date: 29-SEP-2022

BK220763-0 Immucor GTI Diagnostics, Inc.  
20925 Crossroads Circle  
Waukesha, WI 53186  
Trade Name: LIFECODES LifeScreen XP  
Cleared Date: 29-SEP-2022

BK241067-0 Immucor GTI Diagnostics, Inc.  
20925 Crossroads Circle  
Waukesha, WI 53186  
Trade Name: MATCH IT! Antibody  
MatchX  
Cleared Date: 02-JAN-2025

BK130075-0 Immucor Transplant Diagnostics, Inc.  
550 West Avenue  
Stamford, CT 06902-6352  
Trade Name: LIFECODES HLA-A SSO Typing Kit for  
use with Luminex  
LIFECODES HLA-A eRES SSO Typing  
Kit for use with Luminex  
LIFECODES HLA-B SSO Typing Kit for  
use with Luminex  
LIFECODES HLA-B eRES SSO Typing  
Kit for use with Luminex  
LIFECODES HLA-C eRES SSO Typing  
Kit for use with Luminex  
LIFECODES HLA-DQB SSO Typing Kit  
for use with Luminex  
LIFECODES HLA-DRB1 SSO Typing Kit  
for use with Luminex  
LIFECODES HLA-DRB1 eRES SSO Typing  
Kit for use with Luminex  
Cleared Date: 24-DEC-2013

BK150302-0 Immucor Transplant Diagnostics, Inc.  
550 West Avenue  
Stamford, CT 06902-6352  
Trade Name: LIFECODES HLA-DPA1/B1 SSO Typing  
Kit  
LIFECODES HLA-DQAI/B1 SSO Typing  
Kit

Cleared Date: 11-MAY-2016

BK150343-0 Immucor Transplant Diagnostics, Inc.  
550 West Avenue  
Stamford, CT 06902-6352  
Trade Name: LIFECODES MATCH IT! DNA Software  
v1.2  
Cleared Date: 11-MAY-2016

BK820019-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Checkcell  
Cleared Date: 15-DEC-1982

BK830004-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: 22% Bovine Albumin  
Cleared Date: 17-MAR-1983

BK830005-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: 30% Bovine Albumin  
Cleared Date: 17-MAR-1983

BK830007-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Low Ionic Strength Solution (LISS)  
Cleared Date: 11-MAY-1983

BK830013-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Rh-Hr Control  
Cleared Date: 19-JUL-1983

BK830021-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Anti-N Lectin  
Cleared Date: 07-NOV-1983

BK830022-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: ImmuAdd  
Cleared Date: 07-NOV-1983

BK830018-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Anti-A1 Lectin  
Cleared Date: 07-NOV-1983

BK840024-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: corQc Test System  
Cleared Date: 08-NOV-1984

BK860017-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Capture P Solid Phase System  
Cleared Date: 06-OCT-1986

BK880010-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Capture-R (I and II)  
Cleared Date: 03-JUN-1988

BK880011-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Capture-R (Pooled)  
Cleared Date: 03-JUN-1988

BK880014-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Modified Capture-P  
Cleared Date: 08-DEC-1988

BK880015-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Capture-P Platelets Wash & Storage  
Solution  
Cleared Date: 08-DEC-1988

BK880022-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Capture P Ready Screen Solid Phase  
Assay  
Cleared Date: 03-MAY-1989

BK890012-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Capture- R Ready- Screen (Pooled)  
Cleared Date: 21-JUN-1990

BK890013-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Capture-R Ready-Screen (I&II)  
Cleared Date: 21-JUN-1990

BK890014-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Capture-R Ready-Id  
Cleared Date: 21-JUN-1990

BK890022-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Ficin Solution Reagent Set  
Cleared Date: 26-JAN-1990

BK920033-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: pHix  
Cleared Date: 21-SEP-1993

BK950017-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Capture S  
Cleared Date: 24-OCT-1997

BK950029-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Capture - CMV  
Cleared Date: 22-DEC-1995

BK960016-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Hemagglutination/Dilution Strips  
Cleared Date: 04-JUN-1997

BK960017-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Modified Capture-R  
Cleared Date: 30-JUN-1998

BK960018-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: ABS QC Test System/ABS QC Test  
System Plus  
Cleared Date: 21-JUL-1997

BK960019-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: ABS2000  
Cleared Date: 30-JUN-1998

BK960020-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Capture -R Control Cells  
Cleared Date: 04-JUN-1997

BK000021-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Capture-S Solid Phase Assay  
Cleared Date: 22-JUN-2000

BK000024-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: ABS2000, Version 2 software  
(2.05.00A and 2.05.00B)  
Cleared Date: 03-JUL-2001

BK010002-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: ABS2000 (version 1.00.30A SR-1)  
Cleared Date: 16-FEB-2001

BK010020-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: ABS2000 with Version 2.05.00A  
Software  
ABS2000 with Version 2.05.00B  
Software  
ABS2000 with Version1.00.30A SR-2  
Software  
Cleared Date: 24-SEP-2001

BK020053-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Capture-R Ready Indicator Red  
Cells  
Cleared Date: 27-JAN-2003

BK020054-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Capture-R Control Cells  
Cleared Date: 27-JAN-2003

BK040010-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Monoclonal Control  
Cleared Date: 23-APR-2004

BK040013-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Galileo version 1.3.6 SP4  
Cleared Date: 23-APR-2004

BK040014-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Galileo QC Cell  
Cleared Date: 22-APR-2004

BK040023-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: DAT Positive Control Cell  
Cleared Date: 23-APR-2004

BK040024-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Capture-R Select Solid Phase  
System  
Cleared Date: 28-APR-2004

BK040057-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Check cell (Weak)  
Cleared Date: 06-OCT-2004

BK050050-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Capture-CMV  
Galileo Automated Blood Bank  
System

Cleared Date: 14-NOV-2005

BK060009-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Galileo Automated Blood Bank  
System with Capture-S Syphilis  
Screening Assay  
Cleared Date: 11-APR-2006

BK060016-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: corQC Test System  
Cleared Date: 09-MAY-2006

BK070013-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Monoclonal Control  
Cleared Date: 14-JUN-2007

BK070014-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: DAT Positive Control Cell  
Cleared Date: 14-JUN-2007

BK070015-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: WB corQC  
Cleared Date: 14-JUN-2007

BK070016-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Galileo Echo Automated Blood Bank  
System  
Cleared Date: 14-JUN-2007

BK070039-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625

Norcross, GA 30091-5625  
Trade Name: corQC Extend  
Cleared Date: 28-SEP-2007

BK070040-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Galileo Automated Blood Bank  
System with assays to perform red  
blood cell phenotyping  
Cleared Date: 28-SEP-2007

BK070051-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Immucor's WB corQC  
Cleared Date: 16-NOV-2007

BK070054-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Galileo with Reverse ABO Group  
Assay  
Cleared Date: 30-NOV-2007

BK080070-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Automated Blood Bank Analyzer  
Cleared Date: 05-FEB-2009

BK090057-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Galileo  
Cleared Date: 09-JUL-2010

BK100001-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Galileo Neo  
Cleared Date: 29-APR-2010

BK100033-0 Immucor, Inc.

3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Galileo Neo  
Cleared Date: 23-AUG-2010

BK110050-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: Checkcell  
Cleared Date: 03-OCT-2011

BK110067-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: FMH RapidScreen  
Cleared Date: 22-MAY-2012

BK120016-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: ImmuLINK, version 2.0  
Cleared Date: 14-JUN-2012

BK120021-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: TPHA Screen  
Cleared Date: 24-OCT-2012

BK150333-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: ImmuLINK - V.1.7  
Cleared Date: 19-NOV-2015

BK170067-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: Galileo Neo  
Cleared Date: 19-JUL-2017

BK170132-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071

Trade Name: Galileo Echo  
Cleared Date: 27-APR-2018

BK170135-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: Echo Lumena  
Cleared Date: 27-APR-2018

BK180220-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: Galileo Echo  
Cleared Date: 17-JUL-2018

BK180243-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: NEO Iris  
Neo Iris - Version 3  
Cleared Date: 07-NOV-2018

BK180247-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: Capture-CMV  
Cleared Date: 20-NOV-2018

BK190337-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: Galileo NEO  
Cleared Date: 19-JUN-2019

BK200474-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: NEO Iris  
Cleared Date: 12-JUN-2020

BK200483-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: Echo Lumena  
Galileo Echo (v.2.0)  
Cleared Date: 22-JUN-2020

BK200502-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071

Trade Name: Galileo NEO  
Cleared Date: 13-OCT-2020

BK200542-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: Capture-CMV - 0066206, 0066216  
Cleared Date: 08-FEB-2021

BK210560-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: Galileo NEO  
NEO Iris  
Cleared Date: 12-APR-2021

BK210562-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: Galileo NEO  
NEO Iris  
Cleared Date: 12-APR-2021

BK210600-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: Galileo NEO  
NEO Iris  
Cleared Date: 03-SEP-2021

BK210601-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: ECHO Lumena  
Echo Lumena  
Cleared Date: 08-JAN-2025

BK210604-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: Complement Control Cells  
Cleared Date: 08-JAN-2025

BK210605-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: Galileo NEO  
Cleared Date: 03-SEP-2021

BK210608-0 Immucor, Inc.

3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: Galileo Echo  
Galileo Neo  
Cleared Date: 08-JAN-2025

BK220669-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: NEO Iris  
Cleared Date: 26-JUL-2022

BK220670-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: Galileo NEO  
Cleared Date: 26-JUL-2022

BK220779-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: Capture Positive Control Cell  
Cleared Date: 10-MAY-2023

BK230806-0 Immucor, Inc.  
3130 Gateway Drive  
P.O. Box 5625  
Norcross, GA 30091-5625  
Trade Name: ImmuLINK - 3.0  
Cleared Date: 25-APR-2023

BK241080-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: ImmuLINK - 3.2  
Cleared Date: 06-AUG-2024

BK251256-0 Immucor, Inc.  
3130 Gateway Drive  
Norcross, GA 30071  
Trade Name: ImmuLINK - 3.3  
Cleared Date: 24-OCT-2025

BK110054-0 Immunetics, Inc.  
27 Drydock Avenue  
Boston, MA 02210-2377  
Trade Name: BacTx(R) Bacterial Detection Kit  
for Platelets  
Cleared Date: 11-JUN-2012

BK130017-0 Immunetics, Inc.  
27 Drydock Avenue  
Boston, MA 02210-2377  
Trade Name: BacTx Reader  
BacTx Software  
BacTx Bacterial Detection Kit for  
Detection of Bacteria in Platelets  
Cleared Date: 12-AUG-2013

BK170149-0 Immunetics, Inc.  
27 Drydock Avenue  
Boston, MA 02210-2377  
Trade Name: BacTx Bacterial Detection Kits  
Cleared Date: 16-APR-2018

BK910033-0 In-Touch Company  
101 N 700 West  
Salt Lake City, UT 84954  
Trade Name: Alton Dean Model 537 Blood Warmer  
Cleared Date: 18-NOV-1992

BK960068-0 Indico, Inc.  
Suite 137  
6325 103 Street  
Edmonton, ALBERTA CANADA T6H 5H6  
Trade Name: RadTag  
Cleared Date: 30-OCT-1996

BK000008-0 Indico, Inc.  
Suite 137  
6325 103 Street  
Edmonton, ALBERTA CANADA T6H 5H6  
Trade Name: RadTag  
Cleared Date: 01-MAR-2000

BK950064-0 Informatics  
4000 Kruso Way Place  
Building 3 Suite 210  
Lake Oswego, OR 97035  
Trade Name: Lifeline Blood Bank Data  
Management System, Release 4.2  
Cleared Date: 01-JUL-1998

BK950032-0 Information Data Management, Inc.  
9701 West Higgins Road  
Rosemont, IL 60018  
Trade Name: Abbott Data Management System,  
version 3.0.2  
Cleared Date: 18-AUG-1998  
Cleared Under Abbott Laboratories

BK950037-0 Information Data Management, Inc.  
9701 West Higgins Road  
Rosemont, IL 60018  
Trade Name: Components& Distribution  
Information System (CDIS)  
Cleared Date: 26-AUG-1996

BK950045-0 Information Data Management, Inc.  
9701 West Higgins Road  
Rosemont, IL 60018  
Trade Name: DONOR MANAGEMENT INFORMATION  
SYSTEMS  
Cleared Date: 26-AUG-1996

BK980020-0 Information Data Management, Inc.  
9701 West Higgins Road  
Rosemont, IL 60018  
Trade Name: Plasma Center Management System -  
Version 1.0  
Cleared Date: 31-JUL-1998

BK980028-0 Information Data Management, Inc.  
9701 West Higgins Road  
Rosemont, IL 60018  
Trade Name: PCMS - version 1.1  
Cleared Date: 04-SEP-1998

BK990016-0 Information Data Management, Inc.  
9701 West Higgins Road  
Rosemont, IL 60018  
Trade Name: Surround System - 1.0  
Cleared Date: 27-AUG-1999

BK990029-0 Information Data Management, Inc.  
9701 West Higgins Road  
Rosemont, IL 60018  
Trade Name: Plasma Center Management System  
(PCMS) Version 1.2  
Cleared Date: 13-OCT-1999

BK000016-0 Information Data Management, Inc.  
9701 West Higgins Road  
Rosemont, IL 60018  
Trade Name: Information Data Management  
Surround System - 2.0  
Cleared Date: 07-APR-2000

BK990046-0 Information Data Management, Inc.  
9701 West Higgins Road

Rosemont, IL 60018  
Trade Name: Plasma Center Management System  
(PCMS) - Version 2.0  
Cleared Date: 06-JAN-2000

BK010028-0 Information Data Management, Inc.  
9701 West Higgins Road  
Rosemont, IL 60018  
Trade Name: IDM Surround System - 3.0  
Cleared Date: 05-SEP-2001

BK020038-0 Information Data Management, Inc.  
9701 West Higgins Road  
Rosemont, IL 60018  
Trade Name: Surround System, Version 3.2  
Cleared Date: 08-OCT-2002

BK050014-0 Information Data Management, Inc.  
9701 West Higgins Road  
Rosemont, IL 60018  
Trade Name: IDM Prelude System, Version 1.1  
Cleared Date: 18-JUL-2005

BK070031-0 Information Data Management, Inc.  
9701 West Higgins Road  
Rosemont, IL 60018  
Trade Name: IDM Symphony System - 2.0  
Cleared Date: 13-DEC-2007

BK220700-0 Ingeneron Inc.  
8205 EL RIO  
HOUSTON, TX 77054  
Trade Name: SMARTGRAFT 30 SYSTEM (K141591)  
Cleared Date: 24-SEP-2014

BK220701-0 Ingeneron Inc.  
8205 EL RIO  
HOUSTON, TX 77054  
Trade Name: SMARTGRAFT 200 SYSTEM (K141713)  
Cleared Date: 28-OCT-2014

BK241079-0 Innoveren Scientific Inc.  
151 W 4th St.  
Ste. 226  
Cincinnati, OH 45202  
Trade Name: SkinDisc  
SkinDisc Lite  
Cleared Date: 28-MAR-2025

BK860042-0 Insta Cool, Inc of North America

11300 Sanders Drive, Suite 14  
Rancho Cordova, CA 95742  
Trade Name: Insta Cool Model BP2502  
Cleared Date: 04-MAR-1987

BK900032-0 Insta Cool, Inc of North America  
11300 Sanders Drive, Suite 14  
Rancho Cordova, CA 95742  
Trade Name: MP III  
Cleared Date: 30-MAR-1992

BK910011-0 Insta Cool, Inc of North America  
11300 Sanders Drive, Suite 14  
Rancho Cordova, CA 95742  
Trade Name: MT-200 FROZEN PLASMA THAWER  
Cleared Date: 19-DEC-1991

BK940019-0 Insta Cool, Inc of North America  
11300 Sanders Drive, Suite 14  
Rancho Cordova, CA 95742  
Trade Name: Hemopharm PB-500 Pocket Sealer  
Cleared Date: 26-SEP-1994

BK850016-0 Integrated Diagnostics, Inc.  
1901 Sulphur Spring Road  
Baltimore, MD 1227  
Trade Name: HLA COMPREHENSIVE TRAY  
Cleared Date: 30-DEC-1985

BK870018-0 Integrated Diagnostics, Inc.  
1901 Sulphur Spring Road  
Baltimore, MD 1227  
Trade Name: INDX HLA-DR, DQ Lymphocyte  
Phenotyping Tray  
Cleared Date: 28-OCT-1987

BK080006-0 IntellidOT Corporation  
13520 Evening Creek Drive North,  
Suite 400  
San Diego, CA 92128  
Trade Name: IntellidOT Blood Product  
Administration  
Cleared Date: 13-JUN-2008

BK820001-0 International Business Machines  
  
Princeton, NJ 08540  
Trade Name: IBM 2991  
Cleared Date: 28-JUN-1982

BK830003-0 International Business Machines  
Princeton, NJ 08540  
Trade Name: IBM 2991 - Single Unit Leukocytes  
from Whole Blood  
Cleared Date: 27-MAY-1983

BK830020-0 International Business Machines  
Princeton, NJ 08540  
Trade Name: Plastic for 2997  
Plastic for 2991  
Cleared Date: 27-OCT-1983

BK830024-0 International Business Machines  
Princeton, NJ 08540  
Trade Name: Plastic for 2991  
Plastic for 2997  
Cleared Date: 09-MAR-1984

BK820020-0 International Equipment Company  
300 Second Avenue  
Needham Heights, MA 02194  
Trade Name: IEC Centra-W Cell Washer  
Cleared Date: 05-APR-1983

BK940004-0 International Equipment Company  
300 Second Avenue  
Needham Heights, MA 02194  
Trade Name: Seromax  
Cleared Date: 08-APR-1994

BK910018-0 International Specialty Products  
1361 Alps Road  
Wayne, NJ 07470  
Trade Name: RAD-SURE BLOOD IRRADIATION LABEL  
Cleared Date: 12-MAR-1992

BK920035-0 International Specialty Products  
1361 Alps Rd,  
Wayne, NJ 07470  
Trade Name: RAD-Sure 2500  
Cleared Date: 01-APR-1993

BK120048-0 Intra-Lock International  
6560 West Rogers Circle  
Boca Raton, FL 33487  
Trade Name: Intra-Spin System  
Cleared Date: 28-JAN-2013

BK960054-0 Jewett Refrigerator Co., Inc.  
2-18 Letchworth Street  
Buffalo, NY 14213-1098  
Trade Name: Jewett Models BPL13,BPL21,BPL25  
Cleared Date: 08-AUG-1996

BK960073-0 Jewett Refrigerator Co., Inc.  
2-18 Letchworth Street  
Buffalo, NY 14213-1098  
Trade Name: Models BBR17, BBR25, BBR37 & BBR55  
Cleared Date: 30-OCT-1996

BK960089-0 Jewett Refrigerator Co., Inc.  
2-18 Letchworth Street  
Buffalo, NY 14213-1098  
Trade Name: Jewett Model CT1  
Cleared Date: 06-FEB-1997

BK970001-0 Jewett Refrigerator Co., Inc.  
2-18 Letchworth Street  
Buffalo, NY 14213-1098  
Trade Name: Jewett Model CTF-1  
Cleared Date: 16-APR-1997

BK970014-0 Jewett Refrigerator Co., Inc.  
2-18 Letchworth Street  
Buffalo, NY 14213-1098  
Trade Name: Jewett Model BBWM3  
Cleared Date: 18-JUL-1997

BK970028-0 Jewett Refrigerator Co., Inc.  
2-18 Letchworth Street  
Buffalo, NY 14213-1098  
Trade Name: Jewett Model BPL55  
Cleared Date: 15-OCT-1997

BK220716-0 Jointechlabs, Inc.  
8 Graystone Court North  
Barrington, IL 60010  
Trade Name: Jtl-250-01 (K182732)  
Cleared Date: 18-NOV-2019

BK860037-0 Jouan, Inc.  
Route 8, Box 1202; P.O. Box 2716  
Winchester, VA 22601  
Trade Name: Model LR5.22 centrifuge  
Cleared Date: 15-DEC-1986

BK870001-0 Jouan, Inc.

