510(K) SUMMARY

Date Prepared:

July 29, 2010

Owner and Contact Person:

Owner/Operator	Owner/Operator #: 9098803 Fenwal, Inc. Three Corporate Drive Lake Zurich, IL 60047
Contact Name: Title: Address: Telephone: Fax: E-mail:	Cheryl Chamberlain Roscher, Ph.D. Director, Global Regulatory Affairs Three Corporate Drive Lake Zurich, IL 60047 847-550-7909 847-550-2960 cheryl.roscher@fenwalinc.com

Device Name(s):

AMICUS Separator System

Common Name:

Automated Blood Cell Separator (Centrifugal Separation Principle)

Automated Centrifugal Blood Cell Separator

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 with the currently marketed version of the AMICUS Separator System. The AMICUS Separator System was most recently cleared to market under 510(k) BK090065 on March 4, 2010.

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 as well as operating and monitoring the AMICUS instrument during the procedure.

The operator controls the instrument through a touch screen. When necessary, the operator is notified of potential problems with the procedure or instrument via messages on the screen with 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 cells are centrifugally separated within the kit by density differences.

The AMICUS instruments 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.

Indications for 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/μL.

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)
- Plasma
- Fresh Frozen Plasma (FFP)
- Source Plasma
- Red Blood Cells, Leukocytes Reduced (by apheresis)
- Mononuclear Cells

Platelets Pheresis (single, double, or triple units) may be manufactured from products that do not meet leukocyte reduction product standards. This does not apply to Platelets Pheresis, Platelet Additive Solution (PAS or InterSol®) (single, double or triple units).

Technological Characteristics as Compared to the Predicate Device

The technological characteristics of the AMICUS Separator System remain the same as the currently marketed device. AMICUS is a continuous flow centrifugal separation device. AMICUS uses a sterile fluid path disposable kit made of non-PVC polyolefin and PVC plastics.

Performance Data:

The information presented shows that an absolute plasma product equal in volume to the absolute plasma volume replaced by InterSol solution may be collected from a donor while still classifying the donor as a plateletpheresis donor for deferral purposes. If the actual absolute plasma product volume exceeds the volume of absolute plasma replaced by InterSol® by 5 mL the donor should be deferred for at least 4 weeks as an infrequent plasma donor. In order to meet this criterion, the user should consider programming the device to collect a plasma product volume that is 90% of the plasma volume replaced by InterSol.

Conclusion:

For the AMICUS Separator System, when using InterSol solution during a plateletpheresis procedure, the plasma volume for storage replaced by InterSol may be used as plasma product from a donor while still classifying the donor as a plateletpheresis donor for deferral purposes if the absolute plasma product volume does not exceed the absolute volume replaced by InterSol by 5 mL. When the actual absolute plasma product volume exceeds the volume of absolute plasma replaced by InterSol® by 5 mL the donor should be deferred for at least 4 weeks as an infrequent plasma donor. Reference is made to a new Appendix added to the Operator's manual (Appendix A.11) which defines this volume for operations purposes.