

BK02004

Summary of Safety and Effectiveness
for the
COBE® Spectra™ Functionally Closed WBC Set

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Trade Name of Device: COBE® Spectra™ Functionally Closed WBC Set

Common Name: Disposable Blood Tubing Set

Classification Name: Automated Blood Cell Separator and accessories (21 CFR 864.9245)

Predicate Devices: COBE Spectra Sets for Therapeutic Procedures
K831004, K900105 and components from
COBE Spectra Collection Sets BK870022, BK900004, BK920036

Device Description:

The COBE Spectra System is an automated blood cell separator intended for use in collecting blood components from donors for transfusions to patients and for performing several therapeutic procedures on patients. The subject of this Premarket Notification is the COBE Spectra Functionally Closed White Blood Cell (FC WBC) Set created by modifying the current COBE Spectra White Blood Cell (WBC) Set.

The modification consists of the addition of: a pre-attached 17 gauge access needle (with sharps protection); sterile barrier filters below the anticoagulant (AC) and saline spikes; and a plasma bag that is pre-attached at the location that had been used for the optional docking of an accessory bag in the original COBE Spectra WBC Set.

Intended Use / Indications:

The Intended Use of the COBE Spectra Apheresis System remains unchanged (blood cell separation for either collections or therapeutic applications).

The Indications for Use for the Functionally Closed WBC Set are also unchanged from those of the WBC Set and other previous modifications to sets and software. These indications are the collection of white blood cells, including mononuclear cells (MNC) or granulocytes or polymorphonuclear (PMN), from a donor or patient. Plasma from either donors or patients can be collected concurrently, if desired.

Some of the products collected using the COBE Spectra Apheresis System are mononuclear cells and the Food and Drug Administration (FDA) is continuing to develop its regulatory approach for mononuclear cells.

Validation of the Modified Product:

The following characteristics are expressed in the product labeling.

Biocompatibility:

The purpose of the modification to the currently marketed WBC set is to create a tubing set with the same Indications for Use and Performance Characteristics, that is also functionally closed. No changes were made to the COBE Spectra apheresis equipment. Biocompatibility for blood contact materials was previously established for all components except the sterile barrier filter for the saline line, which was validated for use with this new set.

This filter consist of a sterile barrier membrane and an acrylic housing. Both the membrane and housing met the requirements for hemolysis, cytotoxicity, acute systemic toxicity, intracutaneous toxicity, sensitization and genotoxicity testing performed under conditions consistent with Good Laboratory Practices (GLP).

AC pump flow rate:

Samples of the new configuration (FC WBC) were subjected to Simulated Use Testing during normal run conditions. For commanded flow rates during run, the AC flow rates were found to be within the specification range for the COBE Spectra Apheresis System.

Prime:

ACD-A must be used to prime the FC WBC for all procedures including PMN procedures.

4 Inlet Flow Rates:

Inlet Flow Rates must be reduced by the operator during various phases of Rinseback to avoid Access Pressure Low Alarms.

Sterilization:

All COBE Spectra disposable tubing sets are sterilized with ethylene oxide. No changes to the basic sterilization cycle were necessary to accommodate the Functionally Closed White Blood Cell Set. The Sterility Assurance Level (SAL) remains the same.

No changes have been made to the packaging of the current WBC Set to provide packaging for the Functionally Closed WBC Set. The sterile disposable blood collection sets are packaged in a firm, pre-molded plastic tray and sealed with preprinted, lid stock.

The Functionally Closed WBC Set also met the release criteria for EtO residuals. No changes have been made to the pyrogen specification or testing methodology. The labeling of all COBE Spectra Sets indicate that the fluid pathway is sterile and non-pyrogenic and that sets should not be used if visual inspection reveals that: the end caps or needles are not in place; there are kinks in the tubing; the set is assembled incorrectly; or the tubing is damaged.

No changes in the expiration dating of the products marketed by Gambro BCT have been made.

Conclusion:

The Functionally Closed White Blood Cell Tubing Set is substantially equivalent in quality and design to all tubing sets in the COBE Spectra family of disposables. As an option to the currently available sets for appropriate therapeutic procedures, there is no significant change in the safety and effectiveness of the device.