Route 8,Box 1202;P.O. Box 2716  
Winchester, VA 22601  
Trade Name: Model GR 4.11 centrifuge  
Cleared Date: 20-FEB-1987

BK890027-0 Jouan, Inc.  
Route 8,Box 1202;P.O. Box 2716  
Winchester, VA 22601  
Trade Name: Model KR4-22 Centrifuge  
Cleared Date: 02-FEB-1990

BK000003-0 Kawasumi Laboratories, Inc.  
1900 K Street  
Washington,, DC 20006  
Trade Name: Kawasumi Laboratories Phlebotomy  
Sey  
Cleared Date: 20-MAR-2000

BK170113-0 Kawasumi Laboratories, Inc.  
Shinagawa Intercity Tower B  
2-15-2 Konan  
Minato-Ku  
Tokyo, JAPAN 108-6109  
Trade Name: Kawasumi Laboratories Blood  
Drawing Kit (BDK) System - BK-64A  
Kawasumi Laboratories Blood  
Drawing Kit (BDK) System  
Cleared Date: 27-SEP-2017

BK080057-0 Kaylight Corporation  
602 Anacapa  
Irvine, CA 92602  
Trade Name: My Cells Autologous Platelet  
Preparation Kit  
Cleared Date: 25-SEP-2009

BK200456-0 Kedrion S.p.A.  
Loc. Ai Conti  
Barga, Lucca ITALY 55051  
Trade Name: GeTrap  
Cleared Date: 20-APR-2020

BK840005-0 Kontron Blood Bank Systems  
9 Plymouth Street  
Everett, MA 02149  
Trade Name: Kontron Microgroupamatic  
Cleared Date: 27-JUN-1984

BK870012-0 Kontron Blood Bank Systems  
9 Plymouth Street

Everett, MA 02149  
Trade Name: LHS-500 Sampler and Delivery  
System  
Cleared Date: 02-NOV-1987

BK890008-0 Kontron Blood Bank Systems  
9 Plymouth Street  
Everett, MA 02149  
Trade Name: G-1000  
G-2000  
G-2000 MK II  
Cleared Date: 30-AUG-1989

BK040053-0 Korchek Technologies, LLC  
770 Plattsville Road  
Trumbull, CT 06611  
Trade Name: CareChek Patient Identification  
System, CareChek TX - version 1  
Cleared Date: 12-AUG-2005

BK030037-0 Kowa Company, Ltd.  
c/o Quintiles Consulting  
1801 Rockville Pike, Suite 300  
Rockville, MD 20852  
Trade Name: LD-2000 Leukocyte Counter  
Cleared Date: 14-JUN-2004

BK210558-0 LUV0 Medical Technologies, Inc.  
125 Fleming Dr  
, Cambridge CANADA N1T 2B8  
Trade Name: World PRP  
Cleared Date: 23-JUL-2021

BK100024-0 Lab 21 Healthcare Ltd  
184 Cambridge Science Park  
Cambridge, Cambridgeshire UNITED KINGDOM CB4 0GA, UK  
Trade Name: Lab 21 TPHA OC Kit  
Cleared Date: 03-AUG-2010

BK860031-0 Lab-Line Instruments, Inc.  
15th and Bloomingdale Avenues  
Melrose Park, IL 60160  
Trade Name: Hema-Bath  
Cleared Date: 02-MAR-1987

BK110055-0 Lattice, Inc.  
1751 South Naperville Rd  
Suite 100  
Wheaton, IL 60189  
Trade Name: MediCopia Transfusion - v4.1

Cleared Date: 06-JAN-2012

BK860023-0 Level 1 Technologies, Inc.  
160 Weymouth Street  
Rockland, MA 02370  
Trade Name: Level 1 Fluid Warmer  
Cleared Date: 25-SEP-1986

BK920021-0 Level 1 Technologies, Inc.  
160 Weymouth Street  
Rockland, MA 02370  
Trade Name: A/V Rewarming Procedural Kit  
Gentilello Technique  
Cleared Date: 29-JAN-1993

BK940056-0 Level 1 Technologies, Inc.  
160 Weymouth Street  
Rockland, MA 02370  
Trade Name: Level I Fluid Warmer  
Cleared Date: 27-DEC-1994

BK020043-0 Level 1 Technologies, Inc.  
160 Weymouth Street  
Rockland, MA 02370  
Trade Name: level 1 fluid warming system  
Cleared Date: 16-JUN-2003

BK230814-0 Life Plasma, Inc.  
5438 Perkiomen Ave  
Reading, PA 19606  
Trade Name: SmartDMS  
Cleared Date: 16-APR-2024

BK070038-0 Life Technologies Corporation  
9099 North Deerbrook Trail  
Brown Deer, WI 53223  
Trade Name: AllSet Gold SSP  
Cleared Date: 26-SEP-2007  
Cleared Under Invitrogen Corporation

BK070041-0 Life Technologies Corporation  
9099 North Deerbrook Trail  
Brown Deer, WI 53223  
Trade Name: DynaChip HLA Antibody Analysis  
System  
Cleared Date: 30-APR-2008  
Cleared Under Invitrogen Corporation

BK070046-0 Life Technologies Corporation  
9099 North Deerbrook Trail

Brown Deer, WI 53223  
Trade Name: UniMatch Plus Version 4.0  
Cleared Date: 27-SEP-2007  
Cleared Under Invitrogen Corporation

BK110038-0 Life Technologies Corporation  
9099 North Deerbrook Trail  
Brown Deer, WI 53223  
Trade Name: SeCore HLA Sequencing System  
uType Dx HLA Analysis Software v  
1.0  
Cleared Date: 05-FEB-2013

BK110039-0 Life Technologies Corporation  
9099 North Deerbrook Trail  
Brown Deer, WI 53223  
Trade Name: 3500 Dx/3500 xL Dx Genetic  
Analyzer 8 CS2 and 3500 Dx Series  
Software  
Cleared Date: 05-FEB-2013

BK220709-0 LifeCell Corporation  
One Millennium Way  
Branchburg, NJ 08876  
Trade Name: Revolve Envi 600 Advanced Adipose  
System (K163647)  
Cleared Date: 25-AUG-2017

BK220721-0 LifeCell Corporation  
One Millennium Way  
Branchburg, NJ 08876  
Trade Name: REVOLVE ENVI 600 Advanced Adipose  
System (K193539)  
Cleared Date: 28-MAY-2020

BK080017-0 LifeSouth Community Blood Centers Inc.  
4039 Newberry Road  
Gainesville, FL 32607  
Trade Name: Integrated Blood Bank Information  
System (IBBIS) Registration Module  
- v1.0  
Cleared Date: 05-AUG-2008

BK090064-0 LifeSouth Community Blood Centers Inc.  
4039 Newberry Road  
Gainesville, FL 32607  
Trade Name: Integrated Blood Bank Information  
System  
Cleared Date: 08-DEC-2009

BK130054-0 LifeSouth Community Blood Centers Inc.  
4039 Newberry Road  
Gainesville, FL 32607  
Trade Name: Integrated Blood Bank Information  
System, version 3.0 (IBBIS)  
Cleared Date: 17-JAN-2014

BK160004-0 LifeSouth Community Blood Centers Inc.  
4039 Newberry Road  
Gainesville, FL 32607  
Trade Name: Integrated Blood Bank Information  
System (IBBIS), Version 4.0  
Cleared Date: 29-MAR-2016

BK220703-0 Lipogems International SpA  
Viale Bianca Maria 24  
Milan, Milano ITALY 20129  
Trade Name: The Lipogems System (K142682)  
Cleared Date: 22-DEC-2014

BK220707-0 Lipogems International SpA  
Viale Bianca Maria 24  
Milan, Milano ITALY 20129  
Trade Name: Lipogems System (K161636)  
Cleared Date: 04-NOV-2016

BK220712-0 Lipogems International SpA  
Viale Bianca Maria 24  
Milan, Milano ITALY 20129  
Trade Name: Lipogems System (K171135)  
Cleared Date: 18-MAY-2017

BK220685-0 Lipose Corp  
2647 Lin Gate Court  
Pleasanton, CA 94566  
Trade Name: LIPOSE FAT TRANSFER SYSTEM  
(K081848)  
Cleared Date: 04-DEC-2008

BK830006-0 Liquid Crystal Products, Inc.  
724 Algonquin Road  
Arlington Heights, IL 60005  
Trade Name: HemoTemp II Blood Temperature  
Indicator  
Cleared Date: 04-MAY-1983

BK990013-0 Ljungberg & Kogel  
C/O Kamm & Associates  
333 Milford Rd.  
Deerfield, IL 60015

Trade Name: Biomixer 330 & Biomixer 323  
Cleared Date: 07-JUL-1999

BK090010-0 Ljungberg & Kogel  
C/O Kamm & Associates  
333 Milford Rd.  
Deerfield, IL 60015  
Trade Name: Biomixer BM330 with XBee  
(Wireless) Option  
Cleared Date: 17-JUL-2009

BK230986-0 MAK-SYSTEM Group Ltd.  
1 Bartholomew Lane  
, London UNITED KINGDOM EC2N 2AX  
Trade Name: ePROGESA - 5.0.3  
Cleared Date: 03-NOV-2023

BK251188-0 MAK-SYSTEM Group Ltd.  
1 Bartholomew Lane  
, London UNITED KINGDOM EC2N 2AX  
Trade Name: Patient Health Software (P.H.S) -  
2.0  
Patient Health Software (P.H.S.) -  
11.0.0.0  
Cleared Date: 11-JUN-2025

BK180232-0 MAK-SYSTEM SA International Group  
10 Avenue de la Grande-Armee  
, Paris FRANCE 75017  
Trade Name: Patient Health Software (P.H.S) -  
2.0  
Cleared Date: 18-OCT-2018

BK960050-0 MAK-System  
Z.I. Paris Nord II  
14, Rue de la Perdrix  
95946 Roissy C.D.G. CEDEX, FRANCE B.P. 50035  
Trade Name: Progesa  
Cleared Date: 10-DEC-1998

BK060035-0 MAK-System  
10 Avenue de la Grande Armee  
75017 Paris, FRANCE 75017  
Trade Name: Patient Health Software - 1.0  
Cleared Date: 09-MAY-2007

BK070062-0 MAK-System  
10 Avenue de la Grande Armee  
75017 Paris, FRANCE 75017  
Trade Name: PROGESA - 4.4h

Cleared Date: 26-OCT-2007

- BK080002-0 MAK-System  
10 Avenue de la Grande Armee  
75017 Paris, FRANCE 75017  
Trade Name: ePROGESA - 5.0.1  
Cleared Date: 13-MAY-2008
- BK960029-0 MEDITECH Medical Information Technology, Inc.  
MEDITECH Circle  
Westwood, MA 02090  
Trade Name: MEDITECH  
Cleared Date: 19-MAR-1999
- BK980046-0 MEDITECH Medical Information Technology, Inc.  
MEDITECH Circle  
Westwood, MA 02090  
Trade Name: Magic Client Server - 5.1  
Cleared Date: 08-FEB-2000
- BK060029-0 MEDITECH Medical Information Technology, Inc.  
MEDITECH Circle  
Westwood, MA 02090  
Trade Name: MEDITECH MAGIC Blood Bank Software  
- 4.9  
Cleared Date: 06-FEB-2007
- BK080037-0 MEDITECH Medical Information Technology, Inc.  
MEDITECH Circle  
Westwood, MA 02090  
Trade Name: MEDITECH Client Server Blood bank  
module 5.6 - v5.6  
Cleared Date: 30-OCT-2008
- BK080061-0 MEDIWARE INFORMATION SYSTEMS, INC.  
11711 West 79th Street  
Lenexa, KS 66214  
Trade Name: HCLL Donor  
Cleared Date: 02-DEC-2008
- BK100043-0 MEDIWARE INFORMATION SYSTEMS, INC.  
11711 West 79th Street  
Lenexa, KS 66214  
Trade Name: LifeTrak/Donor - 4.6.0  
Cleared Date: 21-OCT-2010
- BK100057-0 MEDIWARE INFORMATION SYSTEMS, INC.  
11711 West 79th Street  
Lenexa, KS 66214  
Trade Name: LifeTrak/Lab and Distribution -

4.6.0

Cleared Date: 16-NOV-2010

BK100069-0 MEDIWARE INFORMATION SYSTEMS, INC.  
11711 West 79th Street  
Lenexa, KS 66214  
Trade Name: LifeTrak/Plasma - 1.0.0  
Cleared Date: 04-MAR-2011

BK980027-0 MEDSEP Corporation  
330 Turnbull Canyon Road  
City of Industry, CA 91745  
Trade Name: Transfer/Freezing Bag Set  
Cleared Date: 26-MAR-1999  
Cleared Under MEDSEP Corp.

BK980030-0 MEDSEP Corporation  
330 Turnbull Canyon Road  
City of Industry, CA 91745  
Trade Name: Medsep Freezing bag  
Cleared Date: 29-AUG-1998  
Cleared Under MEDSEP Corp.

BK980038-0 MEDSEP Corporation  
330 Turnbull Canyon Road  
City of Industry, CA 91745  
Trade Name: Cell Wash/Infusion Bag Set  
Cleared Date: 13-JUL-1999  
Cleared Under MEDSEP Corp.

BK120026-0 MEDSEP Corporation  
1630 Industrial Park Street  
Covina, CA 91722  
Trade Name: Pall Celeris fPC System  
Cleared Date: 29-JUN-2012

BK930021-0 MIGADAS INC  
482 Hudson Terrace  
Englewood Cliffs, NY 07632  
Trade Name: Samplink  
Cleared Date: 16-NOV-1993

BK970022-0 MIGADAS INC  
482 Hudson Terrace  
Englewood Cliffs, NY 07632  
Trade Name: samplink  
Cleared Date: 18-SEP-1997

BK910007-0 MMED  
609 19th Avenue, S.W.

