

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE**

- A. 510(k) Number:
K042473
- B. Manufacturer and Instrument Name:
COBE Diagnostics, Inc., COBE Angel Whole Blood Separation System
- C. Type of Test or Tests performed:
Patient point-of-care preparation of platelet poor plasma and platelet rich plasma from a sample of whole blood.
- D. System Descriptions:
1. Device Description:
The Angel System consists of a blood centrifugation device and two associated disposables: the Processing Set (single use) and the Whole Blood Access Kit.
 2. Principles of Operation:
Whole blood collected either from the patient or a blood bag containing ACD anticoagulant is added to the whole blood compartment of the Processing Set. Upon initiation of the processing cycle, the blood is pumped from the whole blood chamber into the variable volume separation chamber where it is separated into RBCs, platelet poor plasma, and platelet rich plasma. The process involves a two-phase spin cycle consisting of a hard spin and a soft spin. Once the two-phase separation process is complete the machine slows the centrifuge and the process pump is reversed, allowing for collection of the various blood component layers.
 3. Modes of Operation:
N/A
 4. Specimen Identification:
Labels are used to identify collected whole blood and separated components.
 5. Specimen Sampling and Handling:
The Angel Whole Blood Separation Processing Set consists of pre-connected variable volume separation chamber, a tubing set with a platelet sensor/valve assembly, and a three-compartment reservoir bag for the collection of blood products.

6. Calibration:

The centrifuge is factory calibrated. Upon power-up, the system will perform an automatic self test. At this time, the valve assembly will also calibrate and reposition itself.

7. Quality Control:

N/A

8. Software:

FDA has reviewed the applicant's Hazard Analysis and software

Documentation: Yes X or No _____

E. Regulatory Information:

1. Regulation Section:

21 CFR 862.2050, General purpose laboratory equipment labeled or promoted for a specific medical use and 880.5860, Syringe, piston.

2. Classification:

Class II

3. Product Code:

FMF, JQC

4. Panel:

80 General Hospital, 75 Chemistry

F. Intended Use:

1. Indication(s) for Use:

The COBE Angel Whole Blood Separation System 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 can be used for diagnostic tests.

2. Special Condition for use Statement(s):

Components separated from whole blood cannot be used in vivo.

G. Substantial Equivalence Information:

1. Predicate device name(s) and 510(k) numbers:

Medtronic Magellan Autologous Platelet Separator System (K021902)

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Principle of Operation	Separation based on density of liquids	Same
Blood Component separation Method	Centrifuge	Same
Usage	Single	Same
Differences		
Item	Device	Predicate
Intended Use	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.	To be used in the clinical laboratory or intraoperatively at point-of-care for the safe and rapid preparation of platelet poor plasma and platelet rich plasma from a small sample of blood. The plasma and concentrated platelets can be used for diagnostic tests.
Processing Volume	40 to 180 cc/cycle with one cycle/processing set (min/max processing volume/set: 40-180 cc)	30 to 60 cc/cycle with three cycles/processing set (min/max processing volume/set: 30-180 cc)
PRP Collection	20 cc syringe	10 cc syringe
PPP Collection	Automatically collected into a separate compartment	Automatically collected into RBC syringe, or can be collected in a separate syringe.

H. Standard/Guidance Document Referenced (if applicable)

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

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

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

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

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

I. Performance Characteristics:

In Vitro testing was conducted to verify the performance of the Angel System compared to the Medtronic Magellan Autologous Platelet Separator. Platelet count and viability were measured from platelet rich plasma generated in both systems after processing fresh human blood.

The PRP platelet concentration was calculated as the number of platelets times the initial baseline count. These parameters were compared at minimum and maximum processing volumes as well as overall performance. The measurement of each parameter for each separation system was presented in tabular form in the submission.

Summary of Results:

1. There is no statistically significant difference between platelet counts and viability of the PRP produced at the minimum volume specifications of the Angel System vs. the Magellan System.
2. There is no statistically significant difference between platelet count and viability of the PRP produced at the maximum volume specifications of the Angel System and the Magellan System.
3. There is no statistically significant difference between platelet counts and viability of the PRP produced at any of the volumes tested (30ml, 40ml, and 60ml) on the Angel System and the Magellan System.

Conclusions:

No statistically significant difference was found between platelet viability and platelet yield of platelet rich plasma processed by the Angel System versus the Magellan System.

1. Analytical Performance:

- a. *Accuracy:*
N/A
- b. *Precision/Reproducibility:*
N/A
- c. *Linearity:*
N/A
- d. *Carryover:*

N/A
e. Interfering Substances:
N/A

2. Other Supportive Instrument Performance Data Not Covered Above:

J. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.