BK040059

Baxter

Summary of Safety and Effectiveness

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Date of Summary:	September 21, 2004
Trade/Proprietary Name of Device:	Amicus Separator
Common/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 BK960005 Haemonetics MCS+ BK940064 COBE Trima BK970005
Device Description:	The Amicus Separator is an apheresis device utilizing centrifugal technology to separate whole blood into its components. The device has been well-characterized in the 510(k) submissions: Amicus Separator BK960005, BK990009 and BK000039.
Intended Use of the Device:	The Amicus Separator is intended for use for the simultaneous collection of platelet concentrate, plasma and red blood cells.

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Comparison of Technological Characteristics of the Device vs. the Legally Marketed Device:	The function of the Amicus Separator is similar to that of other legally marketed devices such as the Haemonetics MCS+, COBE Trima and other commercially available centrifugal-based blood cell separators.
Brief Discussion of Nonclinical and Clinical Tests and Their Results Submitted in the Application:	A clinical study was performed to evaluate the characteristics of platelets collected by apheresis, and stored for seven (7) days. In vitro, in vivo and bacterial culture testing was performed. Results were within expected limits. Platelets stored for at least 7 days in PL 2410 containers had a mean pH value on Day 8 of 7.0. The lower 95% confidence interval for pH of 6.3 was greater than the industry standard of 6.2. The mean radiolabeled platelet recoveries for platelet products stored for 5* days and for 7** days were 48.6% and 45.4%, respectively. The mean difference between Day 5 and Day 7 was 3.1% with an upper 95% confidence limit of 5.9%, which is less than the protocol-defined limit of 20%. *Platelets stored for 5 days were sampled and tested on day 6 of storage. ** Platelets stored for 7 days were sampled and tested on day 8 of storage.
Conclusion 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:	Platelets stored in PL 2410 containers for 7 days achieved all protocol criteria. Platelet products tested on Day 8 maintained acceptable pH values through the end of storage and had relatively small changes in platelet recovery and survival between Day 6 and Day 8. Only leukoreduced platelet products may be stored for 7 days. All platelet products collected using the marketed device, and stored for 7 days, must be coupled with a 100% screening for bacterial contamination using a device cleared for that purpose with its recommended methods prior to transfusion.

Signature

21 September 2004

Date

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