Rochester, MN 55902  
Trade Name: MMED Vapor Condensation Blood  
Warmer  
Cleared Date: 16-MAR-1992

BK251212-0 MONARCH LABS, LLC.  
17875 SKY PARK CIRCLE  
SUITE K  
IRVINE, CA 92614  
Trade Name: Medical Maggots and maggot  
confinement dressings  
Medical Maggots and maggot  
confinement dressings (K072438)  
Cleared Date: 05-OCT-2007

BK251213-0 MONARCH LABS, LLC.  
17875 SKY PARK CIRCLE  
SUITE K  
IRVINE, CA 92614  
Trade Name: Medical Maggots and maggot  
confinement dressings  
Medical Maggots and maggot  
confinement dressings (K102827)  
Cleared Date: 02-NOV-2011

BK910004-0 MPI/Dupaco, Inc.  
2620 Temple Heights Drive  
Oceanside, CA 92056  
Trade Name: Dupaco Blood/Fluid Warming Cuff  
Set  
Cleared Date: 21-FEB-1992

BK231013-0 MUSCULOSKELETAL TRANSPLANT FOUNDATION  
125 MAY STREET  
EDISON, NJ 08837  
Trade Name: LipoGrafter Kit  
Cleared Date: 16-MAY-2024

BK030008-0 MacoProductions S.A.S.  
3075 Breckinridge Blvd.  
Suite 405  
Duluth, GA 30096  
Trade Name: Leucolab LCG2 Leukoreduction  
System for Red Blood Cells  
Cleared Date: 02-MAY-2003

BK050041-0 MacoProductions S.A.S.  
3075 Breckinridge Blvd.  
Suite 405  
Duluth, GA 30096

Trade Name: Leucolab LCG2 Leukoreduction  
System for Red Blood Cells  
Cleared Date: 12-OCT-2005

BK080060-0 MacoProductions S.A.S.  
3075 Breckinridge Blvd.  
Suite 405  
Duluth, GA 30096  
Trade Name: Leucolab LCG2 Leukoreduction  
System for AS-1, AS-3, and AS-5  
Red Blood Cells  
Cleared Date: 14-JAN-2009

BK120071-0 MacoProductions S.A.S.  
3075 Breckinridge Blvd.  
Suite 405  
Duluth, GA 30096  
Trade Name: Leucolab LCG2 Leukoreduction  
Systems for AS-1 Red Blood Cells  
Leucolab LCG2 Leukoreduction  
Systems for AS-1 and AS-3 Red  
Blood Cells  
Leucolab LCG2 Leukoreduction  
Systems for AS-1, AS-3 and AS-5  
Red Blood Cells  
Cleared Date: 22-FEB-2013

BK160095-0 MacoProductions S.A.S.  
200 chaussee Fernand Forest  
, Tourcoing FRANCE 59200  
Trade Name: MacoMix HM20 and optional Hemolog  
6 Software  
Cleared Date: 11-AUG-2017

BK170085-0 MacoProductions S.A.S.  
200 chaussee Fernand Forest  
, Tourcoing FRANCE 59200  
Trade Name: MacoPress Smart (MPS) and DMS Plus  
Cleared Date: 09-NOV-2017

BK180306-0 MacoProductions S.A.S.  
200 chaussee Fernand Forest  
, Tourcoing FRANCE 59200  
Trade Name: MacoPress Smart Smarter and DMS  
Plus  
Cleared Date: 24-JAN-2019

BK960075-0 Mallinckrodt Medical, Inc.  
675 McDonnell Boulevard  
St. Louis, MO 63134

Trade Name: Alton Dean Fluid Warmer, FW-537  
Cleared Date: 28-FEB-1997

BK090051-0 McKesson Provider Technologies  
5995 Windward Parkway  
Alpharetta, GA 30005  
Trade Name: Horizon MobileCare Transfusion  
Cleared Date: 28-MAY-2010

BK231015-0 MedMira Laboratories Inc.  
155 Chain Lake Drive  
Suite 1  
Halifax, Canada CANADA B3S 1B3  
Trade Name: Reveal G4 Rapid HIV-1/2 Antibody  
Test  
Cleared Date: 13-DEC-2023

BK220686-0 Medi-Khan USA INC  
655 North Berry St  
Brea, CA 92821  
Trade Name: LIPOKIT WITH DISPOSABLE 50CC AFT  
SYRINGE MODEL ZLK-100 (K083455)  
Cleared Date: 18-MAY-2009

BK220697-0 Medi-Khan USA INC  
655 North Berry St  
Brea, CA 92821  
Trade Name: LIPOKIT WITH DISPOSABLE 50CC AFT  
SYRINGE (K121703)  
Cleared Date: 07-DEC-2012

BK220687-0 Medical Device Resource Corp  
23392 Connecticut St  
Hayward, CA 94545  
Trade Name: LIPISYSTEMS AQUAVAGE MODELS AV2000  
AND AV1200 (K092284)  
Cleared Date: 01-SEP-2009

BK180219-0 Medical Information Technology, Inc.  
Meditech Circle  
Westwood, MA 02090  
Trade Name: MEDITECH Expanse Blood Bank  
Cleared Date: 12-SEP-2018

BK920031-0 Medical Marketing Consultants  
3 Bethesda Metro Center, Suite 750  
Bethesda, MD 20814  
Trade Name: sHLA-STAT B27 ELISA for HLA-B27  
Typing  
Cleared Date: 20-AUG-1993

BK140092-0 Medion Grifols Diagnostics AG  
Bonnstrasse 9  
Duedingen,  
Trade Name: DG Gel Extended Control  
Cleared Date: 11-APR-2014

BK180280-0 Medion Grifols Diagnostics AG  
Bonnstrasse 9  
Duedingen,  
Trade Name: DG Gel Essential Control  
Cleared Date: 17-JAN-2019

BK980034-0 Mediware Information Systems, Inc.  
1121 Old Walt Whitman Road  
Melville, NY 11747  
Trade Name: Hemocare Blood Bank Management  
System - Revision 5.2  
Cleared Date: 10-DEC-1998

BK010052-0 Mediware Information Systems, Inc.  
9000 Harry Hines Blvd  
Dallas, TX 75235  
Trade Name: LifeTrak Lab - 2.03  
Cleared Date: 17-JUN-2002

BK020046-0 Mediware Information Systems, Inc.  
900 Oakmont Lane  
Westmont, IL 60659  
Trade Name: Hemocare LifeLine - Version, 1.0  
Cleared Date: 14-FEB-2003

BK030078-0 Mediware Information Systems, Inc.  
4545 Fuller Drive, Ste 320  
Irving, TX 75038  
Trade Name: HCLL - 2.6  
Cleared Date: 08-APR-2004

BK040047-0 Mediware Information Systems, Inc.  
4545 Fuller Drive, Ste 320  
Irving, TX 75038  
Trade Name: Instrument Interface Engine - 1.0  
Cleared Date: 16-JUL-2004

BK050011-0 Mediware Information Systems, Inc.  
4545 Fuller Drive, Ste 320  
Irving, TX 75038  
Trade Name: HCLL Donor - 1.0  
Cleared Date: 10-MAY-2005

BK060019-0 Medware Information Systems, Inc.  
4545 Fuller Drive, Ste 320  
Irving, TX 75038  
Trade Name: Life Trak / Donor - 3.01  
Cleared Date: 21-JUN-2006

BK080049-0 Medware Information Systems, Inc.  
1900 Spring Road, Suite 450  
Oak Brook Service Center  
Oak Brook, IL 60523  
Trade Name: HCLL Transfusion, v3.0  
Cleared Date: 22-OCT-2008

BK120036-0 Medware Information Systems, Inc.  
1900 Spring Road, Suite 450  
Oak Brook Service Center  
Oak Brook, IL 60523  
Trade Name: HCLL(TM) Transfusion 2012  
Cleared Date: 19-SEP-2012

BK120039-0 Medware Information Systems, Inc.  
1900 Spring Road, Suite 450  
Oak Brook Service Center  
Oak Brook, IL 60523  
Trade Name: LifeTrak(R) 2012  
Cleared Date: 05-SEP-2012

BK160066-0 Medware Information Systems, Inc.  
11711 West 79th St  
Lenexa, KS 66214  
Trade Name: HCLL(TM) Transfusion 2015 R2  
Cleared Date: 30-SEP-2016

BK180200-0 Medware Information Systems, Inc.  
11711 West 79th St  
Lenexa, KS 66214  
Trade Name: LifeTrak 2018  
Cleared Date: 03-JUL-2018

BK910019-0 Medsep Corporation  
2200 Northern Boulevard  
East Hills, NY 11548-1289  
Trade Name: Pall BPF4B Leukocyte Removal Blood  
Processing Filter wiht Attached  
Tubing and Blood Bag  
Cleared Date: 16-JAN-1992  
Cleared Under Pall Bio Medical

BK920023-0 Medsep Corporation  
2200 Northern Boulevard

East Hills, NY 11548-1289  
Trade Name: Pall Autostop Leukocyte Removal  
Platelet Filter with Tubing  
Cleared Date: 26-OCT-1992  
Cleared Under Pall Bio Medical

BK940018-0 Medsep Corporation  
2200 Northern Boulevard  
East Hills, NY 11548-1289  
Trade Name: Pall Autoprocessor™ System  
Cleared Date: 07-SEP-1994  
Cleared Under Pall Bio Medical

BK100058-0 Medsep Corporation  
1630 INDUSTRIAL PARK  
COVINA, CA 91722  
Trade Name: The Pall Celeris fPC System  
Cleared Date: 24-FEB-2011

BK010032-0 Medserv, Inc.  
71 South Bedford Road  
Mount Kisco, NY 10549  
Trade Name: Plasmapheresis Data System III -  
1.0  
Cleared Date: 05-FEB-2002

BK030040-0 Medtronic Sofamor Danek  
1800 Pyramid Place  
Memphis, TN 38132  
Trade Name: Magellan Autologous Platelet  
Separation System  
Cleared Date: 03-SEP-2003

BK040068-0 Medtronic Sofamor Danek  
1800 Pyramid Place  
Memphis, TN 38132  
Trade Name: Magellan Autologous Platelet  
Separator System  
Cleared Date: 09-NOV-2004

BK940010-0 Mercia Diagnostics Limited  
Mercia House, Broadford Park  
Shalford, Guildford GU4 8EW, UNITED KINGDOM  
Trade Name: CAPTIA™ Syphilis-G  
Cleared Date: 03-JAN-1995

BK220706-0 Miami Fat Supply  
1510 Max Hooks Rd  
Suite F  
Groveland, FL 34736

Trade Name: The Red Head Collection Device The  
Jordy Connection System (K161372)  
Cleared Date: 24-FEB-2017

BK920004-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: MGR Model ERB-5-0378  
Cleared Date: 12-MAR-1992

BK920013-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: MTS Diluent 2  
Cleared Date: 29-SEP-1993

BK920014-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: MTS Centrifuge  
Cleared Date: 29-SEP-1993

BK920016-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: MTS Buffered Gel Card  
Cleared Date: 29-SEP-1993

BK920030-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: MTS Diluent 1  
Cleared Date: 29-SEP-1993

BK930030-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: MTS Diluent 2 Plus  
Cleared Date: 12-JAN-1994

BK940034-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: MTS Control Card  
Cleared Date: 27-JUL-1994

BK950025-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: MTS Incubator

Cleared Date: 08-MAY-1995

BK950026-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: MTS Work Table  
Cleared Date: 15-MAY-1995

BK950027-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: ID-Pipetor  
Cleared Date: 01-JUN-1995

BK950028-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: MTS Dispenser (0.5ml and 1.0ml)  
Cleared Date: 27-JUN-1995

BK960013-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: MTS-Centrifuge Model NU 9310  
Cleared Date: 15-APR-1996

BK980016-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: ID-Tipmaster  
Cleared Date: 29-OCT-1998

BK990012-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: MTS Reader M  
Cleared Date: 19-NOV-1999

BK000018-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: MTS Reader SA  
Cleared Date: 21-NOV-2000

BK010021-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: MTS Incubator II  
Cleared Date: 01-OCT-2001

BK030023-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: Ortho ProVue, Software Version:  
2.10  
Cleared Date: 14-MAY-2003

BK090013-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: ORTHO ProVue, version 3.1  
Cleared Date: 04-JUN-2009

BK110029-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: Ortho ProVue Analyzer Version 3.1  
Patch 1 (V3.1.1)  
Cleared Date: 14-JUL-2011

BK150280-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: MTS Buffered Gel Card  
MTS Monoclonal Control Card  
Cleared Date: 14-AUG-2015

BK160061-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: MTS TM Buffered Gel Card  
MTS TM Monoclonal Control Card  
Cleared Date: 21-OCT-2016

BK190339-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: MTS Buffered Gel Card  
Cleared Date: 08-JUL-2019

BK190400-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: MTS Buffered Gel Card  
Cleared Date: 17-DEC-2019

BK251237-0 Micro Typing Systems Inc.  
1295 S.W. 29th Ave.  
Pompano Beach, FL 33069  
Trade Name: DAT Control (MTS DAT Card)

Cleared Date: 10-OCT-2025

BK220674-0 MicroAire Surgical Instruments, LLC.  
3590 Grand Forks Boulevard  
Charlottesville, VA 22911  
Trade Name: MicroAire LipoFilter System  
Cleared Date: 16-MAR-2022

BK220705-0 MicroAire Surgical Instruments, LLC.  
3590 Grand Forks Boulevard  
Charlottesville, VA 22911  
Trade Name: LipoFilter - Hospital Pack  
LipoFilter - Clinic Pack (K150779)  
Cleared Date: 22-MAY-2015

BK840023-0 Microdrop, Incorporation  
2227 Corinth Ave.  
Los Angeles, CA 90064  
Trade Name: Leukocyte Typing Serum Trays  
Cleared Date: 12-OCT-1984

BK840013-0 Microdrop, Incorporation  
2227 Corinth Ave.  
Los Angeles, CA 90064  
Trade Name: Lambda Cell Tray  
Cleared Date: 20-NOV-1984

BK100008-0 Micronics  
8463 154th Avenue NE  
Redmond, WA 98052  
Trade Name: ABORhCard  
Cleared Date: 30-APR-2010

BK910034-0 Microwave Medical System  
310-312 School St.  
Acton, MA 01720  
Trade Name: QWIK-1 Bld. and Plasma Warmer  
Cleared Date: 29-JUL-1993

BK940003-0 Microwave Medical System  
310-312 School St.  
Acton, MA 01720  
Trade Name: Qwik - 1 TM - 500  
Cleared Date: 24-FEB-1994

BK970044-0 Microwave Medical System  
310-312 School St.  
Acton, MA 01720  
Trade Name: ThermoStat 900  
Cleared Date: 23-JAN-1998

BK970045-0 Microwave Medical System  
310-312 School St.  
Acton, MA 01720  
Trade Name: ThermoStat 900 Blood & IV Fluid  
Adm. Set  
Cleared Date: 06-MAR-1998

BK860016-0 Miles, Inc.  
4th and Parker Streets, P.O. Box 1986  
Berkeley, CA 94701-1986  
Trade Name: PENTEX MOD-U-CYTE II & VIII  
Cleared Date: 17-APR-1987

BK220726-0 Millennium Medical Technologies Inc (DBA Cellmyx)  
6352 Corte Del Abeto Ste A  
Carlsbad, CA 92011  
Trade Name: IntelliFat Disposable Adipose  
Tissue Harvesting and Transfer  
Kit, IntelliFat Body On Demand  
(BOD) Kit (K210528)  
Cleared Date: 16-MAR-2022

BK220711-0 Millennium Medical Technologies, INC  
460 Saint Michaels Drive  
Suite 901  
Santa FE, NM 87505  
Trade Name: Autoclavable Suction Jar with Luer  
Lock extension - 250 500 1000 2000  
and 3000 ml (K170449)  
Autoclavable Suction Jar without  
Luer Lock extension - 1500 and  
2500 ml Sterile 1500 and 2500  
(K170449)  
Lids with Conical patient  
connection 6-10 and overflow  
protection (K170449)  
Cleared Date: 31-MAR-2017

BK210653-0 Millipore (UK) Ltd  
Fleming Road, Kirkton Campus  
, Livingston UNITED KINGDOM EH54 7BN  
Trade Name: ORTHO Daily QC, Simulated Whole  
Blood Quality Control Kit (ORTHO  
Daily QC Kit)  
Cleared Date: 07-JUN-2022

BK090020-0 Miltenyi Biotec, Inc.  
120 Presidential Way  
Suite 305

Woburn, MA 01801  
Trade Name: CryoMACS Freezing Bag  
Cleared Date: 13-JAN-2010

BK251174-0 MimiX Biotherapeutics, Ltd  
Aarbergstrasse 46, CH-2503  
Biel/Bienne, Canton of Bern SWITZERLAND 2503  
Trade Name: FastSkin Patch  
Cleared Date: 07-NOV-2025

BK030065-0 Mississippi Blood Services, Inc.  
1995 Lakeland Drive  
Jackson, MS 39216  
Trade Name: WebLab Online Laboratory System -  
2.0  
Cleared Date: 22-DEC-2003

BK040065-0 Misys Healthcare Systems  
4801 East Broadway Boulevard  
Tucson, AZ 85711  
Trade Name: Misys Laboratory Blood Bank and  
Blood Donor - 6.0.1  
Cleared Date: 22-OCT-2004

BK940044-0 Mona Barres  
516 Sean Dr.  
Metairie, LA 70005  
Trade Name: VacMatic Ihs 3-15  
Cleared Date: 07-SEP-1994

BK060014-0 Mosum Technology India PVT LTD  
55 Northern Blvd, Suite 200  
Great Neck, NY 11021  
Trade Name: PowerBANK Enterprise Edition -  
version 1.0  
Cleared Date: 30-MAR-2007

BK920024-0 Murex Biologicals, Inc.  
1107 I-45 South  
Conroe, TX 77301  
Trade Name: Murex PEG Potentiator for Antibody  
Detection  
Cleared Date: 01-JUN-1993

BK910016-0 NPBI  
Runde ZZ 41, 7881 HM Emmer Compasuum  
Emmer-Compasuum, NETHERLANDS  
Trade Name: Compomat  
Cleared Date: 30-MAR-1992

BK930018-0 NPBI  
Runde ZZ 41, 7881 HM Emmer Compascuum  
Emmer-Compascumm, NETHERLANDS  
Trade Name: Blood Collection Mixer MW 5001  
Cleared Date: 24-JUL-1994

BK930020-0 NPBI  
Runde ZZ 41, 7881 HM Emmer Compascuum  
Emmer-Compascumm, NETHERLANDS  
Trade Name: Biotrans Separator  
Cleared Date: 27-JUL-1994

BK940061-0 NPBI  
Runde ZZ 41, 7881 HM Emmer Compascuum  
Emmer-Compascumm, NETHERLANDS  
Trade Name: Composeal Mobile and Composeal  
Universal  
Cleared Date: 26-JAN-1995

BK950035-0 NPBI  
Runde ZZ 41, 7881 HM Emmer Compascuum  
Emmer-Compascumm, NETHERLANDS  
Trade Name: Compocool  
Cleared Date: 27-SEP-1995

BK960084-0 NPBI  
Runde ZZ 41, 7881 HM Emmer Compascuum  
Emmer-Compascumm, NETHERLANDS  
Trade Name: Gambro Hemofreeze Bag  
Cleared Date: 28-MAY-1998

BK940053-0 Nanoentek, Inc.  
300 Washington St., STE 416  
Newton, MA 02458  
Trade Name: Olympus PK System  
Cleared Date: 29-NOV-1995  
Cleared Under Schiff & Company

BK120015-0 Nanoentek, Inc.  
300 Washington St., STE 416  
Newton, MA 02458  
Trade Name: ADAM-rWBC  
Cleared Date: 24-JUL-2012

BK120068-0 Nanoentek, Inc.  
300 Washington St., STE 416  
Newton, MA 02458  
Trade Name: ADAM-rWBC  
Cleared Date: 05-DEC-2012

BK180283-0 Nanoentek, Inc.  
12f, 5, Digital-Ro 26-Gil Guro-Gu  
, Seoul KOREA, SOUTH 152-740  
Trade Name: ADAMII CD34 System  
Cleared Date: 09-AUG-2019

BK200525-0 Nanoentek, Inc.  
851 14, Seohae ro, Paltan myeon  
Hwaseong si  
, Gyeonggido KOREA, SOUTH 18521  
Trade Name: ADAM-rWBC HT System  
ADAM-rWBC HT System with ADAM-rWBC  
Kit  
Cleared Date: 01-DEC-2020

BK210621-0 Nanoentek, Inc.  
NanoEntek, Inc.  
851-14 Seohae-ro, Paltan-myeon  
, Hwaseong-si KOREA, SOUTH 18531  
Trade Name: r-Control RBC and PLT  
Cleared Date: 28-OCT-2021

