May 7, 2020

DIAGAST
Attention: Ms. Sonia Lecce
NAMSA
400 Highway 169 South, Suite 500
Minneapolis, MN 55426

Re:	BK190313
Device Name:	PK System Control
Regulation Number:	21 CFR 864.9650
Regulation Name:	Quality Control Kits for Blood Banking Reagents
Regulatory Class:	II
Product Code:	KSF
Dated:	April 29, 2020
Received:	April 29, 2020

Dear Ms. Lecce:

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 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); 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/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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

Enclosure
Indications For Use

Indications for Use

510(k) Number: BK190313

Device Name: PK System Control

Indications for Use:

The *PK SYSTEM BLOOD GROUPING REAGENTS* and *PK SYSTEM CONTROL* are intended for the determination of ABO blood group, Rh and Kell phenotypes in blood donors using the BECKMAN COULTER PK7300 and/or the BECKMAN COULTER PK7400 Automated Microplate System(s). The Anti-A, Anti-B, and Anti-A,B reagents are used in the red blood cell determination of the ABO blood group.They are used to determine the absence or presence of erythrocytic antigens A and/or B on the surface of human red blood cells.

The Anti-D reagents: Anti-D, Anti-D (PK 1), Anti-D (PK 2), are used to determine the Rh(D) type. They are used to detect the presence of the Rh(D) antigen on the surface of human red blood cells. The Anti-C, Anti-E, Anti-c, Anti-e, and Anti-K are used for Rh Subgroups and Kell phenotyping of human red blood cells. These reagents detect the presence of antigens C, E, c, e, and K on the surface of red blood cells. The *CONTROL* is devoid of antibody activity and should be used in parallel testing with the *PK SYSTEM BLOOD GROUPING REAGENTS* to differentiate between specific and non-specific agglutination

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