June 4, 2019

Fresenius Kabi USA, LLC
Attention: Ms. Jody Stoughtenger
Three Corporate Drive
Lake Zurich, IL 60047

Re:	BK190351
Trade/Device Name:	ALYX Component Collection System
Regulation Number:	21 CFR 864.9245
Regulation Name:	Automated blood cell separator
Regulatory Class:	Class II
Product Code:	GKT
Dated:	May 6, 2019
Received:	May 8, 2019

Dear Ms. Stoughtenger:

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); 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

Enclosure
Indications for Use

Indications for Use

510(K) Number: BK190351

Device Name: ALYX Component Collection System

Indications for Use:

The ALYX Component Collection System is intended for use in blood collection establishments to collect and separate whole blood into its components.

Depending on the ALYX Component Collection system apheresis kit used in the collection of products, the ALYX Component Collection System has been cleared for:

- Concurrent collection of two units of Red Blood Cells (2RBC), Leukocytes Reduced – Single Unit Recovery (One Unit of Red Blood Cells, Non-Leukocytes Reduced) permitted
- Concurrent collection of two units of Red Blood Cells (2RBC), Non-Leukocytes Reduced – Single Unit Recovery (One Unit of Red Blood Cells, Non-Leukocytes Reduced) permitted
- Concurrent collection of One Unit of Red Blood Cells, Leukocytes Reduced, and Plasma as:
  - Fresh Frozen Plasma
    - Must be prepared and placed in a freezer at -18°C or colder within 8 hours after phlebotomy.
  - Source Plasma
  - Plasma Frozen Within 24 Hours After Phlebotomy (PF24)
    - Must be stored at 1-6°C within 8 hours after phlebotomy and placed in a freezer at -18°C or colder within 24 hours after phlebotomy.
    - Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.
  - Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy (PF24RT24)
    - Can be stored at room temperature for up to 24 hours after phlebotomy.
    - Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.
- Collection of Plasma as:
  - Fresh Frozen Plasma,
    - Must be prepared and placed in a freezer at -18°C or colder within 8 hours after phlebotomy.
  - Source Plasma
  - Plasma Frozen Within 24 Hours After Phlebotomy (PF24)
    - Must be stored at 1-6°C within 8 hours after phlebotomy and placed in a freezer at -18°C or colder within 24 hours after phlebotomy.
    - Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.
  - Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy (PF24RT24)

- Can be stored at room temperature for up to 24 hours after phlebotomy. Product must be placed in a freezer at -18°C or colder within 24 hours after phlebotomy.
- Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.

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

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Division Sign-Off, Office of Blood Research and Review