BK231031-0 Nanoentek, Inc.  
12f, 5, Digital-Ro 26-Gil Guro-Gu  
, Seoul KOREA, SOUTH 152-740  
Trade Name: ADAMII CD34 System  
BD Stem Cell Enumeration Kit  
Cleared Date: 05-JUN-2024

BK950042-0 National Hospital Specialties  
104 Johnson Avenue  
Hackensack, NJ 07601  
Trade Name: Genesis Blood Collection Mixer  
Cleared Date: 19-SEP-1995

BK840016-0 Neocyte  
199 Weymouth Street  
Rockland, MA 02370  
Trade Name: NEOPACK System  
Cleared Date: 25-JUN-1985

BK050032-0 Neoteric Technology Ltd  
205-1099 W. 8th Ave.  
Vancouver, British Columbia CANADA V6H 1C3  
Trade Name: BloodTrack SafeTx - Version 2.0  
Cleared Date: 16-AUG-2005

BK050059-0 Neoteric Technology Ltd  
205-1099 W. 8th Ave.  
Vancouver, British Columbia CANADA V6H 1C3

Trade Name: BloodTrack Courier - 3.2  
Cleared Date: 13-DEC-2005

BK060041-0 Neoteric Technology Ltd  
205-1099 W. 8th Ave.  
Vancouver, British Columbia CANADA V6H 1C3  
Trade Name: BloodTrack - 4.1  
Cleared Date: 12-OCT-2006

BK180301-0 Newmarket Biomedical Ltd  
Unit 1 Lanwades Business Park  
, Kentford UNITED KINGDOM CB8 7PN  
Trade Name: PK7400 TP HA Controls  
PK7400 TP HA Reagent  
Cleared Date: 01-AUG-2019

BK920020-0 Nor-Lake, Inc.  
Second and Elm Str. P.O. Box 248  
Hudson, WI 54016  
Trade Name: NSBR211, NSBR482, and NSB763 Blood  
Refrigerators  
Cleared Date: 19-JAN-1993

BK930002-0 Nor-Lake, Inc.  
Second and Elm Str. P.O. Box 248  
Hudson, WI 54016  
Trade Name: NSBR61 (Nor-Lake Scientific Blood  
Bank, 6ft Single Door)  
Cleared Date: 13-APR-1995

BK930003-0 Nor-Lake, Inc.  
Second and Elm Str. P.O. Box 248  
Hudson, WI 54016  
Trade Name: NSBR83 (Nor-Lake Scientific Blood  
Bank, 8ft Double Door)  
Cleared Date: 13-APR-1995

BK930004-0 Nor-Lake, Inc.  
Second and Elm Str. P.O. Box 248  
Hudson, WI 54016  
Trade Name: NSBF211 (Nor-Lake Scientific  
Freezers, 21ft Single Door)  
Cleared Date: 13-APR-1995

BK930005-0 Nor-Lake, Inc.  
Second and Elm Str. P.O. Box 248  
Hudson, WI 54016  
Trade Name: NSBF482 (Nor-Lake Scientific  
Plasma Freezers, 48ft Double Door)  
Cleared Date: 13-APR-1995

BK930006-0 Nor-Lake, Inc.  
Second and Elm Str. P.O. Box 248  
Hudson, WI 54016  
Trade Name: NSBF61 (Nor-Lake Scientific Plasma  
Freezer, 6ft Single Door)  
Cleared Date: 13-APR-1995

BK900023-0 North American Biologicals, Inc.  
16500 N.W. 15th Avenue  
Miami, FL 33169  
Trade Name: QC-HIV  
Cleared Date: 13-NOV-1991

BK910006-0 North American Biologicals, Inc.  
16500 N.W. 15th Avenue  
Miami, FL 33169  
Trade Name: QC-Hepatitis  
Cleared Date: 12-MAR-1992

BK920015-0 North American Biologicals, Inc.  
16500 N.W. 15th Avenue  
Miami, FL 33169  
Trade Name: VirocheQC 1  
Cleared Date: 20-MAY-1993

BK910028-0 North American Technical Services Corp.  
407 E Main St.  
Port Jefferson, NY 11777  
Trade Name: ASTOTHERM/ASTOTUBE  
Cleared Date: 13-JUL-1992

BK110060-0 Novartis Vaccines and Diagnostics, Inc.  
4560 Horton St.  
Emeryville, CA 94608-2916  
Trade Name: PROCLEIX NAT TRACKER Version 3.0  
Software  
Cleared Date: 01-DEC-2011

BK930023-0 Nu-Quest, Inc.  
1031 Meadowview Drive  
Webb City, MO 64870  
Trade Name: Little Pig Sticker  
Cleared Date: 24-FEB-1994

BK830017-0 Nuclear-Medical Laboratories, Division  
1800 Hurd Drive  
Irving, TX 75061  
Trade Name: Hepa-SHure  
Cleared Date: 07-OCT-1983

BK080022-0 Olerup SSP AB  
Hasselstigen 1  
SE 133 33 Saltsjobaden  
, SWEDEN  
Trade Name: Olerup SSP HLA Typing Kits  
Cleared Date: 20-FEB-2009

BK090042-0 Olerup SSP AB  
Hasselstigen 1  
SE 133 33 Saltsjobaden  
, SWEDEN  
Trade Name: Olerup SSP HLA Typing Kits  
Cleared Date: 11-SEP-2009

BK010040-0 Olympus America Inc., Diagnostic Systems Division  
3131 West Royal Lane  
Irving, TX 75063-3104  
Trade Name: Olympus PK 7200 Automated  
Microplate System  
Cleared Date: 25-OCT-2001

BK020024-0 Olympus America Inc., Diagnostic Systems Division  
3131 West Royal Lane  
Irving, TX 75063-3104  
Trade Name: Olympus PK7200 Automated  
Microplate System  
Cleared Date: 08-JUL-2002

BK030009-0 Olympus America Inc., Diagnostic Systems Division  
3131 West Royal Lane  
Irving, TX 75063-3104  
Trade Name: Olympus PK7200 Automated  
Microplate System  
Cleared Date: 03-MAR-2003

BK040003-0 Olympus America Inc., Diagnostic Systems Division  
3131 West Royal Lane  
Irving, TX 75063-3104  
Trade Name: Olympus PK7200 Automated  
Microplate System  
Cleared Date: 06-FEB-2004

BK040070-0 Olympus America Inc., Diagnostic Systems Division  
3131 West Royal Lane  
Irving, TX 75063-3104  
Trade Name: Tango Automated Blood Bank  
Analyzer System  
Cleared Date: 22-MAR-2005

BK050076-0 Olympus America Inc., Diagnostic Systems Division  
3131 West Royal Lane  
Irving, TX 75063-3104  
Trade Name: TANGO Automated Blood Bank  
Analyzer System (HW Version 02/SW  
Version 3.0)  
Cleared Date: 16-DEC-2005

BK060024-0 Olympus America Inc., Diagnostic Systems Division  
3131 West Royal Lane  
Irving, TX 75063-3104  
Trade Name: Olympus Bromelin  
Olympus PK7300 Automated  
Microplate System  
Olympus System Control  
Cleared Date: 14-MAY-2007

BK060034-0 Olympus America Inc., Diagnostic Systems Division  
3131 West Royal Lane  
Irving, TX 75063-3104  
Trade Name: TANGO Automated Blood Bank  
Analyzer System  
Cleared Date: 28-AUG-2006

BK090036-0 Olympus America Inc., Diagnostic Systems Division  
3500 Corporate Parkway  
Center Valley, PA 18034  
Trade Name: Olympus PK7300 Automated  
Microplate System  
Cleared Date: 13-JAN-2010

BK860004-0 Olympus Corporation  
4 Nevada Drive  
Lake Success, NY 11042  
Trade Name: Olympus PK7100  
Cleared Date: 14-MAY-1986

BK870025-0 Olympus Corporation  
4 Nevada Drive  
Lake Success, NY 11042  
Trade Name: Olympus PK7100 Automated Blood  
Grouping System  
Cleared Date: 09-OCT-1987

BK890030-0 Olympus Corporation  
4 Nevada Drive  
Lake Success, NY 11042  
Trade Name: SynthEIA Software System  
Cleared Date: 23-JAN-1991

BK930024-0 Olympus Corporation  
4 Nevada Drive  
Lake Success, NY 11042  
Trade Name: Olympus PK7200 Blood Grouping  
Analyzer  
Cleared Date: 26-JAN-1994

BK140093-0 Omrix Biopharmaceuticals Ltd.  
PO Box 151, Route22 West  
Somerville, NJ 08876-0151  
Trade Name: Evicel Application Device  
Cleared Date: 03-SEP-2014

BK120014-0 One Lambda, Inc  
21001 Kittridge St  
Canoga Park, CA 91303  
Trade Name: HLA Fusion Software, Version 3.0  
Cleared Date: 18-DEC-2012

BK120024-0 One Lambda, Inc  
21001 Kittridge St  
Canoga Park, CA 91303  
Trade Name: LABType (R) SSO DNA Typing Tests  
for use with LABScanTM 3D  
Cleared Date: 20-DEC-2012

BK130009-0 One Lambda, Inc  
21001 Kittridge St  
Canoga Park, CA 91303  
Trade Name: LABScreen for use with  
LABScan(TM) 3D  
Cleared Date: 06-NOV-2013

BK140141-0 One Lambda, Inc  
21001 Kittridge St  
Canoga Park, CA 91303  
Trade Name: LABScreen(R) Multi  
Cleared Date: 25-NOV-2014

BK910021-0 One Lambda, Inc.  
21001 Kittridge St.  
Canoga Park, CA 91303  
Trade Name: Lifesource Flash Bag  
Cleared Date: 08-JUN-1992

BK920007-0 One Lambda, Inc.  
21001 Kittridge St.  
Canoga Park, CA 91303  
Trade Name: Lambda Monoclonal Tray Class I and  
II

Cleared Date: 28-DEC-1992

BK920009-0 One Lambda, Inc.  
21001 Kittridge St.  
Canoga Park, CA 91303  
Trade Name: Anti-B27 FITC Conjugated  
Monoclonal Antibody  
Cleared Date: 28-MAR-1997

BK960011-0 One Lambda, Inc.  
21001 Kittridge St.  
Canoga Park, CA 91303  
Trade Name: Lambda Antigen Tray  
Cleared Date: 03-JUL-1997

BK960053-0 One Lambda, Inc.  
21001 Kittridge St.  
Canoga Park, CA 91303  
Trade Name: Anti-B27 FITC/CD3PE Conjugated  
Monoclonal Antibody  
Cleared Date: 30-OCT-1996

BK960062-0 One Lambda, Inc.  
21001 Kittridge St.  
Canoga Park, CA 91303  
Trade Name: Micro SSP HLA Class II DNA Typing  
Kit  
Cleared Date: 11-FEB-1998

BK980015-0 One Lambda, Inc.  
21001 Kittridge St.  
Canoga Park, CA 91303  
Trade Name: FlowPRA  
Cleared Date: 23-JUL-1999

BK020055-0 One Lambda, Inc.  
21001 Kittridge St.  
Canoga Park, CA 91303  
Trade Name: LABTYPE SSO Typing Test  
Cleared Date: 04-FEB-2003

BK030069-0 One Lambda, Inc.  
21001 Kittridge St.  
Canoga Park, CA 91303  
Trade Name: LABScreen Products for use with  
LABScan 100 flow analyzer  
Cleared Date: 31-DEC-2003

BK040049-0 One Lambda, Inc.  
21001 Kittridge St.

Canoga Park, CA 91303  
Trade Name: LabType Visual  
Cleared Date: 09-AUG-2004

BK050008-0 One Lambda, Inc.  
21001 Kittridge St.  
Canoga Park, CA 91303  
Trade Name: LABScreen Software  
Cleared Date: 08-JUL-2005

BK050070-0 One Lambda, Inc.  
21001 Kittridge St.  
Canoga Park, CA 91303  
Trade Name: HLA Visual Software version 1.0  
Cleared Date: 30-JAN-2006

BK050071-0 One Lambda, Inc.  
21001 Kittridge St.  
Canoga Park, CA 91303  
Trade Name: HLA Tools Software version 1.0  
Cleared Date: 30-JAN-2006

BK070070-0 One Lambda, Inc.  
21001 Kittridge St.  
Canoga Park, CA 91303  
Trade Name: HLA Fusion Software v 1.0  
Cleared Date: 10-MAR-2008

BK080071-0 One Lambda, Inc.  
21001 Kittridge St.  
Canoga Park, CA 91303  
Trade Name: LABScreen Multi  
Cleared Date: 10-APR-2009

BK100068-0 One Lambda, Inc.  
21001 Kittridge St.  
Canoga Park, CA 91303  
Trade Name: HNA Genotyping Trays  
Cleared Date: 25-AUG-2011

BK160017-0 One Lambda, Inc.  
21001 Kittridge St.  
Canoga Park, CA 91303  
Trade Name: HLA Fusion  
Cleared Date: 08-MAR-2017

BK160018-0 One Lambda, Inc.  
21001 Kittridge St.  
Canoga Park, CA 91303  
Trade Name: LABType™ XR and CWD DNA Typing

Test

Cleared Date: 06-MAR-2017

BK170053-0 One Lambda, Inc.  
21001 Kittridge St.  
Canoga Park, CA 91303  
Trade Name: LABType? CWD Class I C Locus  
Typing Test  
LABType? CWD Class I C Locus  
Typing Test - 20 tests  
LABType? XR Class I C Locus Typing  
Test  
LABType? XR Class I C Locus Typing  
Test - 20 tests  
Cleared Date: 05-OCT-2017

BK200546-0 One Lambda, Inc.  
22801 Roscoe Blvd  
West Hills, CA 92304  
Trade Name: LABScreen Multi  
Cleared Date: 12-JAN-2021

BK241074-0 One Lambda, Inc.  
22801 Roscoe Blvd  
West Hills, CA 91304  
Trade Name: SeCore CDx HLA Sequencing System  
Cleared Date: 01-AUG-2024

BK190322-0 OrSense Ltd  
17 Ha Mefalsim St  
Petah Tikva, Kiryat Arie ISRAEL 4951447  
Trade Name: NBM-200 Pulse Oximeter and  
Hemoglobin Monitor  
Cleared Date: 09-MAY-2019

BK030036-0 OriGen BioMedical  
7000 Burleson Road, Bldg. D  
Austin, TX 78744  
Trade Name: OriGen Cryostore Freezing Bags  
Cleared Date: 01-OCT-2003

BK140116-0 OriGen BioMedical  
7000 Burleson Road, Building D  
Austin, TX 78744  
Trade Name: Origen Transfer Bag  
Cleared Date: 19-OCT-2016

BK180278-0 OriGen BioMedical  
7000 Burleson Road, Building D  
Austin, TX 78744

Trade Name: OriGen Cryostore Multi-Chamber  
Freezing Bags  
Cleared Date: 21-NOV-2018

BK820003-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO Confidence System  
Cleared Date: 10-AUG-1982

BK820006-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: Simwash  
Cleared Date: 13-APR-1983

BK830023-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: TYTEM Typing and Detection System  
Cleared Date: 08-DEC-1983

BK840017-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO Cell Suspension Tube  
Cleared Date: 16-NOV-1984

BK890021-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: Ortho Confidence System  
Cleared Date: 23-OCT-1989

BK920034-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: Ortho BioVue System  
Cleared Date: 09-MAY-1995

BK960003-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: Ortho Summitt System  
Cleared Date: 19-OCT-1998

BK960052-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: Ortho Summit Processor

Cleared Date: 19-OCT-1998

BK990030-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: Ortho Lab with Ortho Lab IC  
(Instrument Concentrator)  
Cleared Date: 03-APR-2000

BK050044-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: Genetic Systems HIV-1/HIV-2 PLUS O  
Ortho Assay Protocol Disk  
Cleared Date: 03-NOV-2006

BK050046-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: Genetic Systems HBSAg EIA 3.0  
Ortho Assay Protocol Disk  
Cleared Date: 13-JAN-2006

BK070028-0 Ortho-Clinical Diagnostics, Inc.  
100 Indigo Creek Drive  
Rochester, NY 14626-5101  
Trade Name: VITROS Immunodiagnostic Products  
Anti-HIV 1+2 Controls  
Cleared Date: 10-APR-2008

BK090074-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: Ortho Summit System  
Cleared Date: 27-MAY-2009

BK100040-0 Ortho-Clinical Diagnostics, Inc.  
100 Indigo Creek Drive  
Rochester, NY 14626-5101  
Trade Name: VITROS Immunodiagnostic Products  
Anti-HIV 1+2 Controls  
Cleared Date: 22-JUL-2010

BK100061-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO VERSEIA Pipetter as part of  
the ORTHO Summit System  
Cleared Date: 28-OCT-2010

BK110026-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: Ortho Summit System (OSS)  
Cleared Date: 28-JUN-2011

BK120006-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO VERSEIA Pipetter as Part of  
the ORTHO Summit System (OSS) v  
3.0  
Cleared Date: 15-MAR-2012

BK130006-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO VERSEIA Integrated  
Processor (VIP)  
Cleared Date: 23-MAY-2013

BK130032-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO (TM) Workstation  
Cleared Date: 09-AUG-2013

BK140207-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO VISION Analyzer  
Cleared Date: 14-AUG-2015

BK160058-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO VISION Max Analyzer  
Cleared Date: 21-OCT-2016

BK190338-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO VISION Analyzer  
Cleared Date: 09-JUL-2019

BK190399-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO VISION Max Analyzer  
Cleared Date: 17-DEC-2019

BK200549-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO Optix Reader  
Cleared Date: 10-MAR-2021

BK210557-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO VISION Analyzer  
ORTHO VISION Max Analyzer  
Cleared Date: 13-MAY-2021

BK210564-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO VISION Analyzer  
ORTHO VISION Max Analyzer  
Cleared Date: 13-MAY-2021

BK220724-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO Optix Reader  
Cleared Date: 24-JUN-2022

BK251238-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO VISION Analyzer  
ORTHO VISION Max Analyzer  
Cleared Date: 10-OCT-2025

BK261331-0 Ortho-Clinical Diagnostics, Inc.  
1001 U.S. Highway 202  
Raritan, NJ 08869-0606  
Trade Name: ORTHO Optix Reader  
Cleared Date: 13-MAY-2026

BK241083-0 OrthoAscent  
6151 Thornton Avenue  
Suite 400  
Des Moines, IA 50321  
Trade Name: Platelet Rich Plasma (PRP) Device  
Cleared Date: 26-SEP-2024

