510(k) Summary of Safety and Effectiveness

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Date Summary Prepared:	December 14, 2000
Trade/Proprietary Name of Device:	Amicus® Separator, Mononuclear Cell Collection
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. CS-3000® Plus Cell Separator intended for use for mononuclear cell collection cleared for market entry under 510(k) BK950013. Cobe Spectra® Mononuclear Cell Collection Procedure cleared to market under 510(k) BK950065

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 additional intended use which is the subject of this premarket notification is for mononuclear cell collection.

The hardware and apheresis kits used for mononuclear cell collection are modified for this use. The blood processing system used for collecting mononuclear cells is the same as the currently marketed Amicus® Separator. The instrument has pumps, clamps and valves that move and direct donor/patient blood through the kit.

The mononuclear cells are collected from a healthy donor or patient and other components are returned to the donor. A software change enables the collection of mononuclear cells in cycles during a procedure.

A disposable double needle apheresis kit is used for mononuclear cell collection on the Amicus® Separator.

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 of the donor's weight and a post-count greater than 100,000 platelets/μL.

The Amicus® Separator is intended to be used for automated collection of mononuclear cells.

It should be noted that the products collected by this device are

mononuclear cells and the Food & Drug Administration (FDA) is continuing to develop its regulatory approach for mononuclear cells.

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 Mononuclear Cell Collection Procedure to the Baxter Healthcare Amicus® Separator which was originally cleared to market under 510(k) BK960005 on December 19, 1996, the Baxter Healthcare CS-3000® Plus Cell Separator Mononucleated Cell Collection Procedure which was originally cleared to market under 510(k) BK950013 on October 28, 1998 and the Cobe Spectra® System Mononucleated Cell Collection Procedure which was cleared to market under 510(k) BK950065 on October 28, 1998.

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® Mononuclear Cell Collection System for use with patients and healthy donors.

Donor and patient vital signs and hematology parameters were safely maintained during the MNC procedure using the Amicus® Mononuclear Cell Collection Procedure. The mononuclear cell collection efficiency was comparable to the collection efficiency of the previously cleared devices.

Patients reinfused with mononuclear cell products collected using the Amicus® Separator engrafted in a timeframe comparable to historical data. There were no unexpected adverse events observed in healthy subjects or patients during collections. There were two unexpected serious adverse events

post-reinfusion of the cryopreserved products that were either unrelated or probably unrelated to the test device.

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 and patient safety data from the clinical evaluations demonstrate that the Amicus® Separator is safe and effective for the collection of Mononuclear Cells. Healthy subject and patient reactions, safety and comfort are comparable to those observed with the use of the predicate product.

for Jane Wallace

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