K981613

OCT 26 1998

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:	August 6, 1998
DEVICE TRADE NAME:	COBE® SMAR$_x$T™ Tubing and Connectors
COMMON/USUAL NAME:	Cardiopulmonary Bypass Tubing and Connectors
CLASSIFICATION NAMES:	Cardiopulmonary Bypass Pump Tubing Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting
PREDICATE DEVICE:	COBE® Tubing and Connectors

DEVICE DESCRIPTION:

The COBE® SMAR$_x$T™ Tubing and Connectors are sterile devices with non-pyrogenic fluid pathways, for single use only, and are not to be resterilized by the user. The devices are used in connecting oxygenators, reservoirs, filters, and other cardiopulmonary bypass components into circuits used in surgical procedures requiring extracorporeal support. The tubing may also be used in roller-type cardiopulmonary bypass blood pumps. In particular, tubing sizes with a 3/32 inch wall thickness are used in the pump head of a roller-type cardiopulmonary bypass blood pump, where the tubing is cyclically compressed by the pump to cause blood to flow through the cardiopulmonary bypass circuit.

COBE® SMAR$_x$T™ Tubing is polyvinyl chloride (PVC) tubing ranging in size from 0.075" ID x 0.028" wall to 5/8" ID x 1/8" wall. COBE® SMAR$_x$T™ Connectors are of the following generic types: straight with or without luer port, reducer with or without luer port, Y with or without luer port, male or female luer locks, and saturation/hematocrit monitor connectors.

INDICATIONS FOR USE

The COBE® SMAR$_x$T™ Tubing and Connectors are intended to be used in surgical procedures requiring extracorporeal support for periods of up to six hours.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The COBE® SMAR$_x$T™ Tubing and Connectors have the same intended use as currently marketed COBE® Tubing and Connectors. The primary difference is that the COBE® SMAR$_x$T™ Tubing and Connectors contain a non-leaching, surface modifying additive that is added to the formulation prior to fabrication to improve blood compatibility.

Biocompatibility and performance tests were performed to demonstrate that the COBE® SMAR$_x$T™ Tubing and Connectors are substantially equivalent to the currently marketed COBE® Tubing and Connectors.

Performance testing consisted of:

Bond Strength
Static Leak Test
Rated Pressure
Kink Resistance
Tubing Pump Life
Tubing Spallation
Saturation/Hematocrit Connector Testing

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

These data support that the COBE® SMAR$_x$T™ Tubing and Connectors are substantially equivalent to the currently marketed COBE® Tubing and Connectors, and that the addition of the surface-modifying material does not affect safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 1998

Ms. Lynne Leonard
Manager, Regualtory Submissions
COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, CO 80004

Re: K981613
COBE® SMARxT™ Tubing and Connectors
Regulatory Class: II (Two)
Product Code: DWE
Dated: August 7, 1998
Received: August 11, 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): K981613

Device Names: COBE® SMAR$_x$T™ Tubing and Connectors

Indications For Use:

COBE® SMAR$_x$T™ Tubing and Connectors are intended to be used in surgical procedures requiring extracorporeal support for periods of up to six hours.

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 K981613

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