JUN 1 4 2000

510(k) Summary

SUBMITTER:
Stockert Instrumente GmbH
Division of Sorin Biomedica SpA
Lilienthalalle 5-7
D-80939 Munich Germany

APPLICANT:
COBE Cardiovascular, Inc.
Division of Sorin Biomedica SpA
14401 W. 65th Way
Arvada, Colorado 80004-3599 USA

CONTACT PERSON:
Lynne Leonard
Regulatory Affairs Manager
COBE Cardiovascular, Inc.
Arvada, Colorado USA
Phone: (303) 467-6586
Fax: (303) 467-6429

DATE PREPARED:
November 22, 1999

DEVICE TRADE NAME:
Stockert V142 Series Venous Cannulae with Lighthouse Tip

COMMON/USUAL NAME:
Cardiovascular Venous Cannulae

CLASSIFICATION NAME:
Cardiopulmonary Bypass Vascular Catheter, Cannula or Tubing

PREDICATE DEVICE:
Baxter Research Medical Inc. Single Stage Venous Return Cannula Wire Reinforced with Lighthouse Tip

DEVICE DESCRIPTION:

The Stockert V142 Series Venous Cannulae with Lighthouse Tip are sterile, non-pyrogenic devices, for single use only, and are not to be resterilized by the user. The devices are single stage, wire reinforced venous cannulae with a distal open lighthouse tip. They are intended to be used to cannulate the venous vessels during cardiopulmonary bypass surgery.

The product will be offered for sale in various french sizes ranging from 28 Fr to 36 Fr.

The Stockert Venous Cannulae with Lighthouse Tip are composed of two components, the cannula tube and the lighthouse tip. Encapsulated within the cannulae outer wall is a helically wound stainless steel wire which allows the cannula tube to resist kinking. The length of the device is 40 cm.

INDICATIONS FOR USE

The Stockert V142 Series Venous Cannulae with Lighthouse Tip are intended to be used for cannulating the major venous vessels during cardiopulmonary bypass surgery.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The Stockert Venous Cannulae with Lighthouse Tip are substantially equivalent to the Baxter Research Medical Inc. Single Stage Venous Return Cannula Wire Reinforced with Lighthouse Tip. The devices are both single stage, wire reinforced venous return cannulae with an open lighthouse tip on the distal end and

without a connector on the proximal end. The Stockert Venous Cannulae are 40 cm in length, accept a 3/8" connector, and will be offered in sizes from 28 Fr to 36 Fr. The Baxter RMI Venous Cannulae are 35 to 40 cm in length, accept a 3/8" connector, and are offered in sizes from 26 Fr to 40 Fr.

The following tests were performed to demonstrate substantial equivalency of the Stockert V142 Series Venous Cannulae with Lighthouse Tip to the Baxter Research Medical Inc. Single Stage Venous Return Cannula Wire Reinforced with Lighthouse Tip:

1. Pressure Drop
2. Blood Trauma
3. Leak
4. Kink Resistance
5. Bond Strength
6. Dimensional Inspection Post-sterilization and Post-aging

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 14 2000

Ms. Lynne Leonard
Regulatory and Clinical Affairs Manager
COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, CO 80004-3599

Re: K994209
Stockert V142 Series Venous Cannulae with Light
Regulatory Class: II (two)
Product Code: DWF
Dated: May 12, 2000
Received: May 15, 2000

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,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications For Use

510(k) Number (If known): K994209

Device Name:

Stockert V142 Series Venous Cannulae with Lighthouse Tip

Indications For Use:

The Stockert V142 Series Venous Cannulae with Lighthouse Tip are intended to be used for cannulating the superior or the inferior vena cava during standard ~~cardiopulmonary~~ bypass surgery.

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 K994209

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____