Attention: Mr. John Maibauer
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

April 7, 2017

Re:	BK160112
Device Name:	AMICUS Separator System
Regulation Number:	21 CFR 864.9245
Regulation Name:	Automated Blood Cell Separators
Regulatory Class:	II
Product Code:	GKT
Dated:	March 27, 2017
Received:	March 27, 2017

Dear Mr. Maibauer:

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 a legally marketed predicate device 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. 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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: BK160112

Device Name: AMICUS Separator System

Indications for Use:

The AMICUS Separator System is an automated blood cell separator indicated to perform Therapeutic Plasma Exchange (TPE).

The AMICUS Separator System is an automated blood cell separator indicated for the collection of blood components and mononuclear cells.

The Amicus Separator System is designed to collect products while maintaining an extracorporeal volume at or below 10.5 mL/kg and a donor post platelet count greater than or equal to 100,000 platelets/microliter.

Depending on the AMICUS Separator System apheresis kit used in the collection of products, the AMICUS Separator System has been cleared to collect:

- Platelet Pheresis, Leukocyte Reduced (single, double, or triple units)
- Platelet Pheresis, Leukocyte Reduced, Platelet Additive Solution (InterSol) (single, double or triple units)
- Red Blood Cells, Leukocytes Reduced (by apheresis)
- Mononuclear Cells
- Plasma
    - Fresh Frozen Plasma
        - Must be prepared and placed in a freezer at -18°C or colder within 8 hours after phlebotomy.
    - 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 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.
    - Source Plasma

Platelet Pheresis (single, double, or triple units) may be manufactured from products that do not meet leukocyte reduction product standards. This does not apply to Platelet Pheresis, Platelet Additive Solution (InterSol) (single, double, or triple units).

The AMICUS platelet storage container is cleared to store Platelet Pheresis, Leukocyte Reduced in 100% plasma for up to 7 days. Additionally, for platelet units stored past 5 days and through 7 days, every product must be tested with a bacterial detection device cleared by FDA and labeled as a "safety measure."

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 Device Evaluation (ODE)

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Division Sign-Off, Office of Blood Research and Review