



### 510(k) Summary

**Owner/Manufacturer:** CaridianBCT, Incorporated  
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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:** Atreus® Whole Blood Processing System, BK080010

#### **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:**

This submission is specific to two software revisions:

- Minor maintenance fixes to the Atreus System software
- Two new features for Atreus® System Manager (ASM); electronic capture of the sterile connection and reporting of a hemoglobin estimate and identify units outside a configurable hemoglobin range.