

**AMICUS Separator System  
510(k) Summary**

**Date Prepared:**

11 December 2012

**Owner and Contact Person:**

Owner/Operator	Contact Name
Fenwal, Inc. Three Corporate Drive Lake Zurich, Illinois 60047 Owner/Operator Number 9098803	Kristen Bozzelli Specialist, Regulatory Affairs Fenwal, Inc. Three Corporate Drive, 2 <sup>nd</sup> Floor Lake Zurich, Illinois 60047 TEL 847-550-7927 FAX 847-550-2960 kristen.bozzelli@fenwalinc.com

**Device Name(s):**

AMICUS Separator System

The labeling of the system is affected by the modifications described in this premarket notification, and is associated with the parent product code of the instrument:

Fenwal Product Code Number	Product Name
4R4580	AMICUS Separator System
4R4580R	AMICUS Separator System (Refurbished)

The following disposable kits are affected by the modifications described in this premarket notification:

Fenwal Product Code Number	Product Name
4R2337	AMICUS Apheresis Kit, Single Needle with Platelet Additive Solution Connector
4R2340	AMICUS Apheresis Kit, Double Needle with Platelet Additive Solution Connector

The following codes are listed for the first time, but were created to maintain the currently marketed product configuration:

Fenwal Product Code Number	Product Name
P4R2337	AMICUS Apheresis Kit, Single Needle with Platelet Additive Solution Connector
U4R2337	AMICUS Apheresis Kit, Single Needle with Platelet Additive Solution Connector

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**Common Name(s):**

Automated Blood Cell Separator (Centrifugal Separation Principle)

**Classification Name:**

21 CFR 864.9245 - Automated Blood Cell Separator  
Automated blood cell separators which are based on centrifugation 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 November 2007).

**Classification Panel:**

81 GKT (Hematology) – Separator, Automated, Apheresis

**Legally Marketed Device Under Which Substantial Equivalence is Being Claimed:**

AMICUS Separator System

**Device Description:**

The AMICUS Separator System is a continuous flow centrifugal device that separates whole blood into its components. The operator is responsible for preparing and monitoring the donor and operating and monitoring the AMICUS Separator during the procedure.

The operator controls the separator through a touch screen. When necessary, the operator is notified of potential problems with the procedure or the instrument via on-screen messages and corresponding audible alarms.

Blood components are collected using sterile fluid path single use apheresis kits. These kits are provided in either closed or functionally closed configurations. The blood components are separated within the kit by differences in density during centrifugation. Kits are packaged in recyclable plastic trays.

The AMICUS instrument can collect plasma concurrently with other blood components. During this process whole blood is collected from the donor and separated by centrifugation into plasma and cellular components.

Modifications described in this Special 510(k) do not add, delete, or modify the description of the device.

**Modification of Existing Device:**

Two AMICUS Separator System disposable kits with PAS (Platelet Additive Solution) connectors have a modified configuration, replacing a single plasma collection container with an assembly of two smaller plasma containers. This change reduces manual, post-collection processing steps for the user. Instructions for post-collection processing were added to the Operator's Manual. Two additional codes were created to maintain the current product configuration. No changes have been made to the design or function of the hardware or software. There is no change to the intended use, or to the type or volume of products that can be collected with the system.

**Statement of Intended Use:**

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
- Therapeutic Plasma Exchange (TPE)
- Plasma
  - Fresh Frozen Plasma
    - Must be prepared and placed in a freezer at -18° C or colder within 8 hours of collection.
  - Source Plasma
  - Plasma Frozen Within 24 Hours After Phlebotomy (PF24)
    - Must be stored at 1-6°C within 8 hours of collections and prepared and frozen 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 collection. Product must be prepared and frozen within 24 hours after phlebotomy.
    - Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen 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).

**Technological Characteristics as Compared to the Predicate Device:**

Technological characteristics of the AMICUS Separator and its disposable kits remain the same as currently cleared. Modifications to the kits associated with this Special 510(k) do not add, delete, or modify the technological characteristics of the device or the disposable kits.

**Design Control Activities:**

Design control activities for changes described in this premarket notification were conducted under Fenwal procedures for change control and assessment, risk assessment, and design verification and validation, in accordance with 21 CFR 820 Quality System Regulation requirements. Potential risks associated with the proposed changes were identified and testing was performed to verify that device function was maintained within established specifications.

**Performance Data:**

Performance testing and data in previously cleared filings remains valid for demonstrating instrument and disposable kit performance. Additional testing described in this Special 510(k) was performed to verify that device function was maintained within established specifications.

**Conclusions:**

The AMICUS disposable kits with the dual plasma container configuration and the AMICUS Separator System with updated labeling described in this Special 510(k) are substantially equivalent to the current cleared and marketed devices.