November 19, 2021

Immucor GTI Diagnostics Inc.
Attention: Ms. Amy Cochran
20925 Crossroads Circle, Suite 200
Waukesha, WI 53186

Re:

STN	**Trade/Device Name:**
BK210572	MATCH IT! ® Antibody
BK210573	LIFECODES® LSA™ Class I
BK210574	LIFECODES® LSA™ Class II

Regulatory Class: Unclassified
Product Code: MZI
Dated: March 31, 2021
Received: March 31, 2021

Dear Ms. Cochran:

We have reviewed your Section 510(k) premarket notifications of intent to market the devices referenced above and have determined these devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market these devices, subject to the general controls provisions of the Act. Although this letter refers to your products as devices, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the **Federal Register**.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Orieji Illoh, MD
Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Enclosures
Indications for Use

Indications for Use

510(k) Number: BK210572

Device Name: MATCH IT! ® Antibody

Indications for Use:

MATCH IT! ® Antibody software v1.4 is an optional accessory to the following LIFECODES antibody detection kits for use with Luminex:

LIFECODES® Class I ID PN 628200 IFU LC807IVD
LIFECODES® Class II ID v2 PN 628223 IFU LC807IVD
LIFECODES® Lifescreen Deluxe PN 628215 IFU LC1003IVD
LIFECODES® LSA Class I PN 265100IVD IFU LC1683IVD
LIFECODES® LSA Class II PN 265200IVD IFU LC1683IVD

Default settings for all assays are aligned with the IFU and the performance characteristics of the assay. Any other methods of assignment would need to be validated by lab personal prior to use.

IVD

Prescription Use _✓__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CBER, Office of Blood Research and Review

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Division Sign-Off
Office of Blood Research and Review

Indications for Use

510(k) Number:	**Device Name:**
BK210573	LIFECODES® LSA™ Class I
BK210574	LIFECODES® LSA™ Class I

Indications for Use:

LIFECODES® LSA™ Class I and Class II are bead-based immunoassays used to qualitatively detect HLA IgG antibodies to aid donor and recipient matching in transfusion or transplantation. Luminex Instrument and XY Platform are required to run the LIFECODES LSA Class I and Class II assays. The MATCH IT!® Antibody Software is intended as an aid in the analysis of LIFECODES LSA Class I and Class II assays.

IVD

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CBER, Office of Blood Research and Review

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