K973627

NOV - 3 1997

Attachment (5)

510(k) Summary

510(k) Summary

SUBMITTER: COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, CO 80004

CONTACT PERSON: Lynne Leonard
Phone: (303)-467-6586
FAX: (303)-467-6429

DATE PREPARED: September 22, 1997

DEVICE TRADE NAME: Standard Volume Processing Set for the COBE BRAT® 2 Autologous Blood Salvage System

COMMON NAME: Standard Volume Processing Set for Autologous Blood Salvage System

PREDICATE DEVICE: Currently Marketed Standard Volume Processing Set for the COBE BRAT® 2 Autologous Blood Salvage System

DEVICE DESCRIPTION:

A Standard Volume BRAT® 2 Processing Set consists of a plastic disposable 250 ml centrifuge bowl, a tubing harness to connect the centrifuge bowl with other disposables, a waste bag, and a reinfusion bag. The tubing harness consists of tubing, a pump/valve cartridge, and various connectors.

Modifications to the BRAT® 2 Standard Volume Processing Set covered in this 510(k) consists of a design change to the internal spacer of the Baylor centrifuge bowl. No other material or design feature changes to the Processing Set disposables are required. No hardware or software changes are required to the BRAT® 2 instrument to support this device modification.

INDICATIONS FOR USE:

The COBE BRAT® 2 Standard Volume Processing Set is indicated for use for recovery and/or processing of autologous blood.

TECHNOLOGICAL CHARACTERISTICS:

The Modified BRAT® 2 Standard Volume Processing Set is a modification of its predicate device, (510(k) # K933625, K933625, K962689) the Current BRAT® 2 Standard Volume Processing Set. Through a change in part design, a fin feature located at the base of the internal spacer of the centrifuge bowl was added. This change is intended to modify the profile of the internal fluid pathway of the centrifuge bowl. Cellular Performance Characteristics, (i.e. Outlet Hct, Wash Efficiency), which are dependent on fluid pathway design are changed. The intent of this modification is to improve the Wash Efficiency of the device.

NONCLINICAL TEST RESULTS:

The Modified BRAT® 2 Standard Volume Processing Set was tested to assure that it met its functional specifications. In vitro blood testing was done to assure the performance of the modified device was comparable to the predicate device. In vitro bovine blood testing consisted of Blood Salvage test protocols and Plasma Sequestration test protocols. Human blood testing was also performed on the modified device in a laboratory setting at the Mayo Clinic, using Blood Salvage protocols.

The results find improved wash efficiency for the modified device based on reduction in estimated Heparin Load to Patient found in bovine Blood Salvage tests. Mayo Clinic test data for Heparin Load values generated per 1 liter of inlet blood volume processed, meet or exceed values recommended by Yawn[1] for blood salvage applications.

CLINICAL TEST RESULTS:

No clinical testing was performed.

CONCLUSION:

The Modified BRAT® 2 Standard Volume Processing Set is substantially equivalent to its predicate device, the Current BRAT 2 Standard Volume Processing Set.

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[1] Yawn, DH, Ensuring Quality Intraoperative Blood Salvage, LABORATORY MEDICINE, Vol. 25, No. 10, October 1994, p. 629.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lynne Leonard
Manager, Regulatory Submissions
COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, Colorado 80004-3599

NOV - 3 1997

Re: K973627
COBE® BRAT® 2 System with Modified Standard Volume Processing Set
Regulatory Class: II (Two)
Product Code: CAC
Dated: September 22, 1997
Received: September 24, 1997

Dear Ms. Leonard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html."

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

868.5830 - CAC II - Autotransfusion Apparatus

2. *Indications For Use*

510(k) Number (If known): K973627

Device Name: COBE® BRAT® 2 System with Modified Standard Volume Processing Set

Indications For Use:

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

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bette L. Compere

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K973627

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____