November 13, 2019

Fresenius Kabi AG
Aunica Jones
Senior Regulatory Affairs Specialist
Regulatory Affairs
Transfusion and Cell Technologies Division
Fenwal, Inc.
Three Corporate Drive
Lake Zurich, IL 60047

Re: K192150
Trade/Device Name: AMICUS Separator System
Regulatory Class: Unclassified
Regulation Name: None
Regulation Number: None
Product Code: LKN, GKT
Dated: August 14, 2019
Received: August 15, 2019

Dear Aunica Jones:

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 (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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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,

Carolyn Y. Neuland, Ph.D.
Assistant Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192150

Device Name
AMICUS Separator System

Indications for Use *(Describe)*
Depending on the AMICUS Separator System disposable used in the therapeutic apheresis procedure, the AMICUS Separator System has been cleared for the following:

The AMICUS Separator System is an automated blood cell separator indicated to perform therapeutic plasma exchange (TPE). (K111702)

The AMICUS Exchange Kit is indicated for use in therapeutic plasma exchange (TPE). The kit is for use with the AMICUS separator. (K111702)

The AMICUS Separator System is an automated blood component separator indicated to perform red blood cell exchange (RBCX), including exchange and depletion/exchange procedures, for the transfusion management of sickle cell disease in adults and children. (K180615)

The AMICUS Exchange Kit – Therapeutics is indicated for use in therapeutic plasma exchange (TPE) and red blood cell exchange (RBCX). The kit is for use with the AMICUS separator. (K111702, K180615)

The waste transfer set is indicated for use in red blood cell exchange (RBCX). The set is for use with the AMICUS separator. (K180615)

The Blood Component Filter Set with Vented Spike and Luer Adapter is indicated for the administration of blood and blood components during a therapeutic plasma exchange (TPE) or red blood cell exchange (RBCX) therapeutic apheresis procedure. The set is for use with the AMICUS separator. (K111702, K180615)

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

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

- Platelets Pheresis, Leukocytes Reduced (single, double, or triple units) (BK960005) (BK990009)
- Platelets Pheresis, Leukocytes Reduced, Platelet Additive Solution (InterSol) (single, double or triple units) (BK090065)
- Red Blood Cells, Leukocytes Reduced (by apheresis) (BK000039)
- Mononuclear Cells (BK000047)
- Plasma (BK960005, BK120041)
  - o Fresh Frozen Plasma
    - Must be prepared and placed in a freezer at -18° C or colder within 8 hours after phlebotomy.
  - o 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.
  - o Plasma Frozen Within 24 Hours After Phlebotomy (PF24) 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.

o Source Plasma

The device is designed to collect products while maintaining an extracorporeal volume at or below 10.5ml/kg and a donor post platelet count greater than or equal to 100,000 platelets/microliter. (BK080018)

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). (BK090065)

The AMICUS platelet storage container is cleared to store Platelets Pheresis, Leukocytes 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 device cleared by FDA and labeled as a "safety measure." (BK040059, BK150242)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Fresenius Kabi

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510(k) SUMMARY

Date Prepared:

October 17, 2019

Owner/Operator: #9027285
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Device Trade Name:
AMICUS Separator System

Common Name/Usual Name:
Automated Separator, Blood Cell and Plasma, Therapeutic
Automated Blood Cell Separator (Centrifugal Separation Principle)

Classification Name:
Automated separators, used for separation of blood cells and plasma for therapeutic purposes, have not been classified under a regulation by the Center for Devices and Radiological Health due to pre-amendment status.

21 CFR 864.9245 Automated Blood Cell Separator
Automated blood cell separators which are based on centrifugation type technology have been classified by the Center for Biologics Evaluation and Research as Class II devices with Special Controls (Docket 2005N-0017, Final Rule, 30-Nov-07, updated March 28, 2011 OMB Control No: 0910-0594).

Product Code and Classification Panel:
LKN (Gastroenterology/Urology panel) - Unclassified (due to pre-amendment status)

GKT (Hematology panel) - Separator, Automated, Apheresis

Legally Marketed Device Under Which Substantial Equivalence is Being Claimed:
Fresenius Kabi is claiming substantial equivalence with the currently cleared version of the AMICUS Separator System. The AMICUS Separator System is an automated blood cell separator intended for use in therapeutic apheresis applications including Therapeutic Plasma Exchange (TPE), Red Blood Cell Exchange and Red Blood Cell Depletion (RBCX procedures). The AMICUS Separator System was most recently cleared by CDRH under K180615 on Dec 4, 2018. This includes all operating protocols and changes previously cleared for the AMICUS Separator System.

