July 27, 2023

Beckman Coulter, Inc.
Attention: Beth Davis
1000 Lake Hazeltine Drive
Chaska, MN 55318

Re: BK 230833

Trade/Device Names:	Access HIV Ag/Ab combo Access HIV Ag/Ab combo Calibrators Access HIV Ag/Ab combo QC
Regulation Number:	21 CFR 866.3956
Regulation Name:	Human immunodeficiency virus (HIV) serological diagnostic and/or supplemental test
Regulatory Class:	Class II
Product Code:	MZF
Dated:	April 7, 2023
Received:	April 10, 2023

Dear Beth Davis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is 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 the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, 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 device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device 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 device complies 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 801and 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.

You must submit a log of all complaints per 21 CFR part 866.3956. The log must be submitted annually on the anniversary of clearance for 5 years following clearance of a traditional premarket notification.

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,

Hira Nakhasi, PhD
Director
Division of Emerging and Transfusion
Transmitted Diseases
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Enclosure: Indications for Use

Indications for Use

510(k) Number: BK 230833

Device Names: Access HIV Ag/Ab combo
Access HIV Ag/Ab combo Calibrators
Access HIV Ag/Ab combo QC

Indications for Use:

The Access HIV Ag/Ab combo assay is a paramagnetic particle, chemiluminescent immunoassay for the simultaneous qualitative in vitro detection and differentiation of HIV-1 p24 antigen and antibodies to HIV-1 (groups M and O) and/or HIV-2 in human pediatric (ages 2 through 21 years) and adult serum and serum separator tubes or plasma [lithium heparin, lithium heparin separator tubes, dipotassium (K_2) EDTA, tripotassium (K_3) EDTA, sodium citrate, acid-citrate-dextrose (ACD) and citrate phosphate-dextrose (CPD)] using the DxI 9000 Access Immunoassay Analyzer.

The Access HIV Ag/Ab combo assay is intended to be used as an aid in the diagnosis of HIV-1 and/or HIV-2 infection, including acute or primary HIV-1 infection. The assay may also be used as an aid in the diagnosis of HIV-1 and/or HIV-2 infection in pregnant women.

The Access HIV Ag/Ab combo assay is for use on the DxI 9000 Access Immunoassay Analyzer only.

This assay is not intended for use for screening donors of blood or blood products or human cells, tissues, or cellular or tissue-based products (HCT/Ps).

The Access HIV Ag/Ab combo Calibrators are intended to calibrate the Access HIV Ag/Ab combo assay for the simultaneous qualitative detection and differentiation of HIV-1 p24 antigen and antibodies to HIV-1 (groups M and O) and/or HIV-2 in human serum and plasma, using the DxI 9000 Access Immunoassay Analyzer.

The Access HIV Ag/Ab combo QC is intended for monitoring system performance of the Access HIV Ag/Ab combo assay. The Access HIV Ag/Ab combo QC is for use on the DxI 9000 Access Immunoassay Analyzer.

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

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CBER, Office of Blood Research and Review (OBRR)

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Division Sign-Off, Office of Blood Research and Review