510(K) SUMMARY

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Owner and Contact Person:

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Device Name(s):

AMICUS® Separator System

Common Name:

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-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).

Classification Panel:

81 GKT (Hematology panel)- Separator, Automated, Apheresis

Legally Marketed Device Under Which Substantial Equivalence is Being Claimed:

Fenwal, Inc. is claiming substantial equivalence of the revised AMICUS separator system with the currently marketed version of the AMICUS separator system which was cleared to market under 510(k) BK960005 on December 19, 1996, along with its' additional operating protocols, software updates and disposables changes that were subsequently cleared.

Description	510(k) Number	Clearance Date
AMICUS separator system	BK960005	12/19/1996
Collection of Three Platelet Products	BK990009	03/03/2000
Collection of Mononuclear Cells (MNC)	BK000047	07/31/2002
Concurrent Collection of Red Blood Cells (cRBC)	BK000039	08/26/2002
Freezing and Irradiation of Red Blood Cells	BK030085	03/15/2004
Storage of Platelets in a PL2410 plastic container for up to 7 days when coupled with a 100% screening for bacterial contamination using a device cleared for that purpose with its recommended methods prior to transfusion.	BK040059	09/24/2004
AMICUS 7-day platelets with 100% release testing using BacT/ALERT Microbial Detection System	BK050038	11/03/05

Device Description

The AMICUS separator 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 warned of problems with messages on the screen and corresponding audible alarms.

Blood components are collected using sterile fluid path, single-use, apheresis kits. The cells are centrifugally separated within the kit by density differences.

Once the cell separation is complete, the operator removes the needle(s) from the donor/patient, removes the kit, and disposes of the kit per institutional SOPs. The kit is packaged in a recyclable plastic tray.

Modification to the Existing Device

A new AMICUS Operator's Manual is being issued to reflect the new User Interface available when using AMICUS 3.1 software. The labeling is also being revised to provide specifications for the accuracy of platelet storage fluid as compared to the previous specification for total plasma volume. The operating protocols as described in this Operator's Manual are the same as those available on the currently marketed software versions 2.515 or 2.527.

Statement of Intended Use

The AMICUS separator is intended to be used for the simultaneous collection of platelet concentrate, plasma and red blood cells while maintaining an extracorporeal volume at or below 10.5 mL/kg and a post-count greater than 100,000 platelets/μL.

The AMICUS separator is intended to be used for automated collection of mononuclear cells.

The intended use of the AMICUS separator system has not been changed as a result of the modifications that have been made.

Technological Characteristics

The technological characteristics of the AMICUS separator remain the same as the currently marketed device. It is a continuous flow centrifugal separation device. It uses sterile fluid path disposable kits made of polyolefin and PVC plastics. The changes associated with AMICUS 3.1 software update the user interface to simplify the user interaction without changing the way in which blood components are collected and separated. These changes did not have an impact on the safety or efficacy of the AMICUS separator. The labeling has been changed to reflect revised suggested operating parameters within the range of previously cleared values.

Design Control Activities:

The design control activities for these changes were managed under Fenwal's PDP (Project Development Process) series of SOPs, in accordance with the Fenwal Quality System, which is in conformance with the requirements of the US Food and Drug Administration's Quality System Regulation. Potential risks associated with the changes being made were identified, and validation and verification testing has been performed and demonstrated that the performance of the modified device is not adversely affected by the changes.

Performance Data:

A paired study was conducted at 4 customer sites: one site performed double needle procedures only, two sites performed single needle procedures only, and one site performed both double needle and single needle procedures. The paired control was a procedure performed on that donor during the past year using the sites' current operating parameters on software version 2.515 or 2.527.

- The actual storage fluid volume transferred in 95% of the procedures will be within –1.93% to 2.39% with 95% confidence of the programmed storage fluid volume.
- The predicted procedure time for Single Needle procedures in 95% of the procedures will be within –12.79 % to 14.38 % with 95% confidence of the actual procedure time for Single Needle procedures.
- The predicted procedure time for Double Needle procedures in 95% of the procedures will be within –9.16% to 6.98 % with 95% confidence of the actual procedure time for Double Needle procedures.
- Leukocyte reduction by AMICUS fulfills current FDA product performance qualification criteria for leukocyte reduction: 95% confidence that 95% of components tested have $< 5.0 \times 10^6$ residual leukocytes per Guidance for Industry and FDA Review Staff Collection of Platelets by Automated Methods, Dated: December 17, 2007.

Conclusions:

Based on customer evaluations, the AMICUS separator, when run using 3.1 software, can support marketing claims on the accuracy of the estimated times for double and single needle procedures and for plasma storage fluid volume.