BK040017-0 Orthogen Therapeutics, GmbH  
Graf-Adolf-Str. 43  
D-40210 Dusseldorf, GERMANY

Trade Name: Osteokin System  
Cleared Date: 23-JUN-2004

BK080014-0 Pall Corporation  
25 Harbor Park Drive  
Port Washington, NY 11050-4630  
Trade Name: Pall eBDS  
Cleared Date: 13-FEB-2009  
Cleared Under Pall Life Sciences

BK150314-0 Pall Corporation  
25 Harbor Park Drive  
Port Washington, NY 11050-4630  
Trade Name: Pall? Briostor? Transfer/Freezing  
Bag Set  
Cleared Date: 16-JUN-2016

BK120029-0 PatientSafe Solutions  
5375 Mira Sorrento Place  
Suite 500  
San Diego, CA 92121  
Trade Name: Patient Touch(TM) Blood Product  
Administration System v3.2.1  
Cleared Date: 13-NOV-2012

BK820002-0 Pel-Freez Clinical Systems, LLC  
PO Box 68  
Rogers, AR 72756  
Trade Name: Not available from BLT migrated  
data.  
Cleared Date: 06-OCT-1982

BK820023-0 Pel-Freez Clinical Systems, LLC  
PO Box 68  
Rogers, AR 72756  
Trade Name: Leukocyte Typing Serum (Human)  
(Tray Package)  
Cleared Date: 12-JAN-1983

BK850004-0 Pel-Freez Clinical Systems, LLC  
9099 N. Deerbrook Trail  
Brown Deer, WI 53223  
Trade Name: Frozen Leukocyte Panel (Human)  
Cleared Date: 01-AUG-1985

BK000019-0 Pel-Freez Clinical Systems, LLC  
9099 N. Deerbrook Trail  
Brown Deer, WI 53223  
Trade Name: UniTray SSP HLA Typing Kits  
Cleared Date: 29-JAN-2001

BK020068-0 Pel-Freez Clinical Systems, LLC  
9099 N. Deerbrook Trail  
Brown Deer, WI 53223  
Trade Name: Pel Freez HLA High Resolution SSP  
UniTray  
Cleared Date: 14-JAN-2003

BK030003-0 Pel-Freez Clinical Systems, LLC  
9099 N. Deerbrook Trail  
Brown Deer, WI 53223  
Trade Name: UniMatch Plus  
Cleared Date: 25-FEB-2003

BK050055-0 Perfusion Partners & Associates, Inc.  
6227 Foxfire Lane  
Fort Myers, FL 33912  
Trade Name: GenesisCS Component Concentrating  
System  
Cleared Date: 13-OCT-2006

BK900018-0 Polar Products, Inc.  
2808 Oregon Ct. Bldg K-4  
Torrance, CA 90503  
Trade Name: Polar Products' Model MTE-58L  
Cleared Date: 30-AUG-1990

BK140119-0 ProFibrix BV  
Darwinweg 24  
Leiden, NETHERLANDS  
Trade Name: RaplixaSpray Device  
Cleared Date: 30-APR-2015

BK170092-0 Progenika Biopharma, S.A.  
Ibaizabal bidea, Edificio 504  
Parque Tecnologico de Bizkaia  
Derio, Bizkaia,  
Trade Name: ID CORE CONTROL  
Cleared Date: 11-OCT-2018

BK010017-0 Psyche Systems Corp  
Ten Laurel Avenue  
Wellesley, MA 02481  
Trade Name: System Blood Bank (SBB) Software -  
3.0  
Cleared Date: 04-SEP-2001

BK220720-0 Puregraft LLC  
420 Stevens Ave  
Suite 220

Solana Beach, CA 92075  
Trade Name: Dermapose Refresh (K193363)  
Cleared Date: 14-APR-2020

BK180188-0 PuriBlood Medical Co. Ltd.  
2F., No.11, Gongye E. 9th Rd.  
Paoshan Hsiang  
, Hsinchu Hsien TAIWAN 30075  
Trade Name: Leukocyte Reduction Filter for Red  
Blood Cells  
Leukocyte reduction filter for red  
blood cells  
Cleared Date: 23-NOV-2018

BK840020-0 Queue Systems  
22 Airport Industrial Park Rd., Box 1901  
Parkersburg, WV 26102  
Trade Name: Cryostar  
Cleared Date: 23-OCT-1984

BK990005-0 R & D Systems, Inc  
614 McKinley Place N.E.  
Minneapolis, MN 55413  
Trade Name: StatusFlow Pro  
Cleared Date: 21-JUN-1999

BK000035-0 R & D Systems, Inc  
614 McKinley Place N.E.  
Minneapolis, MN 55413  
Trade Name: R & D Leuko-Reduced RBC Control  
Cleared Date: 13-DEC-2000

BK000036-0 R & D Systems, Inc  
614 McKinley Place N.E.  
Minneapolis, MN 55413  
Trade Name: R & D Leuko-Reduced Plt Control  
Cleared Date: 13-DEC-2000

BK040012-0 R & D Systems, Inc  
614 McKinley Place N.E.  
Minneapolis, MN 55413  
Trade Name: R&D Donor Checker Hematology  
Control  
Cleared Date: 05-MAR-2004

BK040063-0 R & D Systems, Inc  
614 McKinley Place N.E.  
Minneapolis, MN 55413  
Trade Name: R & D Plasma Hemoglobin Hematology  
Control

Cleared Date: 17-SEP-2004

BK910012-0 ROCHE BIOMEDICAL LABORATORIES, INC.  
112 ORANGE DRIVE  
ELON COLLEGE, NC 27244  
Trade Name: HLA CLASS I PHENOTYPING TRAYS  
Cleared Date: 06-JAN-1992

BK200543-0 Ranfac Corporation  
30 Doherty St  
Avon, MA 02322  
Trade Name: Ranfac Autologous Platelet  
Seperator  
Cleared Date: 24-FEB-2021

BK220704-0 Ranfac Corporation  
30 Doherty St  
Avon, MA 02322  
Trade Name: Ranfac Fat Aspiration Transfer  
Syringe (FATS) Procedure Pack  
Ranfac Fat Aspiration Transfer  
Syringe (FATS) Containment Vessel  
(K150156)  
Cleared Date: 19-OCT-2015

BK220708-0 Ranfac Corporation  
30 Doherty St  
Avon, MA 02322  
Trade Name: Ranfac Fat Aspiration Cannula  
(K162932)  
Cleared Date: 19-JAN-2017

BK860034-0 Reagent Laboratory, Inc.  
300 East Ottawa Avenue  
Louisville, KY 40209  
Trade Name: Sodium Chloride 1.3%  
Cleared Date: 01-JUN-1987

BK140211-0 Reapplix Aps  
Blokken 45  
Birkerod, DENMARK  
Trade Name: 3C Patch System  
Cleared Date: 24-FEB-2016

BK170002-0 Reapplix Aps  
Blokken 45  
Birkerod, DENMARK  
Trade Name: 3C Patch System  
Cleared Date: 04-APR-2017

BK200471-0 Reapplix Aps  
Blokken 45  
Birkerod, DENMARK  
Trade Name: 3C Patch System  
Cleared Date: 13-JAN-2021

BK230968-0 Reapplix Aps  
Blokken 45  
Birkerod, DENMARK  
Trade Name: 3C Patch System  
Cleared Date: 02-APR-2024

BK170095-0 RedDress Ltd  
Shkedim Street 11  
Pardes Hanna, ISRAEL 370110  
Trade Name: RD1 System  
Cleared Date: 14-JUN-2018

BK190349-0 RedDress Ltd  
Shkedim Street 11  
Pardes Hanna, ISRAEL 370110  
Trade Name: RD2 System  
Cleared Date: 08-NOV-2019

BK200464-0 RedDress Ltd  
Shkedim Street 11  
Pardes Hanna, ISRAEL 370110  
Trade Name: RD2 System  
Cleared Date: 20-MAR-2020

BK210570-0 RedDress Ltd  
Shkedim Street 11  
Pardes Hanna, ISRAEL 370110  
Trade Name: RD2 Ver.02 System  
Cleared Date: 22-JUN-2021

BK251274-0 Regen Lab USA LLC  
95 Green Street  
Jersey City, NJ 07302  
Trade Name: RegenBMC (RegenKit -THT -BMC)  
Cleared Date: 29-MAY-2026

BK090048-0 RegenLab SA  
3428 Avenue Marcil  
Montreal, Quebec CANADA H4A 2Z3  
Trade Name: RegenKit-THT  
Cleared Date: 18-MAY-2010  
Cleared Under RegenLab SARL

BK110061-0 RegenLab SA

En Budron B2  
CH-1052 Le Mont sur Lausanne  
, SWITZERLAND  
Trade Name: RegenKit-BCT Family Kits  
Cleared Date: 08-MAY-2012  
Cleared Under RegenLab SARL

BK120057-0 RegenLab SA  
3428 Avenue Marcil  
Montreal, Quebec CANADA H4A 2Z3  
Trade Name: A-CP-Kit Family Kits  
Cleared Date: 08-AUG-2013

BK120066-0 RegenLab SA  
3428 Avenue Marcil  
Montreal, Quebec CANADA H4A 2Z3  
Trade Name: RegenKit-ATS-3  
RegenKit-BCT-1 Plus  
RegenKit-BCT-2 Plus  
Cleared Date: 05-FEB-2014

BK210661-0 RegenLab SA  
En Budron B2  
CH-1052 Le Mont sur Lausanne  
, SWITZERLAND  
Trade Name: RegenKit-Wound Gel-1  
RegenKit-Wound Gel-2  
Cleared Date: 08-JUL-2022

BK170128-0 Reichert Inc.  
3362 Walden Ave  
Suite 100  
Depew, NY 14043  
Trade Name: TS Meter-DSP  
Cleared Date: 19-DEC-2017

BK880029-0 Revco/Lindberg  
275 Aiken Road  
Asheville, NC 28804  
Trade Name: MBF700 Blood Freezer  
Cleared Date: 16-JUN-1989

BK890023-0 Revco/Lindberg  
275 Aiken Road  
Asheville, NC 28804  
Trade Name: HLT-20DR-87 Blood Freezer  
Cleared Date: 21-SEP-1990

BK890025-0 Revco/Lindberg  
275 Aiken Road

Asheville, NC 28804  
Trade Name: HLT-50V-4BB Blood Refrigerator  
Cleared Date: 02-FEB-1990

BK890026-0 Revco/Lindberg  
275 Aiken Road  
Asheville, NC 28804  
Trade Name: REB3704 Blood Refrigerator  
Cleared Date: 02-FEB-1990

BK950054-0 Revco/Lindberg  
275 Aiken Road  
Asheville, NC 28804  
Trade Name: Blood Storage Refrigerator REB2304  
Cleared Date: 11-JAN-1996

BK950066-0 Revco/Lindberg  
275 Aiken Road  
Asheville, NC 28804  
Trade Name: Revco HLT 30V-4BB  
Cleared Date: 31-JAN-1996

BK890006-0 Rexco  
275 Aiken  
Asheville, NC 28804  
Trade Name: MBF 500 Blood Freezer  
Cleared Date: 16-JUN-1989

BK251211-0 Ricarimpex SAS  
245 Avenue de Saint Mddard  
Eysines, Gironde FRANCE 33320  
Trade Name: Medicinal Leeches  
Medicinal Leeches (K040187)  
Cleared Date: 21-JUN-2004

BK251201-0 Rmedica Co., Ltd.  
2-Dong 709-Ho (Gasam-Dong, IT Castle)  
98, Gasam Digital 2-Ro  
Seoul, Geumcheon-Gu KOREA, SOUTH 08506  
Trade Name: DR. PRP-30  
DR.PRP-30  
Dr.PRP-30  
Cleared Date: 22-OCT-2025

BK230839-0 Roche Diagnostics  
9115 Hague Rd  
Indianapolis, IN 46250  
Trade Name: Elecsys Syphilis  
Elecsys Syphilis for use on Cobas  
Pro Serology Solution

PreciControl Release Syphilis  
PreciControl Syphilis  
Cleared Date: 31-JUL-2023

BK230840-0 Roche Diagnostics  
9115 Hague Rd  
Indianapolis, IN 46250  
Trade Name: Cytomegalovirus serological  
reagents  
Elecsys Anti-CMV  
Elecsys CMV IgG  
PreciControl Anti-CMV  
PreciControl CMV IgG  
PreciControl Release Anti-CMV  
PreciControl Release CMV IgG  
Cleared Date: 03-NOV-2023

BK241132-0 Roche Diagnostics  
9115 Hague Rd  
Indianapolis, IN 46250  
Trade Name: cobas pro serology solution  
Cleared Date: 06-NOV-2024

BK241148-0 Roche Diagnostics  
9115 Hague Rd  
Indianapolis, IN 46250  
Trade Name: cobas pro serology solution  
Cleared Date: 10-JAN-2025

BK251280-0 Roche Diagnostics  
9115 Hague Rd  
Indianapolis, IN 46250  
Trade Name: Elecsys Anti-CMV  
Elecsys Syphilis  
cobas pro serology solution  
Cleared Date: 09-OCT-2025

BK251285-0 Roche Diagnostics  
9115 Hague Rd  
Indianapolis, IN 46256  
Trade Name: Elecsys Syphilis  
Cleared Date: 10-DEC-2025

BK020018-0 Roche Molecular Systems, Inc.  
4300 Hacienda Drive  
P.O. Box 9002  
Pleasanton,, CA 94588-0900  
Trade Name: Cobas Ampliscreen System  
Cleared Date: 26-NOV-2002

BK020025-0 Roche Molecular Systems, Inc.  
4300 Hacienda Drive  
P.O. Box 9002  
Pleasanton,, CA 94588-0900  
Trade Name: COBAS AmpliScreen Data Output  
Management System (DOMS) - 1.00.04  
Cleared Date: 10-DEC-2002

BK140195-0 Roche Molecular Systems, Inc.  
4300 Hacienda Drive  
P.O. Box 9002  
Pleasanton,, CA 94588-0900  
Trade Name: Cobas p 680 Instrument  
Cobas 8800 System  
Cleared Date: 20-OCT-2016

BK140196-0 Roche Molecular Systems, Inc.  
4300 Hacienda Drive  
P.O. Box 9002  
Pleasanton,, CA 94588-0900  
Trade Name: cobas p 680 Instrument  
cobas 6800 System  
Cleared Date: 20-OCT-2016

BK251233-0 Roche Molecular Systems, Inc.  
4300 Hacienda Drive  
Pleasanton, CA 94588  
Trade Name: cobas HIV-1/HIV-2 Qualitative  
Nucleic acid test for use on the  
cobas 5800/6800/8800 systems  
Cleared Date: 27-JUN-2025

BK251235-0 Roche Molecular Systems, Inc.  
4300 Hacienda Drive  
Pleasanton, CA 94588  
Trade Name: cobas HIV-1 Quantitative nucleic  
acid test for use on the cobas  
5800/6800/8800 systems  
Cleared Date: 01-JUL-2025

BK251286-0 Roche Molecular Systems, Inc.  
4300 Hacienda Drive  
Pleasanton, CA 94588  
Trade Name: cobas HIV-1 Quantitative nucleic  
acid test for use on the cobas  
5800/6800/8800 systems  
cobas HIV-1/HIV-2 Qualitative  
Nucleic acid test for use on the  
cobas 5800/6800/8800 systems  
Cleared Date: 21-NOV-2025

BK251209-0 Ronald A. Sherman  
36 Urey Court  
Irvine, CA 92612  
Trade Name: CYTORI PUREGRAFT 250/PURE SYSTEM  
(K092923)  
Medical Maggots  
Medical Maggots (K033391)  
Cleared Date: 12-JAN-2004

BK110045-0 Rowny Systems, Inc.  
7555 Spring Lake Drive  
Bethesda, MD 20817-6507  
Trade Name: Antigen PLUS - 7.4  
Cleared Date: 25-MAY-2012

BK210563-0 Royal Biologics Inc  
401 Hackensack Ave  
Hackensack, NJ 07601  
Trade Name: Royal Maxx Autologous PRP  
Concentration System  
Cleared Date: 16-APR-2021

BK210632-0 Royal Biologics Inc  
401 Hackensack Ave  
Hackensack, NJ 07601  
Trade Name: Royal MAXX BMC Concentration  
System  
Royal MAXX PRP Concentration  
System  
Cleared Date: 11-FEB-2022

BK180204-0 Royal Biologics LLC  
190 Columbus Drive  
Suite #2A  
Jersey City, NJ 07302  
Trade Name: Royal MaxxPRP Concentration System  
Cleared Date: 12-JUL-2018

BK251232-0 Royal Wound-X, Inc.  
401 Hackensack Ave.  
Suite 604  
Hackensack, NJ 07061  
Trade Name: PRF-Matrix System  
Cleared Date: 20-FEB-2026

BK990008-0 Rubin & Poor, Inc.  
155 Maplewood Avenue #5  
Maplewood, NJ 07040  
Trade Name: Rubin & Poor Configurable Manual

Blot System - 1.0C  
Cleared Date: 29-OCT-1999

BK000030-0 Rubin & Poor, Inc.  
155 Maplewood Avenue #5  
Maplewood, NJ 07040  
Trade Name: Configurable Laboratory Result  
Manager (CLRM) - 1.0E  
Cleared Date: 23-NOV-2001

BK030073-0 Rubin & Poor, Inc.  
155 Maplewood Avenue #5  
Maplewood, NJ 07040  
Trade Name: Configurable Manual Batch Entry -  
1.1A  
Cleared Date: 14-JAN-2004

BK080028-0 Rubin & Poor, Inc.  
155 Maplewood Avenue #5  
Maplewood, NJ 07040  
Trade Name: Pool results Manager  
Cleared Date: 03-SEP-2008

BK050045-0 SCC Soft Computer  
34350 U.S. Highway 19 North  
Palm Harbor, FL 34684  
Trade Name: SoftDonor 4.3 with SoftScape  
Cleared Date: 26-OCT-2005

BK060059-0 SCC Soft Computer  
34350 U.S. Highway 19 North  
Palm Harbor, FL 34684  
Trade Name: SoftDonor 4.4 with DMSI - 4.4  
Cleared Date: 21-DEC-2006

