510(K) SUMMARY

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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	11/03/2005
AMICUS® Separator System-Change in Labeling, Software Version 3.1	BK080018	08/26/2008

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

Change pages to the AMICUS Operator's Manual are being issued to reflect the ability to export data when using AMICUS 3.1 software. In support of data export, the Caution statements surrounding using the EDI port have been modified, and a qualified barcode scanner has been added to the Operator's Manual. A supplemental EDI Interface Development Guide has been

created to provide the information required to create and use an interface to the AMICUS separator's EDI port.

No other changes to the manual have been made, and the operation of the instrument for component collection remains identical to that of the current marketed manual for the AMICUS 3.1 software.

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 that uses sterile fluid path disposable kits made of polyolefin and PVC plastics.

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:

Bench testing performance data were collected during software and systems validation activities to demonstrate functionality using the EDI port. The EDI infrastructure operation was regression tested for overall robustness by numerous prolonged informal session-based tests. Additionally, formal verification test cases were performed addressing the new requirements and existing EDI-related anomalies. With the exception of the recorded and mitigated anomalies, the EDI port functions as specified and has no adverse impact on the normal Amicus instrument operation.

Conclusions:

Based on the validation and verification activities performed on AMICUS 3.1 SW, the AMICUS separator can export donation, procedure and instrument data in a defined electronic format.