Device Description:
The AMICUS Separator System is comprised of the AMICUS separator instrument and a disposable apheresis kit specific to the procedure being performed. The instrument is a continuous-flow, centrifugal device that draws whole blood from a donor/patient, separates the blood into its components, collects one or more of the blood components, and returns the remainder of the blood components to the donor/patient. The instrument operates using pumps, clamps and valves that move donor/patient blood through a single-use, sterile fluid path disposable kit. The cells are centrifugally separated within the kit by density differences.

The operator is responsible for connecting and monitoring the donor/patient and operating and monitoring the AMICUS separator during the procedure. The operator controls the separator through a touch screen. When necessary, the operator is warned of problems with messages on the screen and corresponding audible alarms.

Once the cell separation is complete, the operator disconnects the donor/patient, dismantles the kit, and disposes of the kit in a safe manner. The kit is packaged in a recyclable plastic tray.

Modification to the Existing Device:
Software version 6.0 has been developed for use with the AMICUS Separator System. The AMICUS software 6.0 release included enhancements for Single Needle Platelet (SNP), Double Needle Platelet (DNP), Mononuclear Cell (MNC), Therapeutic Plasma Exchange (TPE), and Red Blood Cell Exchange (RBCX) protocols. These functional changes include:

- Added Blood Warmer Primer Option – MNC Procedure
- Added Prime and Go Option – MNC Procedure
- Ability to Configure Mini-Cycle as On/Off – MNC Procedure
- Ability to Decrease Custom AC Citrate Concentration – TPE and RBCX Procedures
- Change to MNC Reinfusion Rate – MNC Procedure
- Update Parameters for ACD Ratio – MNC and ECP Procedures
- Additional Output Values – MNC, TPE and RBCX Procedures
- Data Management Enhancements
- Additional Minor Enhancements/Updates

Modifications have also been made to the operating instructions, both in support of the software changes and as a result of review and update. The cumulative changes in the software and operator's manual are such that a 510(k) should be submitted for the changes.

The AMICUS instrument hardware remains the same as the currently cleared device. The AMICUS apheresis Kits remain the same as the currently cleared kits.

Statement of Intended Use:
The AMICUS Separator System is an automated blood component separator intended for use in the collection of blood components and mononuclear cells.

The AMICUS Separator System is an automated blood cell separator intended for use in therapeutic apheresis applications and may be used to perform Therapeutic Plasma Exchange (TPE).

The AMICUS Separator System is an automated blood component separator intended for use in therapeutic apheresis applications and may be used to perform red blood cell exchange, depletion, and depletion/exchange (RBCX) procedures.

Indications for Use:
Depending on the AMICUS Separator System disposable used in the therapeutic apheresis procedure, the AMICUS Separator System has been cleared for the following:

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        - Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.
    - Plasma Frozen Within 24 Hours After Phlebotomy (PF24) 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.
    - Source Plasma

The device is designed to collect products while maintaining an extracorporeal volume at or below 10.5ml/kg and a donor post platelet count greater than or equal to 100,000 platelets/microliter. (BK080018)

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Technological Comparison as Compared to the Predicate Device

The technological characteristics of the AMICUS separator remain the same as the predicate AMICUS device. This includes the centrifuge system, fluid control system, safety management system (including safety sensors and alarms), and anticoagulant management system. The physical design of the AMICUS separator instrument is identical to the marketed AMICUS device. The AMICUS apheresis kits remain the same as the currently cleared kits, including design, materials and manufacturing methods. The data management capabilities remain the same as the cleared AMICUS device.

Performance Data:
The Design Verification and Design Validation processes are designed to meet the requirements for software development and testing as described in the following standards and guidance documents:

- IEC 62304 Ed. 1.0, "Medical device software - Software life cycle processes"
- ISO 14971:2012 Medical Devices – Applications of Risk Management to Medical Devices
- FDA/CDRH "General Principles of Software Validation; Final Guidance for Industry and FDA Staff." Issued January 11, 2002.
- ES 60601-1:2005/(R)2012 and A1:2012, C1: 2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

Software and systems verifications were performed in support of this submission. The results of the testing were acceptable.

Conclusion:
Based on the verification activities performed, the AMICUS Separator System modified with software 6.0 provides a device system that is substantially equivalent to the currently marketed AMICUS Separator System.