BK080020-0 SCC Soft Computer  
5400 Tech Data Drive  
Clearwater, FL 33760  
Trade Name: SoftBank II - v23.2  
Cleared Date: 12-AUG-2008

BK080069-0 SCC Soft Computer  
5400 Tech Data Drive  
Clearwater, FL 33760  
Trade Name: SoftDonor 4.5 - 4.5  
Cleared Date: 16-JAN-2009

BK090017-0 SCC Soft Computer  
5400 Tech Data Drive  
Clearwater, FL 33760

Trade Name: SoftBank II Version 25 - 25  
Cleared Date: 23-JUN-2009

BK090078-0 SCC Soft Computer  
5400 Tech Data Drive  
Clearwater, FL 33760  
Trade Name: SoftID.Tx Version 1.0  
Cleared Date: 28-APR-2010

BK100045-0 SCC Soft Computer  
5400 Tech Data Drive  
Clearwater, FL 33760  
Trade Name: SoftBank II - 25.1  
Cleared Date: 29-JUL-2010

BK140128-0 SCC Soft Computer  
5400 Tech Data Drive  
Clearwater, FL 33760  
Trade Name: SoftBank Version 25.5  
Cleared Date: 05-AUG-2014

BK200531-0 SCC Soft Computer  
5400 Tech Data Drive  
Clearwater, FL 33760  
Trade Name: SoftBank - 25.6.1.0  
SoftBank.web - 25.6.1.0  
Cleared Date: 18-DEC-2020

BK210607-0 SCC Soft Computer  
5400 Tech Data Drive  
Clearwater, FL 33760  
Trade Name: SoftDonor Version 4.5.5.0 -  
4.5.5.0  
Cleared Date: 14-SEP-2021

BK950057-0 SG Scientific  
5745 SW 75th Street  
#284  
Gainseville, FL 32608  
Trade Name: The Saber (Segment Piercing  
Device)  
  
Cleared Date: 13-NOV-1995

BK090047-0 SPINESMITH PARTNERS LP  
93 Red River  
Austin, TX 78701  
Trade Name: Fusinary Graft Delivery System  
Cleared Date: 10-FEB-2010

BK050052-0   STEMCO Biomedical, Inc.  
                  2810 Meridan Parkway  
                  Suite 148  
                  Durham, NC 27713  
Trade Name: Aldecourt Progenitor Cell  
                  Enumeration Kit  
Cleared Date: 02-DEC-2005

BK130052-0   STRATEC Biomedical UK Limited  
                  1 Barberry Court, Callister Way  
                  Burton upon Trent  
  
Trade Name: Procleix NAT Manager Software  
                  (Version 1.1)  
Cleared Date: 17-APR-2014

BK160071-0   STRATEC Biomedical UK Limited  
                  Third Ave, Centrum 100  
                  Burton upon Trent  
                  Straffordshire, DE14 2WD UNITED KINGDOM  
Trade Name: Aurora Enterprise - Cat. No.  
                  AUR-ENT-001  
Cleared Date: 30-OCT-2017

BK160113-0   STRATEC Biomedical UK Limited  
                  98 Main Street  
                  Suite 205  
                  Southington, CT 06489  
Trade Name: cobas Synergy Software (Version  
                  1.0)  
Cleared Date: 19-APR-2017

BK160124-0   STRATEC Biomedical UK Limited  
                  Third Ave, Centrum 100  
                  Burton upon Trent  
                  Straffordshire, DE14 2WD UNITED KINGDOM  
Trade Name: ORTHO CONNECT  
Cleared Date: 17-OCT-2017

BK160125-0   STRATEC Biomedical UK Limited  
                  Third Ave, Centrum 100  
                  Burton upon Trent  
                  Straffordshire, DE14 2WD UNITED KINGDOM  
Trade Name: Procleix? NAT Manager? v1.2  
                  Software - v1.2  
Cleared Date: 25-APR-2017

BK190434-0   STRATEC Biomedical UK Limited  
                  Third Ave, Centrum 100  
                  Burton upon Trent

Straffordshire, DE14 2WD UNITED KINGDOM  
Trade Name: ORTHO CONNECT - 3.0  
Ortho Connect - 3.0  
Cleared Date: 10-MAR-2020

BK231018-0 SUNPHORIA CO., LTD.  
12F-1, No. 51, Hengyang Rd.  
.  
Taipei City, Zhongzheng Dist TAIWAN 10045  
Trade Name: AHC Platelet Concentrate Separator  
Cleared Date: 10-JAN-2025

BK940017-0 SangStat Medical Corporation  
6300 Dumbarton Circle  
Freemont, CA 94555  
Trade Name: PRA-STAT Elisa/Panel React  
Anti-HLA Class I IgG Antibody  
Cleared Date: 27-SEP-1994

BK950009-0 SangStat Medical Corporation  
6300 Dumbarton Circle  
Freemont, CA 94555  
Trade Name: CROSS STAT  
Cleared Date: 09-MAY-1995

BK970019-0 SangStat Medical Corporation  
6300 Dumbarton Circle  
Freemont, CA 94555  
Cleared Date: 30-JUL-1997

BK970037-0 SangStat Medical Corporation  
6300 Dumbarton Circle  
Freemont, CA 94555  
Trade Name: PRA-STAT Anti-HLA CLASS I IgG  
Antibodies/Two Patients per Plate  
Format  
Cleared Date: 18-NOV-1998

BK940011-0 Sanguin International  
1020 Sherman Avenue  
Hamden, CT 06514  
Trade Name: Sanguin Medusa 2000  
Cleared Date: 29-SEP-1994

BK960065-0 Sanguin International  
1020 Sherman Avenue  
Hamden, CT 06514  
Trade Name: Sanguin Medusa 2000 - 3.4  
Cleared Date: 17-DEC-1998

BK980003-0 Sanguin International  
1020 Sherman Avenue  
Hamden, CT 06514  
Trade Name: Aurora/Fenestra (version 1.0)  
Cleared Date: 29-SEP-1999

BK980039-0 Sanguin International  
1020 Sherman Avenue  
Hamden, CT 06514  
Trade Name: Medusa 2000 Srimport, Version 1.2  
Cleared Date: 11-JUN-1999

BK090061-0 Sanguin International  
1020 Sherman Avenue  
Hamden, CT 06514  
Trade Name: Sanguin Aurora version 2.0  
Cleared Date: 22-DEC-2009

BK100030-0 Sanguin International  
1020 Sherman Avenue  
Hamden, CT 06514  
Trade Name: Sanguin Liberty SRIMPORT - 3.1  
Cleared Date: 08-JUL-2010

BK010042-0 Sarstedt, Inc.  
1025 Saint James Church Rd.  
Newton, NC 20865  
Trade Name: Transwaag KL  
Cleared Date: 12-DEC-2001

BK010045-0 Sarstedt, Inc.  
1025 Saint James Church Rd.  
Newton, NC 20865  
Trade Name: Sahara Blood & Plasma Warming  
Device  
Cleared Date: 21-DEC-2001

BK030006-0 Sarstedt, Inc.  
1025 Saint James Church Rd.  
Newton, NC 20865  
Trade Name: Transwaag Disk 01  
Cleared Date: 27-FEB-2003

BK040080-0 Sarstedt, Inc.  
1025 Saint James Church Rd.  
Newton, NC 20865  
Trade Name: Sahara-TSC  
Cleared Date: 09-FEB-2005

BK070029-0 Sarstedt, Inc.

1025 Saint James Church Rd.  
Newton, NC 20865  
Trade Name: S-Monovette ACD-A  
Cleared Date: 21-SEP-2007

BK870028-0 Saturn BioTech Corporation  
P.O. Box 3823  
Littleton, CO 80161  
Trade Name: RMED Finger Heme Trap  
Cleared Date: 01-FEB-1988

BK940029-0 Scimed Life Systems, Inc.  
6655 Wedgewood Rd.  
Maple Grove, MN 55311  
Trade Name: SCIMED UltraFuse Coron.  
Infusion/Guidewire Exchange  
Catheter  
Cleared Date: 15-MAR-1995

BK870011-0 Seabrook Medical Systems, Inc.  
673 Wilmer Aveune  
Cincinnati, OH 45226  
Trade Name: ECMO-TEMP  
Cleared Date: 14-SEP-1987

BK820005-0 Separation Science Corporation  
169 Avon Street, P.O. Box 643  
Stratford, CT 06497  
Trade Name: SEPCOR Cell Line Monitor  
Cleared Date: 06-JUL-1982

BK880005-0 Separation Science Corporation  
169 Avon Street, P.O. Box 643  
Stratford, CT 06497  
Trade Name: Blood Bank Saline, Preserved  
Cleared Date: 09-JUN-1988

BK050056-0 Separation Technology, Inc.  
1096 Rainier Drive  
Altamonte Springs, FL 32714-3855  
Trade Name: UltraChek Reference Controls -  
Product Code GLK  
UltraCrit™ Hematocrit Measurement  
Device - Product Code GKF  
Cleared Date: 12-DEC-2005

BK960036-0 Shared Medical Systems  
51 Valley Stream Parkway  
Malvern, PA 19355  
Trade Name: SMS BB Transfusion System

Cleared Date: 12-DEC-1997

BK220688-0 Shippert Medical Technologies Corp.  
6248 South Troy Circle  
Centennial, CO 80111  
Trade Name: TISSU TRANS FILTRON MODELS  
3-TT-FILTRON 2000-500 (K092482)  
Cleared Date: 04-DEC-2009

BK220692-0 Shippert Medical Technologies Corp.  
6248 South Troy Circle  
Centennial, CO 80111  
Trade Name: TISSU TRANS FILTRON SYRINGE FILL  
(K102117)  
Cleared Date: 06-AUG-2010

BK990018-0 Shotwell & Carr, Inc.  
3535 Firewheel Drive  
Suite A  
Flower Mound, TX 75028-2628  
Trade Name: Hot Shot Fluid Warmer Model 100  
Hot Shot Fluid Warmer Model 101  
Hot Shot Fluid Warmer Model 102  
Hot Shot Fluid Warmer Model 103  
Cleared Date: 13-OCT-1999

BK090077-0 Siemens Healthcare Diagnostics, Inc.  
P.O. Box 2466  
Berkeley, CA 94702  
Trade Name: TRUGENE HIV-1 Genotyping Kit and  
OpenGene DNA Sequencing System  
Cleared Date: 28-DEC-2009  
Cleared Under Siemens Healthcare Diagnostics Inc.

BK110007-0 Siemens Healthcare Diagnostics, Inc.  
P.O. Box 2466  
Berkeley, CA 94702  
Trade Name: TRUGENE HIV-1 Genotyping Kit and  
OpenGene DNA Sequencing System  
Cleared Date: 04-MAR-2011  
Cleared Under Siemens Healthcare Diagnostics Inc.

BK120013-0 Siemens Healthcare Diagnostics, Inc.  
P.O. Box 2466  
Berkeley, CA 94702  
Trade Name: TRUGENE HIV-1 Genotyping Kit and  
OpenGene DNA Sequencing System  
Cleared Date: 27-MAR-2012  
Cleared Under Siemens Healthcare Diagnostics Inc.

BK140152-0 Siemens Healthcare Diagnostics, Inc.  
511 Benedict Ave  
Tarrytown, NY 10591  
Trade Name: ADVIA Centaur System (Software  
Version 4.0 with SP4  
Cleared Date: 08-JUN-2015

BK140153-0 Siemens Healthcare Diagnostics, Inc.  
511 Benedict Ave  
Tarrytown, NY 10591  
Trade Name: ADVIA Centaur XP System (SW v 7.1)  
Cleared Date: 08-JUN-2015

BK241075-0 Siemens Healthcare Diagnostics, Inc.  
511 Benedict Ave  
Tarrytown, NY 10591  
Trade Name: Atellica IM HIV Ag/Ab Combo (CHIV)  
(10995459)  
Cleared Date: 07-NOV-2024

BK960051-0 Siemens Medical Solutions Diagnostics  
800 Dwight Way  
Berkeley, CA 94701-1986  
Trade Name: PPIS - Version 2.0  
Cleared Date: 07-AUG-1998  
Cleared Under Bayer Corporation

BK990024-0 Siemens Medical Solutions Diagnostics  
800 Dwight Way  
Berkeley, CA 94701-1986  
Trade Name: Plasma Procurement Information  
System (PPIS) - 3.0  
Cleared Date: 03-NOV-1999  
Cleared Under Bayer Corporation

BK990037-0 Siemens Medical Solutions Diagnostics  
800 Dwight Way  
Berkeley, CA 94701-1986  
Trade Name: Plasma Procurement Information  
System (PPIS) - Version 4.0  
Cleared Date: 17-NOV-1999  
Cleared Under Bayer Corporation

BK060015-0 Siemens Medical Solutions Diagnostics  
P.O. Box 2466  
Berkeley, CA 94702-0466  
Trade Name: TRUGENE HIV-1 Genotyping Kit and  
OpenGene DNA Sequencing System  
Cleared Date: 21-MAR-2006  
Cleared Under Bayer HealthCare Diagnostics Division

BK070009-0 Siemens Medical Solutions Diagnostics  
P.O. Box 2466  
Berkeley, CA 94702-0466  
Trade Name: TRUGENE HIV-1 Genotyping Kit and  
OpenGene DNA Sequencing System  
Cleared Date: 19-MAR-2007

BK080036-0 Siemens Medical Solutions Diagnostics  
P.O. Box 2466  
Berkeley, CA 94702-0466  
Trade Name: TRUGENE HIV-1 Genotyping Kit and  
OpenGene DNA Sequencing System  
Cleared Date: 20-OCT-2008

BK080073-0 Siemens Medical Solutions Diagnostics  
P.O. Box 2466  
Berkeley, CA 94702-0466  
Trade Name: TRUGENE HIV-1 Genotyping Kit and  
OpenGene DNA Sequencing System  
Cleared Date: 15-JAN-2009

BK060004-0 Smith & Nephew  
1450 Brooks Road  
Memphis, TN 38116  
Trade Name: Promote Platelet Rich Concentrate  
(PRC) Preparation System  
Cleared Date: 02-MAY-2006

BK850011-0 Smithkline Beckman Corp.  
999 West Valley Road  
Wayne, PA 19087  
Trade Name: Accugenics (Tray)  
Cleared Date: 07-AUG-1985

BK850012-0 Smithkline Beckman Corp.  
999 West Valley Road  
Wayne, PA 19087  
Trade Name: Accugenics (HLA Control Cells)  
Cleared Date: 07-AUG-1985

BK080047-0 SofTov Ltd  
32 HaShacham Street  
Petach Tikva, ISRAEL 49170  
Trade Name: AutoFusion - v3.02  
Cleared Date: 05-JUN-2009

BK960033-0 Soft Computer Consultants Inc.  
34350 U.S. HWY 19 N.  
Palm Harbor, FL 34684

Trade Name: SoftBank II Version 19.1  
Cleared Date: 10-JUL-1998

BK000040-0 Soft Computer Consultants Inc.  
34350 U.S. HWY 19 N.  
Palm Harbor, FL 34684  
Trade Name: SoftBank II - 21.2  
Cleared Date: 20-APR-2001

BK020006-0 Soft Computer Consultants Inc.  
34350 U.S. HWY 19 N.  
Palm Harbor, FL 34684  
Trade Name: SoftDonor - 4.1  
Cleared Date: 27-FEB-2003

BK020021-0 Soft Computer Consultants Inc.  
34350 U.S. HWY 19 N.  
Palm Harbor, FL 34684  
Trade Name: SoftBank II - 22  
Cleared Date: 11-SEP-2002

BK030018-0 Soft Computer Consultants Inc.  
34350 U.S. HWY 19 N.  
Palm Harbor, FL 34684  
Trade Name: SoftBank II - 23  
Cleared Date: 17-APR-2003

BK040028-0 Soft Computer Consultants Inc.  
34350 U.S. HWY 19 N.  
Palm Harbor, FL 34684  
Trade Name: SoftBank II with SoftScape - 23  
Cleared Date: 07-MAY-2004

BK040048-0 Soft Computer Consultants Inc.  
34350 U.S. HWY 19 N.  
Palm Harbor, FL 34684  
Trade Name: SoftBank II with Database  
Management System Interface (DMSI)  
- v23.1  
Cleared Date: 23-AUG-2004

BK970032-0 Sorvall, Inc.  
31 Pecks Lane  
Newtown, CT 06470  
Trade Name: RC12BP  
Cleared Date: 05-DEC-1997

BK220694-0 Sound Surgical Technologies Inc.  
357 McCaslin Boulevard  
Louisville, CO 80027

Trade Name: ORIGINS LIPOHARVESTING SYSTEM  
(K120328)

Cleared Date: 17-SEP-2012

BK220767-0 StemC Biotechnology Inc  
Merkez Mah. Baglar Cad. No:14, B IC Kap  
, Kagthane/ Istanbul TURKEY 34330

Trade Name: Centrifuge Container 15 cc  
Centrifuge Container 20cc  
Lipocube Hybrid I  
Lipocube Hybrid II  
Lipocube Nano

Cleared Date: 21-DEC-2022

BK251196-0 StemC Biyoteknoloji Anonim Sirketi  
StemC Biyoteknoloji Anonim Sirketi  
B:2 Blok I Kapi No:27 Kagithane  
Istanbul, Istanbul TURKEY 34406

Trade Name: Exocube Set  
Cleared Date: 28-AUG-2025

BK030064-0 Stemco Biomedical, Incorporated  
2810 Meridian Parkway  
Suite 148  
Durham, NC 27713  
Trade Name: Aldecourt Progenitor Cell  
Enumeration Kit

Cleared Date: 31-DEC-2003

BK040075-0 Stemco Biomedical, Incorporated  
2810 Meridian Parkway  
Suite 148  
Durham, NC 27713

Trade Name: Aldecourt Progenitor Cell  
Enumeration Kit

Cleared Date: 06-JAN-2005

BK220718-0 Stemics S.A.S  
2 Rue Professeur Paul Milleret  
, Besancon FRANCE 25000

Trade Name: KTA Adipose Treatment Kit  
(K190386)

Cleared Date: 10-OCT-2019

BK860030-0 Stephens Scientific  
7 Astro Place Box 1116  
Denville, NJ 07834

Trade Name: Stephens Scientific Certified  
Blood Bank Saline

Cleared Date: 16-DEC-1986

BK870015-0 Stephens Scientific  
7 Astro Place Box 1116  
Denville, NJ 07834  
Trade Name: Certified Blood Bank Saline,  
Preserved  
Cleared Date: 02-NOV-1987

BK870016-0 Stephens Scientific  
7 Astro Place Box 1116  
Denville, NJ 07834  
Trade Name: Certified Saline, Preserved  
Cleared Date: 02-NOV-1987

BK880013-0 Stericon Inc.  
2315 Gardner Road.  
Broadview, IL 60153  
Trade Name: RCM-10 Pediatric Sized Freezing  
Bag  
Cleared Date: 09-NOV-1988

BK920022-0 Stericon Inc.  
2315 Gardner Road.  
Broadview, IL 60153  
Trade Name: MB-30 Empty Plastic Containers  
Cleared Date: 03-JUN-1993

BK200477-0 Suneva Medical, Inc.  
5870 Pacific Center Blvd  
San Diego, CA 92121  
Trade Name: Amplifine Gel Separator Tubes  
Suneva HD PRP Platelet Preparation  
System  
Cleared Date: 30-SEP-2020

BK990002-0 Sunquest Information Systems, Inc.  
4801 Broadway Boulevard  
Tucson, AZ 85711  
Trade Name: Flexilab - 5.2  
Cleared Date: 16-AUG-1999

BK990034-0 Sunquest Information Systems, Inc.  
4801 Broadway Boulevard  
Tucson, AZ 85711  
Trade Name: FlexiLab Blood Bank and Blood  
Donor System - Version 5.2  
Cleared Date: 17-NOV-1999

BK080021-0 Sunquest Information Systems, Inc.  
250 S. Williams Blvd.

