Fresenius Kabi USA, LLC

Three Corporate Drive
Lake Zurich, Illinois 60047
T 847-550-2300
T 888-391-6300
www.fresenius-kabi.us

510(K) SUMMARY

Date Prepared: November 9, 2016

I. Submitter

Fresenius Kabi
3 Corporate Drive
Lake Zurich, IL 60047

Contact Person:
John Maibauer
Sr. Manager, Regulatory Affairs
Phone: 847-550-2966
Fax: 847-550-2690
Email: john.maibauer@fresenius-kabi.com

II. Device

Trade Name:	AMICUS Separator System
Common/Usual Name:	Automated Blood Cell Separator (Centrifugal Separation Principle) Automated Separator, Blood Cell and Plasma, Therapeutic
Product Code:	GKT - Separator, Automated Apheresis LKN - Automated Separator, Blood Cell and Plasma, Therapeutic
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:	GKT - Hematology LKN - Gastroenterology/Urology panel
Device Class:	Class II

III. 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.

IV. 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).

V. 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:

- 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”.

VI. Modification to the Existing Device:

Modifications described in this 510(k) do not add, delete, or modify the description of the AMICUS Separator System. No changes have been made to the design or function of the hardware or software.

The materials for the sheeting and port tubing of the platelet/MNC storage container in currently marketed Amicus Kits are being changed to an alternate material. The alternate material is functionally equivalent to the current material. All other materials used in the kit will remain the same.

VII. Legally Marketed Device under Substantial Equivalence is Being Cleared:

Fresenius Kabi is claiming substantial equivalence with the currently marketed AMICUS Separator most recently cleared to market under 510(k) BK150357 on April 24, 2016.

VIII. 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. Material changes to the platelet storage container do not change the systems fundamental scientific

technology or principle of operation.

IX. Performance Data:

Performance testing and data in previously cleared AMICUS filings remains valid for demonstrating instrument and disposable kit performance. Additional testing was performed to demonstrate that the platelet storage container function was maintained and alternate material meets specifications. This testing included, but was not limited to:

- Biocompatibility testing according to ISO 10993
- Expiration Dating and Functional Testing
- In Vitro Storage Studies
- UV Transmission
- Gas (O_2 and CO_2) Transmission
- Infrared Spectroscopy
- Extractable Acidity Comparison

The results of the testing were acceptable and demonstrate equivalence between the currently marketed and proposed materials.

X. Conclusions:

Based on the verification activities, the Amicus apheresis kits described in this 510(k) are substantially equivalent to the currently marketed product.