510(k) Summary of Safety and Effectiveness

Submitter Name and Address:	Baxter Healthcare Corporation Fenwal Division Route 120 and Wilson Road Round Lake, IL 60073
Contact Person:	Steven B. Binion, Ph.D. Vice President, Regulatory Affairs Phone: 847-270-4294 FAX: 847-270-2886
Date Summary Prepared:	August 26, 2002
Trade/Proprietary Name of Device:	Amicus® Separator, Concurrent Collection of Red Blood Cells
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 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 intended to be used for the simultaneous collection of leukoreduced platelet concentrate, plasma and red blood cells. The hardware and apheresis kits and the blood processing system used for collecting red blood cells are 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. The software change enables the collection of red blood cells at the end of a procedure in conjunction with plasma and platelet collection.

There are four disposable apheresis kits which can be used for blood component collection on the Amicus® Separator. Two of these are single needle kits that can be used for concurrent collection of red blood cells. The anticoagulated red blood cells are combined with preservative solution, then leukoreduced using a red blood cell kit containing an Asahi Sepacell® R-3000 Leukocyte Reduction Filter, using a separate disposables kit, 4C2304.

Intended Use of Device:

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.

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

Baxter Healthcare Corporation, Fenwal Division, is claiming substantial equivalence of the Baxter Healthcare Amicus® Separator Red Blood Cell Concurrent Collection to the Baxter Healthcare Amicus® Separator which was originally cleared to market under 510(k) BK960005 on December 19, 1996, the Cobe Trima® System, cleared to market under 510(k) BK970005 on October 13, 1998, the Haemonetics MCS+® System, cleared to market under 510(k) BK940064 on October 23, 1995.

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

A clinical study was conducted to establish the performance and safety of the Amicus® Red Blood Cell Concurrent Collection System, to validate the performance of the Asahi Sepacell® R-3000 Leukocyte Reduction Filter and to establish forty-two day storage of the packed ACD-A/ADSOL® Red Blood Cells using *in vitro* analysis and *in vivo* radiolabeled Red Blood Cell recoveries.

An additional laboratory study to evaluate clot formation was conducted on units of Red Blood Cells that had been stored for 42 days. All units were found to be free of clots following storage.

Donor vital signs and hematology laboratory parameters were safely maintained during the apheresis procedures using the Amicus® Red Blood Cell Concurrent Collection System. The Asahi Sepacell® R-3000 Leukocyte Reduction Filter produced more than adequate levels of leukoreduction ($<7.5 \times 10^5$) with a mean Red Blood Cell recovery rate greater than 93%. The *in vitro* storage data and *in vivo* radiolabeled Red Blood Cell recovery data of 84.4% show that the ACD-A/ADSOL® Red Blood Cells collected with the Amicus® Red Blood Cell Concurrent Collection System and leukoreduced prior to storage are suitable for transfusion following up to 42 days of storage. The study does not include data to support irradiation or freezing of ACD-A/AS-1 Red Blood Cells collected by the Amicus separator.

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 demonstrate that the Amicus® Separator is safe and effective for the concurrent collection of a unit of packed Red Blood Cells while collecting plasma and platelet products. Donor reactions, safety and comfort are comparable to the predicate product.

The Amicus® Red Blood Cell Set with its Asahi Sepacell® R-3000 Leukoreduction Filter successfully reduced the white blood cell content to a level well below acceptable limits.

In vitro and *in vivo* test results show the Red Blood Cell product to exceed the requirements for transfusion for up to 42 days of storage.

for Steven B. Binion, Ph.D.
Vice President, Regulatory Affairs
Baxrter Healthcare, Fenwal Division