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510(k) Summary

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Device:

Trade Name:	AMICUS Separator System
Common or Usual Name:	Automated Blood Cell Separator (Centrifugal Separation Principle) Automated Separator, Blood Cell and Plasma, Therapeutic
Product Code:	GKT (Hematology panel) – Separator, Automated Apheresis LKN (Gastroenterology/Urology panel)-Unclassified (due to pre-amendment status)
Classification Regulation:	21 CFR 864.9245
Classification Name:	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).

Review Panel:	81 GKT Hematology LKN – Gastroenterology/Urology - Unclassified (due to pre-amendment status)
Device Class:	Class II

Legally Marketed Device under Substantial Equivalence is Being Cleared:
Fresenius Kabi is claiming substantial equivalence of the AMICUS Separator System when used with the AMICUS Apheresis Kits with the integrated Platelet Sampling System when used with the currently marketed AMICUS Separator most recently cleared to market under 510(k) BK150288 on August 28, 2015. The AMICUS Separator System, indicated for the collection of blood components, mononuclear cells, and for use in Therapeutic Plasma Exchange. The Amicus Apheresis Kits with the integrated Platelet Sampling System will have the same intended use as the originally cleared apheresis kits (BK960005, 12/19/96) and all subsequent apheresis kits cleared for market.

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. Blood components are collected using a 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:
The AMICUS Instrument codes 4R4580 and 4R4580R remains the same as the currently cleared device. The current closed kits 4R2337 (AMICUS Single Needle with PAS Connect and Dual Plasma Containers) and 4R2340 (AMICUS Double Needle with PAS Connector and Dual Plasma Containers) have been modified to integrate a platelet sampling system to allow for sampling of larger volume of platelets.

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 therapeutic apheresis applications and may be used to perform Therapeutic Plasma Exchange (TPE).

The platelet sampling system is intended to allow aseptic removal of a sample from the platelet storage container for subsequent bacterial or/and other applicable testing. The platelet sampling system does not have contact with blood fluids that are reinfused to a donor or patient.

Indications for Use:
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 an automated blood cell separator indicated to perform Therapeutic Plasma Exchange (TPE).

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:

- 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 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 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 detection 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 Special 510(k) application.

Technological Comparison as Compared to the Predicate Device:
Technological characteristics of the AMICUS Separator and the AMICUS apheresis kits remain the same as the predicate AMICUS device. Creating disposable kits with an integrated platelet sampling system subassembly associated with this Traditional 510(k) do not in any way change the systems fundamental scientific technology or principle of operation.

Performance Data:
Performance testing and data in previously cleared AMICUS filings remains valid for demonstrating instrument and disposable kits performance. Additional testing was performed to demonstrate that the device function was maintained and that the integrated platelet sampling system meets specifications. The results of the testing were acceptable.

Conclusions:
Based on the verification activities, the AMICUS Separator System and the apheresis kits with integrated platelet sampling system described in this Traditional 510(k) are substantially equivalent to the currently marketed product.