

BK990009

510(k) Summary of Safety and Effectiveness

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Trade/Proprietary Name of Device: Amicus® Separator, Collection of Three Platelet Products

Common or Usual Name of Device: Automated Centrifugal Blood Cell Separator

Classification Name of Device: Automated Blood Cell Separator
(21 CFR 864.9245)

Legally Marketed Device Under Which Substantial Equivalence is Being Claimed: Amicus® Separator cleared for market entry under 510(k) BK960005.

Device Description:

The Amicus® Separator and apheresis kits constitute a system for centrifugal blood separation and is intended to be used for the simultaneous collection of leukoreduced platelet concentrate and plasma. The hardware, software, disposable apheresis kits including the solutions, and the blood processing system used for collecting three platelet products is the same as the currently marketed Amicus® Separator. The instrument has pumps, clamps and valves that move and direct donor blood through the kit. The desired blood components are collected and other components are returned to the donor.

There are four disposable apheresis kits which can be used on the instrument. The apheresis kits include a platelet storage container, which supports platelet storage for up to five (5) days. The third dose of platelets will be stored in an additional Fenwal PL2410 Plastic Storage Container which is identical to the container supplied with the Amicus® Separator apheresis kit as described in the Amicus® Separator original 510(k) submission BK960005.

Intended Use of Device:

The Amicus® Separator is intended to be used for the simultaneous collection of platelet concentrate and plasma. The Amicus® Separator Collection of Three Platelet Products will be used for the simultaneous collection of platelet concentrate and plasma when with suitable donors in one apheresis procedure greater than 9.0×10^{11} platelets are collected and can be used as three (3) platelet doses. Under normal operating conditions, the residual white blood cell level in the resulting platelet product meets the current regulatory and blood banking standards for leukoreduced blood products of less than 5×10^6 per platelet dose. Platelet concentration range for the additional PL2410 Plastic Storage Container and recommended storage parameters remain unchanged from the original Amicus® Separator.

*Comparison of Technological
Characteristics of the Device vs.
A Legally Marketed Device:*

Baxter Healthcare Corporation, Fenwal Division, is claiming substantial equivalence of the Amicus® Separator Collection of Three Platelet Products to the Amicus® Separator which was originally cleared under 510(k) BK960005 on December 19, 1996 and the COBE Spectra Apheresis System (Triple Platelet Products) BK930017 cleared on July 27, 1994. The hardware, software, disposable apheresis kits including the solutions, and the blood processing system used for collecting three platelet products is the same as the currently marketed Amicus® Separator. The collected third platelet product parameters, including leukoreduction during platelet collection, and storage conditions also remain the same. This third dose of platelets will be stored in an additional Fenwal PL2410 Plastic Storage Container which is identical to the container supplied with the Amicus® Separator apheresis kit as described in the Amicus® Separator original 510(k) submission BK960005.

*Brief Discussion of Nonclinical and
Clinical Tests and Their Results
Submitted in the Application:*

A clinical study was performed to evaluate donor safety, when collecting greater than 9×10^{11} , from suitable donors in one apheresis procedure using the Amicus® Separator which can be used as three platelet products. Some of these suitable donors repeated their platelet product donations within three weeks to assess the effect on these donors of repeated triple platelet product collections.

The results of these studies show that the Amicus® Separator can be used to collect greater than 9×10^{11} platelets from suitable donors in one apheresis procedure and can be used as three (3) platelet doses.

*Conclusions Drawn from the
Nonclinical and Clinical Tests that
Demonstrate that the Device is
Safe, Effective, and Performs As
Well As or Better than the Legally
Marketed Device:*

Donor safety data from the clinical evaluations demonstrated that the Amicus® Separator is safe and effective for the collection of greater than 9×10^{11} , from suitable donors in one apheresis procedure and can be used as three (3) platelet products. As is described in the original Amicus® Separator submission, an algorithm calculates a blood volume to process based on the donor's pre-platelet count, weight and hematocrit. When the operator supplies the predicted platelet yield, the donor's predicted post platelet count is displayed on the screen. This information helps identify the suitable donor profile. Suitable donors showed no significant differences in their vital signs or clinically significant alterations in their hematology parameters. The operation of the Amicus® Separator when collecting greater than 9×10^{11} which can be used as three (3) platelet products is as safe and effective as it is in the operation of collecting greater than 9×10^{11} which can be used as two (2) platelet products.


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