SEP 10 1998

K982254

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 25, 1998

DEVICE TRADE NAME: COBE® *Sentry®* SMAR$_x$T™ 43 Micron Arterial Filter with PrimeGard®

COMMON/USUAL NAME: Arterial Filter

CLASSIFICATION NAMES: Cardiopulmonary Bypass Arterial Line Blood Filter

PREDICATE DEVICE: COBE® *Sentry®* 43 Micron Arterial Filter with PrimeGard®

DEVICE DESCRIPTION:

The COBE® *Sentry®* SMAR$_x$T™ 43 Micron Arterial Filter with PrimeGard® is a sterile device with a non-pyrogenic fluid pathway. It is for single use only and is not to be resterilized by the user. The device is indicated for use in the arterial line of an extracorporeal circuit during cardiopulmonary bypass procedures, for periods of up to six hours. It is designed to filter out micro-particles introduced through the arterial line of a cardiopulmonary bypass circuit.

The *Sentry®* SMAR$_x$T™ Arterial Filter consists of a transparent cap and casing with 3/8" barbed inlet and outlet ports. The cap has an integral luer lock vent/purge port. The filter cartridge consists of a 43 micron screen filter media, fan-folded with support netting. The filter cartridge is attached to an internal support which minimizes the blood volume within the device and directs blood flow. Blood coming into the device contacts the flow director plate of the support, which slows the blood flow to facilitate removal of air. The PrimeGard® heparin coating enhances air removal during priming. The *Sentry®* SMAR$_x$T™ Arterial Filter contains surface-modifying additives that improve the blood compatibility of the device.

INDICATIONS FOR USE

The COBE® *Sentry®* SMAR$_x$T™ 43 Micron Arterial Filter with PrimeGard® is indicated for use in the arterial line of an extracorporeal circuit during cardiopulmonary bypass procedures, for periods of up to six hours.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The COBE® *Sentry®* SMAR$_x$T™ 43 Micron Arterial Filter with PrimeGard® has the same intended use as currently marketed COBE® *Sentry®* 43 Micron Arterial Filter with PrimeGard®. The primary difference is that the COBE® *Sentry®* SMAR$_x$T™ 43 Micron Arterial Filter with PrimeGard® contains non-leaching, surface modifying additives that are added to the device to improve blood compatibility.

Biocompatibility and performance tests were performed to demonstrate that the COBE® *Sentry®* SMAR$_x$T™ 43 Micron Arterial Filter with PrimeGard® is substantially equivalent to the currently marketed COBE® *Sentry®* SMAR$_x$T™ 43 Micron Arterial Filter with PrimeGard®.

Performance testing consisted of:

1. Mechanical Integrity
2. Air Challenge
3. Pressure Drop
4. Blood Trauma (including platelet reduction, white blood cell reduction, and plasma free hemoglobin generation)
5. Filtration Efficiency
6. Ease of Prime
7. Priming Volume

In-vitro testing was also performed to demonstrate improved blood compatibility of the materials containing the surface modifying additives.

These data support that the COBE® *Sentry®* SMAR$_x$T™ 43 Micron Arterial Filter with PrimeGard® is substantially equivalent to the currently marketed COBE® *Sentry®* 43 Micron Arterial Filter with PrimeGard®, and that the addition of the surface-modifying materials does not affect safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 1998

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

Re: K982254
COBE® *Sentry®* SMAR$_x$T™ 43 Micron Arterial Filter with PrimeGuard®
Regulatory Class: III (three)
Product Code: DTM
Dated: June 25, 1998
Received: June 26, 1998

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.

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" (21CFR 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,

Thomas J. Callahan

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

Enclosure

Indications For Use

510(k) Number (If known): K982254

Device Name: COBE® *Sentry®* SMAR$_x$T™ 43 Micron Arterial Filter with PrimeGard®

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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 Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982254

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