



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 23, 2016

Fresenius Kabi USA, LLC
Kim Forch
Manager, Regulatory Affairs
Three Corporate Drive
Lake Zurich, IL 60047

Re: K162462
Trade/Device Name: AMICUS Separator System
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LKN, GKT
Dated: September 1, 2016
Received: September 2, 2016

Dear Kim Forch:

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. 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); 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" (21 CFR 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,

For Division

Douglas Silverstein -S
2016.11.23 07:14:25 -05'00'

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K162462

Device Name
AMICUS Separator System

Indications for Use (Describe)

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 device 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:

- Platelets Pheresis, Leukocytes Reduced (single, double, or triple units)
- Platelets Pheresis, Leukocytes Reduced, Platelet Additive Solution (InterSol) (single, double or triple units)
- Red Blood Cells, Leukocytes Reduced (by apheresis)
- Mononuclear Cells

Continues on next page

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Indications for Use

510(k) Number (if known)
K162462

Device Name
AMICUS Separator System

Indications for Use (Describe)
Continued from previous page

- Plasma
 - 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

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 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."

NOTE – No changes to the AMICUS Separator System indications for use are requested in this 510(k) filing.

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)

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510(K) SUMMARY

Date Prepared:

September 1, 2016

Owner/Operator:

Fresenius Kabi AG
Else-Kroner-Strasse 1
Bad Homburg, GERMANY 61346
Owner/Operator Number: 9027285

Contact Person:

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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:

Fenwal is claiming substantial equivalence with the currently cleared version of the AMICUS Separator System. The AMICUS Separator System was most recently cleared for therapeutic apheresis purposes under 510(k) K141019 on June 10, 2014. The AMICUS Separator System was most recently cleared for blood collection apheresis purposes under 510(k) BK150357 on April 20, 2016. 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 preparing and monitoring the donor/patient and operating and monitoring the AMICUS separator during the automatic blood collection cycle. 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 removes the needle(s) from 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 5.1 has been developed for use with the AMICUS separator system. This software includes procedure enhancements and correction of anomalies to all four cleared AMICUS procedures, Single Needle Platelets (SN), Double Needle Platelets (DN), Mononuclear Cell Collection (MNC), and Therapeutic Plasma Exchange (TPE). 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 only change being made to the AMICUS device in support of this submission is the implementation of software 5.1 and the updated operator's manual. The AMICUS instrument

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 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 cell separator intended for use in the collection of blood components and mononuclear cells.

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 device 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:

- Platelets Pheresis, Leukocytes Reduced (single, double, or triple units)
- Platelets Pheresis, Leukocytes Reduced, Platelet Additive Solution (InterSol) (single, double or triple units)
- Red Blood Cells, Leukocytes Reduced (by apheresis)
- Mononuclear Cells
- Plasma
 - Fresh Frozen Plasma
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NOTE – No changes to the AMICUS Separator System indications for use are requested in this 510(k) application.

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:

Software and systems verification 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 5.1 provides a device system that is substantially equivalent to the currently marketed AMICUS Separator System.