K962689

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510(k) SUMMARY

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DATE PREPARED:	July 8, 1996
DEVICE TRADE NAME:	Plasma Sequestration Option for the COBE® BRAT® 2 Autologous Blood Salvage System
COMMON NAME:	Plasma sequestration option for autologous blood salvage system
CLASSIFICATION NAME:	Autotransfusion Apparatus
PREDICATE DEVICES:	Plasma Recovery Program (PRP) for the COBE® BRAT® 2 Autologous Blood Salvage System Electromedics Autotransfusion Machine AT 500

DEVICE DESCRIPTION:

The COBE BRAT 2 Autologous Blood Salvage System with Modified Plasma Recovery Program (PRP) consists of a number of changes from the original Plasma Recovery Program for the COBE BRAT® 2 approved per 510(k) number K933960. These changes include:

- Expanded volume delivery range of 25 to 200 ml/min for the fill cycle of PRP
- Addition of a manual mode of operation for PRP
- Hardware and software modifications for detection and prevention of pump reversal
- Development of a disposables set to permit direct connection to the patient for blood collection
- Other minor changes to the software to improve usability of the BRAT 2 instrument

INDICATIONS FOR USE:

The COBE BRAT 2 is indicated for use for recovery and/or processing of autologous blood.

TECHNOLOGICAL CHARACTERISTICS:

The COBE BRAT 2 Autologous Blood Salvage System with Modified Plasma Recovery Program (PRP) is a modification of its predicate, the Plasma Recovery Program (PRP) for the COBE® BRAT® 2 Autologous Blood Salvage System.

Through software modifications, the process pump has the capability to run at a wider range of fill speeds for plasma sequestration purposes. Redundant hardware has been added for detection and prevention of pump direction reversal and hardware has been added to prevent clockwise pump rotation with the fill valve open which would result in fluid flow towards the patient if directly connected in a PRP mode of operation. Software modifications have also been made to create a manual mode of operation for plasma sequestration.

A disposable set for the COBE BRAT 2 with Modified PRP permits the collection, anticoagulation, and delivery of blood directly from the patient to the BRAT 2 instrument for plasma sequestration purposes, as is done in the predicate Electromedics AT 500 System.

NONCLINICAL TEST RESULTS:

The COBE BRAT 2 with Modified PRP was tested to assure that it met its functional specifications. In vitro blood testing was done to assure the performance of the modified system was comparable to the predicate BRAT 2 PRP system. In vitro testing consisted of plasma volume per liter of blood processed, plasma free hemoglobin generated per liter of blood processed, percent platelets harvested, percent white blood cells recovered, percent platelets recovered, percent red cells recovered, hematocrit in reinfused blood and hematocrit in collected plasma. In addition, human blood testing was performed with the direct draw set to measure platelet aggregation and pH following storage for 6 hours.

CLINICAL TEST RESULTS:

No clinical testing was performed.

CONCLUSIONS:

The COBE BRAT 2 Autologous Blood Salvage System with Modified Plasma Recovery Program (PRP), through hardware and software modifications and disposables design, is substantially equivalent to the Plasma Recovery Program (PRP) for the COBE BRAT 2 Autologous Blood Salvage System and the Electromedics Autotransfusion Machine AT 500.