Tucson, AZ 85711  
Trade Name: Sunquest Transfusion Manager -  
v1.0  
Cleared Date: 14-SEP-2017

BK080042-0 Sunquest Information Systems, Inc.  
250 S. Williams Blvd.  
Tucson, AZ 85711  
Trade Name: Sunquest Blood Bank Donor - 6.4  
Cleared Date: 03-MAR-2009

BK140124-0 Sunquest Information Systems, Inc.  
250 S. Williams Blvd.  
Tucson, AZ 85711  
Trade Name: Sunquest Transfusion Manager  
version 2.0  
Cleared Date: 18-JUN-2014

BK160005-0 Sunquest Information Systems, Inc.  
250 S. Williams Blvd.  
Tucson, AZ 85711  
Trade Name: Sunquest Blood Bank and Blood  
Donor - Version 8.0  
Cleared Date: 25-MAR-2016

BK210556-0 Sunquest Information Systems, Inc.  
3330 East Sunrise Dr  
Tucson, AZ 85718  
Trade Name: Sunquest Transfusion Manager - 3.0  
Sunquest Transfusion Manager  
Version 3.0  
Cleared Date: 16-APR-2021

BK120061-0 SynGen, Inc  
2125 19th Street, Suite 120  
Sacramento, CA 95818  
Trade Name: SynGenX-1000  
Cleared Date: 12-JUL-2013

BK251268-0 Synova Life Sciences, Inc.  
1927 Paseo Rancho Castilla  
Los Angeles, CA 90032  
Trade Name: Synova WAVE Adipose Processing  
System  
Cleared Date: 17-NOV-2025

BK220723-0 Syntr Health Technologies, Inc.  
5270 California Ave  
Irvine, CA 92617  
Trade Name: Syntrfuge System (K203800)

Cleared Date: 02-JUL-2021

BK120067-0 SysLogic, Inc.  
375 Bishops Way, Suite 105  
Brookfield, WI 53005  
Trade Name: iTrace for Blood Centers -  
1.0.924.0  
Cleared Date: 14-SEP-2017

BK960034-0 SysTec Computer Associates, Inc.  
738 Smithtown Bypass  
Smithtown, NY 11787  
Trade Name: Lifetec Comm. Blood Center  
System-Rev 2.10  
Cleared Date: 28-JUL-1998

BK990003-0 SysTec Computer Associates, Inc.  
28 North Country Road  
Mt. Sinai, NY 11766  
Trade Name: LifeTec - 2.20  
Cleared Date: 30-JUL-1999

BK040026-0 SysTec Computer Associates, Inc.  
28 North Country Road  
Mt. Sinai, NY 11766  
Trade Name: LifeTec Donor Verification and  
Collection System (DOVAC) - 1.00  
Cleared Date: 21-OCT-2004

BK060032-0 SysTec Computer Associates, Inc.  
28 North Country Road  
Mt. Sinai, NY 11766  
Trade Name: LifeTec Elite - 1.0  
Cleared Date: 15-AUG-2006

BK210559-0 Sysmex America, Inc.  
577 Aptakistic Rd  
Lincolnshire, IL 60069  
Trade Name: Sysmex XN-10 Automated Hematology  
Analyzer  
Cleared Date: 27-MAY-2021

BK210631-0 Sysmex America, Inc.  
577 Aptakistic Rd  
Lincolnshire, IL 60069  
Trade Name: Sysmex XN-10 Automated Hematology  
Analyzer  
Cleared Date: 23-MAY-2022

BK120076-0 TERUMO BCT

10811 W. Collins Ave  
Lakewood, CO 80215-4440  
Trade Name: Spectra Optia Apheresis System  
Cleared Date: 25-FEB-2013

BK130031-0 TERUMO BCT  
10811 W. Collins Ave  
Lakewood, CO 80215-4440  
Trade Name: Spectra Optia Apheresis System  
Cleared Date: 25-JUL-2013

BK130065-0 TERUMO BCT  
10811 W. Collins Ave  
Lakewood, CO 80215-4440  
Trade Name: Spectra Optia Apheresis System  
Cleared Date: 16-JAN-2014

BK130080-0 TERUMO BCT  
10811 W. Collins Ave  
Lakewood, CO 80215-4440  
Trade Name: Trima Accel System, Version 6.2  
Cleared Date: 19-MAR-2014

BK140151-0 TERUMO BCT  
10811 W. Collins Ave  
Lakewood, CO 80215-4440  
Trade Name: Spectra Optia Apheresis System  
Cleared Date: 13-AUG-2014

BK150251-0 TERUMO BCT  
10811 W. Collins Ave  
Lakewood, CO 80215-4440  
Trade Name: Spectra Optia Apheresis System  
Cleared Date: 16-JUL-2015

BK160116-0 TERUMO BCT  
10811 W. Collins Ave  
Lakewood, CO 80215-4440  
Trade Name: Trima Accel Automated Blood  
Collection System  
Cleared Date: 23-DEC-2016

BK230838-0 TERUMO BCT  
10810 W. Collins Ave  
Lakewood, CO 80215  
Trade Name: IMUGARD WB PLT Platelet Pooling  
Set  
Reveos Equipment  
Reveos SELECT Disposable Set  
Reveos Automated Whole Blood

Processing System  
Cleared Date: 27-JUL-2023

BK231035-0 TERUMO BCT  
10810 W. Collins Ave  
Lakewood, CO 80215  
Trade Name: Rika Plasma Donation System - 2.1  
Cleared Date: 07-MAR-2024

BK120012-0 TERUMO Corporation  
10811 W. Collins Avenue  
Lakewood, CO 80215  
Trade Name: Spectra Optia Apheresis System  
Cleared Date: 09-JUL-2012

BK120017-0 TERUMO Corporation  
10811 W. Collins Avenue  
Lakewood, CO 80215  
Trade Name: Trima Accel Automated Blood  
Component Collection System  
Cleared Date: 31-MAY-2012

BK120040-0 TERUMO Corporation  
10811 W. Collins Avenue  
Lakewood, CO 80215  
Trade Name: Trima Accel System  
Cleared Date: 03-OCT-2012

BK120049-0 TERUMO Corporation  
10811 W. Collins Avenue  
Lakewood, CO 80215  
Trade Name: Trima Accel System  
Cleared Date: 17-DEC-2012

BK220695-0 THE GID GROUP INC.  
901 Front Street  
Louisville, CO 80027  
Trade Name: GID 700 (K120902)  
Cleared Date: 15-AUG-2012

BK220702-0 THIEBAUD SAS  
2 impasse des primbois  
Margencel, Haute-Savoie FRANCE 74200  
Trade Name: ST'RIM (K142073)  
Cleared Date: 29-APR-2015

BK220750-0 THIEBAUD SAS  
2 impasse des primbois  
Margencel, Haute-Savoie FRANCE 74200  
Trade Name: macro st rim

macro st rim  
mini st rim  
mini st rim  
nano st rim  
nano st rim  
st rim

Cleared Date: 26-AUG-2022

BK970012-0 Tahoe Chemical R & D  
2230 Damon Road  
Carson City, NV 89701  
Trade Name: Nover Trip Scale Alarm  
Cleared Date: 14-JUL-1997

BK040062-0 Talisman Ltd.  
421 Church Street NE. Suite F  
Vienna, VA 22180  
Trade Name: Quality Donor System 2004 - 2.0  
Cleared Date: 18-OCT-2004

BK060031-0 Talisman Ltd.  
421 Church Street NE. Suite F  
Vienna, VA 22180  
Trade Name: Talisman Phlebotomy System Release  
1.0  
Cleared Date: 27-JUL-2006

BK070020-0 Talisman Ltd.  
421 Church Street NE. Suite F  
Vienna, VA 22180  
Trade Name: Quality Donor System - v2.1  
Cleared Date: 16-JUL-2007

BK980021-0 Talon Medical, Ltd.  
18160 Highway 281 N  
Suite 108  
San Antonio, TX 78232  
Trade Name: Cord-X System  
Cleared Date: 20-JAN-1999

BK251207-0 Techno-Path Manufacturing Ltd.  
Fort Henry Business Park  
Ballina  
Co. Tipperary, Munster IRELAND V94 FF1P  
Trade Name: Multichem ID-HIV p24  
(09915494190)  
Multichem ID-HIV p24 (SR1111U)  
Multichem ID-HIV p24 Mini Kit  
(SR1111MU)  
Cleared Date: 02-JAN-2026

BK050003-0 Tepnel Lifecodes Corporation  
550 West Avenue  
Stamford, CT 06902  
Trade Name: LIFECODES HLA-A Typing Kit for use  
with Luminex 100, LIFECODES HLA-B  
Typing Kit for use with Luminex  
100, HLA-C Typing Kit for use with  
Luminex 100  
LIFECODES HLA-DQB Typing Kit for  
use with Luminex 100 and  
LIFECODES HLA-DRB Typing Kit for  
use with Luminex 100  
Cleared Date: 18-JUL-2005

BK080050-0 Tepnel Lifecodes Corporation  
550 West Avenue  
Stamford, CT 06902  
Trade Name: LIFECODES HLA Typing Kits (HLA-A,  
B, C, DQB, DRB, DRB1) for use with  
Luminex  
Cleared Date: 13-NOV-2008

BK090018-0 Tepnel Lifecodes Corporation  
550 West Avenue  
Stamford, CT 06902  
Trade Name: LIFECODES Evolution Software,  
version 1.0  
Cleared Date: 04-JUN-2009

BK010006-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Trima Automated Blood Component  
Collection System  
Cleared Date: 27-FEB-2002  
Cleared Under Gambro BCT, Inc

BK010037-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Platelet collection sets for the  
COBE Spectra Apheresis System and  
the Trima Automated Blood  
Component Collection System.  
Cleared Date: 24-SEP-2003  
Cleared Under Gambro BCT, Inc

BK010046-0 Terumo BCT, Inc  
10811 W. Collins Ave.

Lakewood, CO 80215-4498  
Trade Name: Trima Automated Blood Collection  
System (Single Stage)  
Cleared Date: 18-SEP-2002  
Cleared Under Gambro BCT, Inc

BK010050-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Trima Automated Blood Collection  
System  
Cleared Date: 18-SEP-2002  
Cleared Under Gambro BCT, Inc

BK020015-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Vista Information System,  
Independent Solution  
Cleared Date: 15-JUL-2002  
Cleared Under Gambro BCT, Inc

BK020041-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: COBE Spectra Apheresis  
System/Blood component disposable  
collection sets for apheresis  
Cleared Date: 23-APR-2003  
Cleared Under Gambro BCT, Inc

BK030021-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Vista Information System - 2.1  
Cleared Date: 01-MAY-2003  
Cleared Under Gambro BCT, Inc

BK030083-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Trima Accel  
Cleared Date: 14-JAN-2004  
Cleared Under Gambro BCT, Inc

BK040069-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Trima Automated Blood Component  
Collection System - Blood

Component Sampling Accessory

Cleared Date: 28-OCT-2004

Cleared Under Gambro BCT, Inc

- BK040086-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: COBE Spectra Apheresis System &  
Trima Automated Blood Component  
Collection System  
Cleared Date: 15-MAR-2005  
Cleared Under Gambro BCT, Inc
- BK070001-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Vista Information System - 3.0  
Cleared Date: 27-JUN-2007  
Cleared Under Gambro BCT, Inc
- BK070066-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Vista Information System, Version  
3.0 with Medical Review Module  
Cleared Date: 13-DEC-2007  
Cleared Under Gambro BCT, Inc
- BK080010-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: The Atreus Whole Blood Processing  
System  
Cleared Date: 27-JUN-2008  
Cleared Under Gambro BCT, Inc
- BK080029-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Trima Accel Automated Blood  
Component Collection System  
Cleared Date: 18-MAY-2010  
Cleared Under Gambro BCT, Inc
- BK140104-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Vista Information System Version  
3.2  
Cleared Date: 01-APR-2014

BK140158-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Trima Accel System  
Version 6.4  
Cleared Date: 29-AUG-2014

BK140180-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Model 81000  
Trima Accel System Mobile Pro  
Package  
Cleared Date: 05-NOV-2014

BK140191-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Spectra Optia Apheresis System  
Cleared Date: 09-MAR-2015

BK150228-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Vista Information System - 4.0  
Cleared Date: 22-SEP-2015

BK150269-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Trima Accel system  
Cleared Date: 06-AUG-2015

BK150321-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Trima Accel System  
Cleared Date: 16-OCT-2015

BK160082-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: T-Cuff  
Cleared Date: 19-AUG-2016

BK160108-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: TSCD-II Sterile Tubing Welder with

or without Trucise Total System  
(TM), Model ME-SC203A  
Cleared Date: 23-NOV-2016

BK170059-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Trima Accel (R) Blood Collection  
System  
Cleared Date: 07-JUL-2017

BK170098-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: TSCD-II Sterile Tubing Welder with  
or without Trucise Total System  
(TM)  
Cleared Date: 29-SEP-2017

BK170157-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215  
Trade Name: Trima Accel(R) Blood Collection  
System  
Cleared Date: 06-APR-2018

BK180231-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215  
Trade Name: Trima Accel(R) Blood Collection  
System  
Trima Accel Automated Blood  
Collection System  
Cleared Date: 17-AUG-2018

BK180258-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215  
Trade Name: Vista Information System  
Cleared Date: 18-JAN-2019

BK190332-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215  
Trade Name: Trima Accel Blood Collection  
System  
Cleared Date: 22-MAY-2019

BK190333-0 Terumo BCT, Inc  
10811 W. Collins Ave.

Lakewood, CO 80215  
Trade Name: TOMEs - 7  
Cleared Date: 03-DEC-2019

BK210591-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215  
Trade Name: Harvest PRP Separation System  
Harvest PRP Separation System with  
ACDA (30 mL)  
Harvest PRP Separation System with  
LP-10  
SmartPrep2 System  
Cleared Date: 11-FEB-2022

BK210635-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215  
Trade Name: Rika Plasma Bottle  
Rika Plasma Donation System  
Rika Plasma Separation Set  
Cleared Date: 07-MAR-2022

BK210658-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215  
Trade Name: IMUGARD WB PLT Platelet Pooling  
Set  
Cleared Date: 26-AUG-2022

BK230843-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215  
Trade Name: IMUGARD WB PLT Platelet Pooling  
Set  
Reveos Automated Whole Blood  
Processing System  
Cleared Date: 27-JUL-2023

BK241097-0 Terumo BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Trade Name: Rika Plasma Donation System  
(42000)  
Cleared Date: 05-NOV-2024

BK820015-0 Terumo Corporation  
2805 East Ana Street  
Compton, CA 90221  
Trade Name: Plasmaflex Pooling Bottle

Cleared Date: 12-NOV-1982

BK850017-0 Terumo Corporation  
2805 East Ana Street  
Compton, CA 90221  
Trade Name: Plasmaflex Bottles  
Cleared Date: 04-NOV-1985

BK860012-0 Terumo Corporation  
2805 East Ana Street  
Compton, CA 90221  
Trade Name: Imugard Leukocyte Filter  
Cleared Date: 16-MAY-1990

BK890005-0 Terumo Corporation  
2805 East Ana Street  
Compton, CA 90221  
Trade Name: Stericell Cell Processor  
Cleared Date: 10-OCT-1989

BK890017-0 Terumo Corporation  
2805 East Ana Street  
Compton, CA 90221  
Trade Name: Teruflex Transfer Bag  
Cleared Date: 18-JUL-1990

BK890032-0 Terumo Corporation  
125 Blue Ball Road  
Elkton, MD 21921  
Trade Name: Immugard-E- Leukocyte Removal From  
Red Blood Cells  
Cleared Date: 18-JUL-1990

BK900028-0 Terumo Corporation  
2805 East Ana Street  
Compton, CA 90221  
Trade Name: Terufusion Plasma Transfer Set  
Cleared Date: 22-OCT-1990

BK920040-0 Terumo Corporation  
2805 East Ana Street  
Compton, CA 90221  
Trade Name: Venoject II Holder  
Cleared Date: 20-MAY-1993

BK950039-0 Terumo Corporation  
2100 Cottontail Lane  
Somerset, NJ 08873  
Trade Name: Teruflex B-600 Terumo Blood Bag  
without anticoagulant

Cleared Date: 25-AUG-1995

BK950058-0 Terumo Corporation  
2100 Cottontail Lane  
Somerset, NJ 08873  
Trade Name: Terumo Sampling Site Coupler  
Cleared Date: 13-NOV-1995

BK860041-0 Terumo Medical Corporation  
125 Blue Ball Road  
Elkton, MD 21921  
Trade Name: SCD 312  
Cleared Date: 01-JUN-1987

