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510(K) SUMMARY

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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 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, November 30, -2007, updated March 28, 2011, OMB Control No: 0910-0594).

Product Code and Classification Panel:
LKN (Gastroenterology/Urology panel) - Unclassified (due to pre-amendment status)
81 GKT (Hematology panel) - Separator, Automated, Apheresis

Legally Marketed Device under Which Substantial Equivalence is Being Claimed:
Fresenius Kabi is claiming substantial equivalence with the AMICUS Separator System most recently cleared for apheresis blood collection purposes by CBER under BK160112 on April 7, 2017. The AMICUS Separator System will have the same intended use as originally cleared under BK960005.

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 safely disposes of the kit. The kit is packaged in a recyclable plastic tray.

Modification to the Existing Device:
Software version 5.12 has been developed for use with the AMICUS separator system. This software includes a procedural enhancement to the Single Needle Platelet (SN) and Double Needle Platelet (DN) procedures to allow an optional extended initial processing whole blood volume after the sample pouch is sealed off and before the blood is directed to the centrifuge. Additionally, the Unique Device Identifier (UDI) data string will be added to the AMICUS splash screen.

The only change being made to the AMICUS device in support of this submission is the implementation of software 5.12 and one associated change to the AMICUS 5.1 operator's manual. The following "Note" has been added to Section 4.1, Volume 2 (Platelet Collection) of the operator's manual:

> Note: When the Diversion Feature is enabled with Amicus software 5.12, the initial volume of whole blood drawn from the donor will be diverted from the separation chamber. This volume will be returned to the donor without being processed through the centrifuge.

Following diversion, whole blood is then pumped into the separation chamber. The increased blood diversion prior to separation that is enabled with Amicus Software 5.12 has not been studied to show that it further reduces the risk of bacterial contamination in the collected components.

There are no changes being made to the AMICUS instrument or the AMICUS apheresis kits; they remain the same as currently cleared. The labeling for the AMICUS instrument (i.e., shipping carton, back plate) and apheresis kits has not been modified The AMICUS 5.1 operator's manual has also been updated to include changes made under design control and warranted minor updates not related to the 5.12 software change.

Statement of Intended Use:
The AMICUS Separator System is an automated blood cell 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 apheresis applications and may be used to perform Therapeutic Plasma Exchange (TPE).

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
        - 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 (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

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) 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. There is no change to the design of the AMICUS separator instrument. 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 testing verified that the AMICUS Separator System modified with Software 5.12 performs as intended in a safe and effective manner that is substantially equivalent to the currently marketed version of the AMICUS Separator System.

Conclusion:
Based on the verification activities performed, the AMICUS Separator System modified with software 5.12 provides a device system that is substantially equivalent to the currently marketed AMICUS Separator System.