

510(k) Summary

Owner/Manufacturer: CaridianBCT, Inc.
10811 W. Collins Ave.
Lakewood, CO 80215

Contact Person: Isabel A. McGann, Senior Regulatory Affairs Specialist

Date of Summary Preparation: August 27, 2008

Trade Name of Device: Trima Accel Automated Blood Component Collection System
AND
COBE Spectra Apheresis System

Common Name: Automated Blood Component Collection System

Classification Name: Automated Blood Cell Separator

Predicate Devices: Trima Accel Automated Blood Component Collection System
(*BK010046, BK040069- for disposable predicates*)

COBE Spectra Apheresis System (*BK920036, BK950030, BK950065, BK020041- for disposable predicates*)

Device Description(s):

The Trima system is an automated blood component collection system that uses centrifugal force to separate blood into platelet, plasma, and red blood cell components. These components are either collected into storage bags, or returned to the donor depending on the blood components needed by the blood center.

The COBE Spectra Apheresis system, an automated blood component separator, is intended for use in platelet collections and in multiple therapeutic applications.

510(k) Summary, continued

Indications for Use:

The Trima Accel Automated Blood Component Collection System is intended for use in automated blood component collection procedures. The disposable Tubing Set is intended for use with the Trima Accel Collection System to collect platelets, plasma, and red blood cells for extended storage.

The COBE Spectra Apheresis System is intended for use in apheresis procedures for either collections or therapeutic applications involving donors or patients.

Technological Comparison:

This notification provides information regarding a change in the manufacturing process of the vinyl used in some of the bags in the disposable tubing sets. The vinyl is substantially equivalent to the vinyl used in the predicate disposables. There is no change in safety or effectiveness of the disposables as a result of the manufacturing process change of the vinyl.