BK970008-0 Terumo Medical Corporation  
125 Blue Ball Road  
Elkton, MD 21921  
Trade Name: Terumo Sterile Tubing Welder  
SC-201A (TSCD)  
Cleared Date: 28-MAY-1998

BK970011-0 Terumo Medical Corporation  
125 Blue Ball Road  
Elkton, MD 21921  
Trade Name: Terumo Phlebotomy Needle Cap  
Holder  
Cleared Date: 19-JUN-1997

BK000045-0 Terumo Medical Corporation  
125 Blue Ball Road  
Elkton, MD 21921  
Trade Name: Imugard III-PL  
Cleared Date: 28-SEP-2001

BK020033-0 Terumo Medical Corporation  
125 Blue Ball Road  
Elkton, MD 21921  
Trade Name: Imugard III-PL Leukocyte reduction  
filter  
Cleared Date: 22-MAY-2003

BK040082-0 Terumo Medical Corporation  
125 Blue Ball Road  
Elkton, MD 21921  
Trade Name: TSCD-II Terumo Sterile Tubing  
Welder  
Cleared Date: 05-APR-2005

BK070018-0 Terumo Medical Corporation  
125 Blue Ball Road

Elkton, MD 21921  
Trade Name: TRUCISE Total System  
Cleared Date: 22-JAN-2008

BK110071-0 Terumo Medical Corporation  
950 Elkton Blvd  
Elkton, MD 21921  
Trade Name: TSCD (R) II Sterile Tubing Welder  
& Trucise Total System (R)  
Cleared Date: 12-SEP-2012

BK980002-0 Teva Medical LTD  
482 Hudson Terrace  
Englewood Cliffs, NJ 07632  
Trade Name: SegMed  
Cleared Date: 02-MAR-1998

BK060060-0 Texas BioGene, Inc.  
635 Presidential Drive  
Richardson, TX 75081  
Trade Name: Morgan HLA SSP ABDR Typing Kit  
Cleared Date: 22-MAR-2007

BK080039-0 Texas BioGene, Inc.  
635 Presidential Drive  
Richardson, TX 75081  
Trade Name: Morgan HLA SSP ABCDRDQ Typing Kit  
Cleared Date: 22-APR-2009

BK050058-0 The Surgical Company International  
Terminalweg 19a  
Amersfoort, NETHERLANDS 3821 AJ  
Trade Name: Fluido Blood and Fluid Warmer  
System  
Cleared Date: 05-MAY-2006

BK070055-0 The Surgical Company International  
Terminalweg 19a  
Amersfoort, NETHERLANDS 3821 AJ  
Trade Name: Fluido Air Guard  
Fluido Compressor  
Fluido IV-Pole  
Fluido Pressure Chamber  
Cleared Date: 15-JAN-2008

BK950067-0 Thermal Transfer Technology  
681 Main Street  
Placerville, CA 95667  
Trade Name: Thermal Ware  
Cleared Date: 14-FEB-1996

BK160044-0 Thermo Electron LED GmbH (a subsidiary of Thermo Fisher Scientific Inc.)

Am Kalkberg  
Osterode am Harz,  
Trade Name: Thermo Scientific CW3 Cell Washer  
Cleared Date: 07-OCT-2016

BK180198-0 ThermoGenesis Corp

2700 Citrus Rd  
Rancho Cordova, CA 95741  
Trade Name: AXP II AutoXpress Platform  
Cleared Date: 14-NOV-2018

BK960072-0 Thermogenesis

3146 Gold Camp Drive  
Suite 206  
Rancho Cordova, CA 95670-6022  
Trade Name: CryoSeal System  
Cleared Date: 12-FEB-1999

BK960074-0 Thermogenesis

3146 Gold Camp Drive  
Suite 206  
Rancho Cordova, CA 95670-6022  
Trade Name: HemoMatic Blood Collection Monitor  
Cleared Date: 03-APR-1997

BK030011-0 Thermogenesis

3146 Gold Camp Drive  
Suite 206  
Rancho Cordova, CA 95670-6022  
Trade Name: ThermoGenesis Thawer  
Cleared Date: 10-JUN-2003

BK070006-0 Thermogenesis

2711 Citrus Road  
Rancho Cordova, CA 95742  
Trade Name: AXP AutoXpress Platform  
Cleared Date: 05-OCT-2007

BK100066-0 Thermogenesis

2711 Citrus Road  
Rancho Cordova, CA 95742  
Trade Name: ThermoGenesis Res-Q60 PRP Device  
Cleared Date: 27-MAY-2011

BK900017-0 Thermopol Inc.

2481 B Delta Ln,  
Elk Grove Village, IL 60007

Trade Name: Solid State Portable Refrigerator  
Cleared Date: 30-AUG-1990

BK940038-0 Thomson & Neilsen, Ltd.  
1050 Baxter Road  
Ottawa, Ontario, Canada, CANADA  
Trade Name: Blood Irradiator Dosimetry System  
TN-ID-50  
Cleared Date: 18-MAY-2026

BK190433-0 Tiger Aesthetics Medical, LLC  
9779 S. Franklin Dr.  
Suite #300  
Franklin, WI 53132  
Trade Name: AuraGen 1-2-3 with AuraClens  
Suction Lipoplasty System (A123+  
AuraClens)  
Cleared Date: 13-MAR-2020

BK261326-0 Tiger Aesthetics Medical, LLC  
9630 S. 54th St  
Franklin, WI 53132  
Trade Name: Viality Lipoaspirate Wash System  
for Aesthetic Body Contouring  
(Viality-1400)  
Cleared Date: 13-MAY-2026

BK150289-0 Timestrip UK Ltd.  
22 Friars Street  
Sudbury  
, Suffolk UNITED KINGDOM C0102AA  
Trade Name: Timestrip(R) Blood Temp 10 (BT10)  
Cleared Date: 14-DEC-2015

BK190363-0 Timestrip UK Ltd.  
22 Friars Street  
Sudbury  
, Suffolk UNITED KINGDOM C0102AA  
Trade Name: Timestrip Blood Temp 10  
Cleared Date: 22-JUL-2019

BK850007-0 Trayser, Inc.  
P.O. Box 83  
Cabin John, MD 20818  
Trade Name: Trayser DR/DQ Typing Tray Kit  
Cleared Date: 25-APR-1985

BK030066-0 Tyco Healthcare  
15 Hampshire Street  
Mansfield, MA 02048

Trade Name: Kendall LIFETRACE Umbilical Blood  
Collection Kit  
Cleared Date: 03-NOV-2003

BK070037-0 Typenex Medical LLC  
303 East Wacker Drive  
Suite 311  
Chicago, IL 60601  
Trade Name: TypeSafe Segment Dispenser  
Cleared Date: 05-OCT-2007

BK150351-0 Typenex Medical LLC  
303 East Wacker Drive  
Suite 311  
Chicago, IL 60601  
Trade Name: Typesafe 2.0 Segment Piercing  
Device (Model Number SP0201QD &  
SP0201QM)  
Cleared Date: 28-DEC-2015

BK820012-0 UCLA Tissue Typing Laboratory  
1000 Veteran Avenue  
Los Angeles, CA 90024  
Trade Name: HLA Typing Tray  
Cleared Date: 04-MAR-1983

BK970026-0 Utah Medical Products, Inc.  
7043 South 300 West  
Midvale, UT 84047  
Trade Name: Umbilicup  
Cleared Date: 28-JAN-1998

BK970027-0 Utah Medical Products, Inc.  
7043 South 300 West  
Midvale, UT 84047  
Trade Name: Umbilicup II Cord Blood System  
Cleared Date: 06-JAN-1998

BK010043-0 VEEGEE Scientific  
13600 NE 126th Place  
Suite A  
Kirkland, WA 98034  
Trade Name: Atago SP-D2 Refractometer  
Cleared Date: 02-JAN-2002

BK870008-0 Val Tech Diagnostics  
14 Werner Camp Road  
Pittsburgh, PA 15238  
Trade Name: Normal Saline-Buffered  
Cleared Date: 31-JUL-1987

BK880004-0 Val Tech Diagnostics  
14 Werner Camp Road  
Pittsburgh, PA 15238  
Trade Name: Buffered Normal Saline Concentrate  
Cleared Date: 11-APR-1988

BK070044-0 Verax Biomedical Incorporated  
148 Bartlett Street  
Marlborough, MA 01752  
Trade Name: Platelet PGD Controls  
Platelet PGD Test  
Cleared Date: 17-SEP-2007

BK090028-0 Verax Biomedical Incorporated  
148 Bartlett Street  
Marlborough, MA 01752  
Trade Name: Platelet PGD Test System  
Cleared Date: 10-NOV-2009

BK110014-0 Verax Biomedical Incorporated  
148 Bartlett Street  
Marlborough, MA 01752  
Trade Name: Platelet PGD Test System  
Cleared Date: 08-SEP-2011

BK140201-0 Verax Biomedical Incorporated  
148 Bartlett Street  
Marlborough, MA 01752  
Trade Name: Platelet PGD(R) Test System  
Cleared Date: 13-MAY-2015

BK160087-0 Verax Biomedical Incorporated  
148 Bartlett Street  
Marlborough, MA 01752  
Trade Name: Platelet PGD Test System  
Cleared Date: 06-APR-2017

BK120008-0 Vertical Spine, LLC  
2201 Marconi Road  
Wall, NJ 07719  
Trade Name: FIBRINET (R) Autologous PRP System  
Cleared Date: 01-AUG-2012  
Cleared Under Cascade Medical Enterprises, LLC

BK020005-0 Visible Genetics, Inc.  
700 BAY Street, Suite 1000  
Toronto, Ontario M5G 1Z6 CANADA  
Trade Name: Trugene HIV-1 Genotyping Kit and  
Open Gene DNA Sequencing System

Cleared Date: 24-APR-2002

BK020042-0 Visible Genetics, Inc.  
700 BAY Street, Suite 1000  
Toronto, Ontario M5G 1Z6 CANADA  
Trade Name: TRUGENE HIV-1 Genotyping Kit and  
OpenGene DNA Sequencing System  
Cleared Date: 07-NOV-2002

BK030015-0 Visible Genetics, Inc.  
700 BAY Street, Suite 1000  
Toronto, Ontario M5G 1Z6 CANADA  
Trade Name: TRUGENE HIV-1 Genotyping Kit and  
OpenGene DNA Sequencing System  
Cleared Date: 14-MAR-2003

BK910010-0 WHITTAKER BIOPRODUCTS, INC.  
8830 Biggs Ford Road  
Walkersville, MO 21793  
Trade Name: ENDOTOXIN CHALLENGE VIALS  
Cleared Date: 09-AUG-1991

BK860039-0 Wako Chemicals, USA, Inc.  
12300 Ford Road, Suite 130  
Dallas, TX 75234  
Trade Name: Toxinometer ET-201  
Cleared Date: 10-FEB-1987

BK230826-0 WellSky Corporation  
11300 Switzer Rd  
Overland Park, KS 66210  
Trade Name: WellSky Transfusion 2022 R3  
Cleared Date: 19-JUL-2023

BK910005-0 Whitman Medical Corporation  
990 Raritan Road  
Clark, NJ 07066  
Trade Name: Safe-T-Vue Irreversible  
Temperature Indicator  
Cleared Date: 12-MAY-1992

BK220673-0 Wuhan BMS Medicaltech Co., Ltd  
5th Floor, Units C/D, Building 9, Area B, Me  
, Wuhan CHINA 430206  
Trade Name: Sterile Tube Welder (Model:  
STW6810-RFID)  
Cleared Date: 24-OCT-2022

BK950059-0 Wyndgate Technologies  
11121 Sun Center Drive

Suite C  
Rancho Cordova, CA 95670  
Trade Name: Safe Trace  
Cleared Date: 14-APR-1997

BK980023-0 Wyndgate Technologies  
11060 White Rock Road  
Suite 200  
Rancho Cordova, CA 95670  
Trade Name: SafeTrace TX, version 1.0  
Cleared Date: 29-JAN-1999

BK070010-0 Wyndgate Technologies  
4925 Robert J. Matthews Parkway  
Suite 100  
El Dorado Hills, CA 95762  
Trade Name: ElDorado Donor Doc - 1.0.0  
Cleared Date: 23-MAY-2007

BK070064-0 Wyndgate Technologies  
4925 Robert J. Matthews Parkway  
Suite 100  
El Dorado Hills, CA 95762  
Trade Name: ElDorado Donor - 1.0.0  
Cleared Date: 13-FEB-2008

BK090026-0 Wyndgate Technologies  
4925 Robert J. Matthews Parkway  
Suite 100  
El Dorado Hills, CA 95762  
Trade Name: Safe Trace Tx  
Cleared Date: 03-SEP-2009

BK090033-0 Wyndgate Technologies  
4925 Robert J. Matthews Parkway  
Suite 100  
El Dorado Hills, CA 95762  
Trade Name: ElDorodo Donor Doc  
Cleared Date: 28-OCT-2009

BK090063-0 Wyndgate Technologies  
4925 Robert J. Matthews Parkway  
Suite 100  
El Dorado Hills, CA 95762  
Trade Name: Test Result Interface for ElDorado  
Donor  
Cleared Date: 20-NOV-2009

BK100002-0 Wyndgate Technologies  
4925 Robert J. Matthews Parkway

Suite 100  
El Dorado Hills, CA 95762  
Trade Name: Component Manufacturing Interface  
for ElDorado Donor  
Cleared Date: 24-FEB-2010

BK230818-0 YTS Global Inc  
7406 Alban Station Ct  
Springfield, VA 22150-2310  
Trade Name: Dr. PRP  
Cleared Date: 31-MAY-2023

BK860005-0 bioMerieux, Inc.  
5300 S. Portland Avenue  
Oklahoma City, OK 73119  
Trade Name: Plasma Collection Bag  
Cleared Date: 19-DEC-1986  
Cleared Under BioMerieux, Inc.

BK870019-0 bioMerieux, Inc.  
5300 S. Portland Avenue  
Oklahoma City, OK 73119  
Trade Name: Quik-Chek  
Cleared Date: 19-MAY-1988  
Cleared Under BioMerieux, Inc.

BK880003-0 bioMerieux, Inc.  
5300 S. Portland Avenue  
Oklahoma City, OK 73119  
Trade Name: Therapeutic Plasmapheresis  
Collection Bag  
Cleared Date: 11-MAR-1988  
Cleared Under BioMerieux, Inc.

BK920037-0 bioMerieux, Inc.  
5300 S. Portland Avenue  
Oklahoma City, OK 73119  
Trade Name: PEG+  
Cleared Date: 21-OCT-1993  
Cleared Under BioMerieux, Inc.

BK960026-0 bioMerieux, Inc.  
100 Akzo Avenue  
Durham, NC 27712  
Trade Name: Status Symbol TM II System  
Software  
Cleared Date: 16-MAR-1999  
Cleared Under Organon Teknika Corporation

BK000042-0 bioMerieux, Inc.

100 Akzo Avenue  
Durham, NC 27712  
Trade Name: BacT/ALERT Culture Bottles  
Cleared Date: 15-FEB-2002  
Cleared Under BioMerieux, Inc.

BK020022-0 bioMerieux, Inc.  
100 Rodolphe Street  
Durham, NC 27712  
Trade Name: BacT/ALERT SN Culture Bottle  
Cleared Date: 10-OCT-2002  
Cleared Under BioMerieux, Inc.

BK020023-0 bioMerieux, Inc.  
100 Rodolphe Street  
Durham, NC 27712  
Trade Name: BacT/ALERT SA Culture Bottle  
Cleared Date: 10-OCT-2002  
Cleared Under BioMerieux, Inc.

BK020060-0 bioMerieux, Inc.  
100 Rodolphe Street  
Durham, NC 27712  
Trade Name: NuclieSens HIV-1 QT RNA External  
Controls  
Cleared Date: 18-DEC-2002  
Cleared Under BioMerieux, Inc.

BK030034-0 bioMerieux, Inc.  
100 Rodolphe Street  
Durham, NC 27712  
Trade Name: BacT/ALERT BPN Culture Bottle  
Cleared Date: 18-JUL-2003  
Cleared Under BioMerieux, Inc.

BK030035-0 bioMerieux, Inc.  
100 Rodolphe Street  
Durham, NC 27712  
Trade Name: BacT/ALERT BPA Culture Bottle  
Cleared Date: 06-AUG-2003  
Cleared Under BioMerieux, Inc.

BK030075-0 bioMerieux, Inc.  
100 Rodolphe Street  
Durham, NC 27712  
Trade Name: BacT/ALERT BPN Culture Bottles  
Cleared Date: 08-MAR-2004  
Cleared Under BioMerieux, Inc.

BK030076-0 bioMerieux, Inc.

100 Rodolphe Street  
Durham, NC 27712  
Trade Name: BacT/ALERT BPA Culture Bottles  
Cleared Date: 08-MAR-2004  
Cleared Under BioMerieux, Inc.

BK050037-0 bioMerieux, Inc.  
100 Rodolphe Street  
Durham, NC 27712  
Trade Name: BacT/ALERT BPA Culture Bottle  
Cleared Date: 27-DEC-2005  
Cleared Under BioMerieux, Inc.

BK050043-0 bioMerieux, Inc.  
100 Rodolphe Street  
Durham, NC 27712  
Trade Name: BacT/ALERT BPN Culture Bottle  
Cleared Date: 27-DEC-2005  
Cleared Under BioMerieux, Inc.

BK170142-0 bioMerieux, Inc.  
595 Anglum Road  
Hazelwood, MO 63042  
Trade Name: BacT/ALERT BPA Culture Bottle  
BacT/ALERT BPN Culture Bottle  
Cleared Date: 01-FEB-2018

BK180266-0 bioMerieux, Inc.  
595 Anglum Road  
Hazelwood, MO 63042  
Trade Name: BACT/ALERT BPA Culture Bottle  
BACT/ALERT BPN Culture Bottle  
Cleared Date: 29-NOV-2018

BK200472-0 bioMerieux, Inc.  
595 Anglum Road  
Hazelwood, MO 63042  
Trade Name: BACT/ALERT BPA Culture Bottle  
BACT/ALERT BPN Culture Bottle  
Cleared Date: 20-MAY-2020

BK040018-0 sienna partners  
P.O. Box 103  
Baldwin, MD 21013  
Trade Name: Vacuette EDTA K2 tube; Vacuette  
EDTA K3 tube  
Cleared Date: 28-JUL-2004