Summary of Safety and Effectiveness

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Date of Summary:	October 25, 2005
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 System BK960005 Amicus Separator System BK040059 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, BK040059.
Intended Use of the Device:	The Amicus Separator is intended for use for the simultaneous collection of platelet concentrate, plasma and red blood cells. Leukocyte-reduced apheresis platelets collected with the AMICUS Separator System may be stored in a PL 2410 plastic container for up to and including 7 days when coupled with a 100% release testing for bacterial contamination using BacT/ALERT Microbial Detection Systems as described in the Directions for Use in the AMICUS Separator Operator's Manual and Product Insert. Each PL 2410 plastic container can store up to a maximum of 4.7×10^{11} platelets in the appropriate plasma volume.

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:

In order to determine a baseline bacterial contamination rate in Single Donor Platelets (SDPs) in the United States, a survey was done of the bacterial testing results of two major Blood Collection Organizations in the United States. Bacterial testing was done by these organizations according to the recommendations of AABB Standard 5.1.5.1. A total of 493,766 single donor platelet units were tested between the two major Blood Collection Organizations over approximately a twelve month period.

The first organization tested 432,578 SDPs between March 1, 2004 and March 12, 2005. After a minimum time of 24 hours after collection, a single 4 mL platelet sample was taken and inoculated into an aerobic culture bottle. SDPs were held for a minimum of 12 hours before being released negative-to-date. The second organization tested 61,188 SDPs between January 1 and December 31, 2004. Their testing protocol was identical to that listed above, except that their SDPs were held for a minimum of 24 hours after inoculation before being released as negative-to-date.

The first major Blood Collection Organization reported 76 confirmed positive results out of 432,578 SDP units (17.6/100,000, 95% CI 13.8 to 22.0 per 100,000). An additional 41 units were considered indeterminate. Assuming all indeterminate events were also true positives, 117 units would be considered positive (27.0/100,000, 95% CI 22.4 to 32.4 per 100,000). A total of 120 false positives were attributed to either equipment failure or negative confirmatory testing. No septic events were associated with platelets transfused prior to the detection of a positive culture.

The confirmed positive cultures reported were detected an average of 18.7 hours after inoculation (range 5.9 to 105.6 hr). Of the 76 confirmed positive cultures, 12 were gram-negative bacteria and 64 were gram-positive bacteria. The majority of gram positive cultures detected were either Staphylococcus or Streptococcus species (58/64).

The false positive and indeterminate cultures were detected an average of 30.1 hr (range 0.0 to 117.0 hr) and 50.9 hr (range 4.1 to 120 hr) after inoculation, respectively.

The second major Blood Collection Organization reported 13 confirmed positive results out of 61,188 SDP units. (21.2/100,000, 95% CI 11.3 to 36.3 per 100,000). An additional 12 units were considered indeterminate. Assuming all indeterminate events were also true positives, 25 units would

be considered positive (40.9/100,000, 95% CI 26.4 to 60.3 per 100,000). A total of 77 false positives were attributable to either equipment failure or negative confirmatory testing. No septic events were associated with platelets transfused prior to the detection of a positive culture.

The confirmed positive cultures reported were detected an average of 14.2 hours after inoculation (range 6.7 to 26.4 hr). . Of the 13 confirmed positive cultures, all were gram-positive bacteria (Bacillus species (5); Staphylococcus species (6); and Streptococcus species (2)). The false positive and indeterminate cultures were detected an average of 29.7 hr (range 8.6 to 91.9 hr) and 78.4 hr (range 20.2 to 115.9 hr) after inoculation, respectively.

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:

The data collected from the two blood collection organizations, reflecting aerobic testing results, show that the combined rate of bacterial contamination in these two blood collection organizations ranged from 1:5,548 (confirmed positives only) to 1:3,477 (confirmed positive and indeterminate units). Based on these data, a standardized bacterial testing regimen using BacT/ALERT, per its directions for use except for specific narrower specifications, is described in the AMICUS Separator Operator's Manual for use as a release test for leukoreduced AMICUS apheresis platelets stored in PL 2410 storage containers for up to and including 7 days post collection.

To further characterize the performance of the bioMérieux BacT/ALERT Microbial System when used as a Release Test with leukoreduced AMICUS-derived SDP a post marketing surveillance study will be conducted. The proposed post-market surveillance study requires bacterial detection testing of all leukoreduced AMICUS-derived platelet products stored for 7 days. Extending the storage of the platelet product to 7 days in conjunction with bacterial detection is not anticipated to increase the risk of transfusing a bacterially contaminated platelet product based on the following:

a) the initial bacterial detection culture will be monitored for the entire shelf life of the platelet product;

b) all positive platelet products will be removed from inventory as soon as identified;

c) no platelet product will be released unless the culture is negative. The general risks of transfusing platelets are well documented in the literature and in the AABB Circular of Information.

Blood Collection Organizations desiring to comply with this testing regimen should contact CBER for the appropriate regulatory pathway and submission requirements prior to implementation of 7-day storage.