K991986

SEP 9 1999

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: June 10, 1999

DEVICE TRADE NAME: COBE® BRAT® 2 Autologous Blood Salvage System with *CRIT-LINE™* Hematocrit Sampling System

COMMON/USUAL NAME: Autologous Blood Salvage System with Hematocrit Sampling Option

CLASSIFICATION NAME: Autotransfusion Apparatus

PREDICATE DEVICE: COBE® BRAT® 2 Autologous Blood Salvage System

DEVICE DESCRIPTION:

The COBE® BRAT® 2 Autologous Blood Salvage System is being modified to add the *CRIT-LINE™* Hematocrit Sampling System, which will be used to measure the hematocrit of the finished red cell product as it is being emptied into the reinfusion bag. The *CRIT-LINE™* Hematocrit Sampling System will be offered as an option for the COBE® BRAT® 2 Autologous Blood Salvage System.

The purpose of the *CRIT-LINE™* Hematocrit Sampling System is to give the user a noninvasive, real-time measurement of the hematocrit of the red cell product in the reinfusion bag. It eliminates exposure of the clinician to collection of a blood sample. Because the *CRIT-LINE™* Hematocrit Sampling System measures the hematocrit of the blood ten times per second as it is being collected in the reinfusion bag, the system is able to capture changes in hematocrit as the blood is exiting the centrifuge bowl, and is able to provide a more representative hematocrit result based upon multiple sampling of the blood product, rather than on a single sample.

INDICATIONS FOR USE

The COBE® BRAT® 2 Autologous Blood Salvage System in indicated for use for the recovery and/or processing of autologous blood. The *CRIT-LINE™* Hematocrit Sampling System option is used in conjunction with the COBE® BRAT® 2 Autologous Blood Salvage System to measure the hematocrit of the finished product in the reinfusion bag.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The COBE® BRAT® 2 Autologous Blood Salvage System with *CRIT-LINE™* Hematocrit Sampling System is substantially equivalent to the currently marketed COBE® BRAT® 2 Autologous Blood Salvage System. The two devices are identical with the exception of the addition of the *CRIT-LINE™* Hematocrit Sampling System option with its associated hardware, software, and disposables. Otherwise, the intended use,

specifications, method of operation, accessories, design, and features, of the COBE® BRAT® 2 Autologous Blood Salvage System remain the same.

Testing of the COBE® BRAT® 2 Autologous Blood Salvage System with *CRIT-LINE™* Hematocrit Sampling System consisted of:

1. Electrical safety testing in accordance with EN 60601-1: International Standard for Medical Electrical Equipment, Part 1
2. Electromagnetic immunity testing in accordance with EN60601-1-2: International Standard for Medical Electrical Equipment, Part 1.2
3. Electromagnetic emmisions testing in accordance with EN 55011: Limits and Methods of Measurement of Radio Distrubance Characteristics of Industrial, Scientific, and Medical Radio-Frequency Equipment
4. Hematocrit performance testing in accordance with the *CRIT-LINE™* product specifications using human blood

These data support substantial equivalence of the COBE® BRAT® 2 Autologous Blood Salvage System with *CRIT-LINE™* Hematocrit Sampling System to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 9 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K991986
Trade Name: COBE® BRAT® 2 Autologous Blood Salvage System with CRIT-LINE™ Hematocrit Sampling System Option
Regulatory Class: II
Product Code: CAC, KOC
Dated: June 10, 1999
Received: June 14, 1999

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 legally marketed predicate 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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) 594-4588. 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/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. Indications For Use

510(k) Number (If known): K991986

Device Name: COBE® BRAT® 2 System with *CRIT-LINE*™ Hematocrit Sampling System Option

Indications For Use:

The COBE BRAT 2 is indicated for use for the recovery and/or processing of autologous blood. The *CRIT-LINE* Hematocrit Sampling System option is used in conjunction with the BRAT 2 System to measure the hematocrit of the finished product in the reinfusion bag.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991986

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)