5 510(k) Summary

Gambro BCT, Inc. requests that the attached “Summary” for the Atreus® Whole Blood Processing System 2, Component be distributed upon request under the Freedom of Information Act. This report is a summary of the information presented in this 510(k) submission. It describes the collection and storage of Red Blood Cell and Plasma processed from Whole Blood units using the Atreus® System 2 Component Dry Set Configuration.

510(k) Summary [807.92(c)]

Owner/Manufacturer:	Gambro BCT, Incorporated 10811 W. Collins Avenue Lakewood, Colorado 80215
Contact Person:	William Duffell, Sr. Director, Regulatory and Government Affairs Atlanta Office: 478-968-7872
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Trade Name of Device:	Atreus® Whole Blood Processing System
Common Name:	Automated Whole Blood Processing System
Classification Name:	GKT, Automated blood cell separator
Predicate Device:	COBE 2991 (BK820001)

Device Description

The Atreus® system provides for the automatic separation of Whole Blood into blood components. The system consists of a computer-controlled centrifuge, hydraulic expression system, tube sealing valves with associated processing blood bag sets (disposables). The concept is suitable for the primary processing of donated Whole Blood, for the production of blood components for transfusion or further processing. The Atreus system incorporates appropriate software control and monitoring features for running the automated procedures.

This submission is specific to the processing of Whole Blood units into packed Red Blood Cells, and Plasma.

Indications For Use:

The Atreus® Whole Blood Processing System is indicated for the automatic separation of one unit of CPD Whole Blood into two transfusable components:

- Plasma or Plasma, Leukocytes Reduced (by Atreus® centrifugation) and
- CPD/AS-3 Red Blood Cells, Leukocytes Reduced (by manual gravity leukocyte reduction filtration).

The Atreus® Whole Blood Processing System is intended to be used with an Atreus® System Manager.

The Atreus® Whole Blood Processing System is intended to be used with a disposable processing set with a leukoreduction filter, which does not contain anticoagulant or storage solutions (dry set).

The Atreus® Whole Blood Processing System is intended to be used with a CPD Whole Blood collection bag that is FDA approved for the collection of 500 mL of Whole Blood.

Studies have not been performed to support freezing or gamma irradiation of CPD/AS-3 RBC products.

Intended Use:

The Atreus ® Whole Blood Processing System is intended to be used by trained operators in a blood center.

Technological Comparison:

In the United States, the processing of Whole Blood units is a manual process requiring several steps. A large proportion of these processing steps are automated in the Atreus® system using the same technological characteristics as the predicate devices. The separation, expression, and sealing processes are automated, requiring little intervention by the operator. The centrifuge spins, separating the blood into its blood components. The blood components are expressed using hydraulic fluid under a membrane. The destination of each component is determined by the position (open or closed) of a set of valves. Once the components are expressed into the appropriate storage bags, the valves automatically seal the lines to each component bag in the Atreus® system. When the process is complete, the lids are opened and the blood components are removed from the machine.

Discussion of Clinical Data:

The safety and effectiveness of the Atreus® system were validated for the processing of Whole Blood units into Red Blood Cell and Plasma components in four studies at four centers. The studies were either a paired cross-over in design, or a single arm design with designated acceptance criteria for the outcome. The Atreus® system 2 Component Configuration produced RBC and Plasma units that meet the desired yield and quality specifications for leukoreduced blood components for patient transfusion or further processing.

Summary of Results. Leukoreduced RBC Unit Studies.

- **All leukoreduced Atreus® Test (69/69) and Manual Control (69/69) packed Red Blood Cell units showed less than 1% hemolysis after 42 days of storage**, averaging 0.34 +/- 0.2%, 0.1 +/- 0.04%, and 0.17 +/- 0.09% for the Test samples; and 0.45 +/- 0.2%, 0.18 +/- 0.08%, and 0.41 +/- 0.12% respectively for the Control units for the three study sites. **These values met the FDA-CBER criteria of <1% hemolysis 95% of the time with 95% confidence with 0/69 with > 1% hemolysis.**

- **22/23 leukoreduced Atreus® RBC units had > 75% radiolabelled recovery at 24 hour post infusion, averaging 86.3 +/- 3.5 and 82.4 +/- 8.5% for the two study sites.** These values met the FDA-CBER criteria for twenty-four hour radiolabelled RBC percent recovery determined following 42 days of refrigerated storage, where the RBC recovery results should average 75%, with a standard deviation less than 9%. In addition, the 95% one-sided lower confidence limit for the population proportion of successes should be > 70%, with a success being defined as an individual red blood cell unit's *in vivo* recovery being at least a 75%.

- **All leukoreduced Atreus® Test units (69/69) had less than 5×10^6 contaminating White Blood Cells.** These results met the FDA-CBER criteria of $< 5 \times 10^6$ White Blood Cells, 95% of the time with 95% confidence with 0/69 > 5×10^6 WBCs.

- The percent recovery in the final RBC unit post leukoreduction of the initial RBC dose in the Whole Blood units was 92.3 +/- 1.3%, 90.9 +/- 1.6%, and 93.5 +/- 1.7% in the three sites. **All values (69/69) were above 85% recovery.**

- All mean Test values for the *in vitro* RBC assays without defined requirements were within 20% of mean of the Control, were better than the Control with statistical significance, or the differences were not clinically significant.

- Although 2, 3 Diphosphoglycerate (DPG) is completely depleted after 42 days of storage, treating stored Atreus® Red Blood Cells with rejuvenating solution regenerates the 2,3 DPG concentrations to values comparable to those seen on Day 0.

- The Plasma units produced by the Atreus® system have significantly lower cellular contamination as compared to the Control units. **All Atreus® Plasma units had $< 5 \times 10^6$ WBCs.**

- The mean Plasma protein factor levels in Atreus® and Control Plasma are equivalent, and within 20% with no statistical significance in the difference between values.