510(k) Summary

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DATE PREPARED:	August 17, 2005
DEVICE TRADE NAME:	COBE Angel Whole Blood Separation System
COMMON/USUAL NAME:	Platelet Separation/Concentration System
CLASSIFICATION:	Class II (Product Code JQC)
PREDICATE DEVICE:	Medtronic Magellan Autologous Platelet Separator System (K021902, BK030040)

DEVICE DESCRIPTION:

The COBE Angel Whole Blood Separation System consists of a blood centrifugation device and associated disposable processing set and whole blood access kit. The device is intended to be used at the patient's point-of-care for the safe and rapid preparation of platelet poor plasma and platelet rich plasma from a sample of whole blood. The plasma and concentrated platelets produced can be used for diagnostic tests. The platelet rich plasma can also be mixed with autograft and/or allograft bone prior to application to an orthopedic site as deemed necessary by the clinical use requirements.

The Blood Access Kit contains syringes, needles, anticoagulant, and a site preparation kit for collecting the blood to be processed with the Angel System. The Processing Set utilizes a variable volume separation chamber that separates autologous whole blood into red blood cells, platelet poor plasma, and platelet rich plasma. The Processing Set is provided sterile with a non-pyrogenic fluid pathway, and is for single patient use only. The Processing Set consists of the pre-connected variable volume separation chamber, a tubing set with a platelet sensor/valve assembly, and a three-compartment reservoir bag to hold the blood products (whole blood, red blood cells, and platelet poor plasma). A syringe is provided to collect the platelet rich plasma.

The primary features of the Angel System hardware are the centrifuge well and lid, roller pump, platelet sensor, valve assembly driver, touch screen user interface, and emergency stop switch. The platelet sensor detects the presence of the separated blood components as they exit the variable volume separation chamber, and switches the position of a rotating valve in the Processing Set to channel the individual blood components into their respective collection containers.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

A comparison of device features and test data demonstrate that the Angel Whole Blood Separation System is substantially equivalent to the currently marketed Medtronic Magellan Autologous Platelet Separator System.

Declarations of Conformity

The Angel System is in compliance with the following FDA recognized Consensus Standards:

IEC 60601-1:1988, A1:1991, A2:1995, and Corrigendum:1995, *Medical Electrical Equipment – Part 1: General Requirements for Safety*

IEC 60601-1-2:2002, *Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard, Electromagnetic Compatibility – Requirements and Tests*

ISO 10993-1:2003, *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing*

ANSI/AAMI/ISO 11135:1994, *Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*

ANSI/AAMI/ISO 10993-7:1995, *Biological Evaluation of Medical Devices - Part 7:Ethylene Oxide Sterilization Residuals*

A declaration of conformity to these standards can be found in Appendix 16.

Truthful and Accurate Statement

A statement attesting to the truthfulness and accuracy of the information contained in this submission is attached as Appendix 23.

Further Information

In the event that additional information is required, please contact:

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