K022321
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510(K) SUMMARY

OCT 0 9 2002

SUBMITTER: Stöckert Instrumente GmbH
Lindberghstr.25
D-80939 Munich Germany

APPLICANT: COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, Colorado 80004-3599 USA

CONTACT PERSON: Shawn Riedel
Regulatory and Quality Assurance Manager
COBE Cardiovascular, Inc.
Arvada, Colorado USA
Phone: (303) 467-6521
Fax: (303) 467-6525
Email: shawn.riedel@cobecv.com

DATE PREPARED: 11 July 2002

DEVICE TRADE NAME: Stöckert V172-28 Venous Femoral Cannula

COMMON/USUAL NAME: Cardiovascular Femoral Cannula

CLASSIFICATION NAME: Cardiopulmonary Bypass Vascular Catheter, Cannula or Tubing

PREDICATE DEVICE: Medtronic DLP Venous Femoral Cannula

DEVICE DESCRIPTION:

The Stöckert V172-28 Venous Femoral Cannula is a sterile, non-pyrogenic device, for single use only, and is not to be resterilized by the user. The device is a polyvinyl chloride (PVC) wire reinforced Cannula with a non-wire reinforced proximal end for clamping and for connecting the device to a cardiopulmonary bypass circuit. The Stöckert V172-28 Cannula is intended to be used to cannulate the femoral venous vessels during cardiopulmonary bypass surgery. During use, the cannula is inserted into the vena femoralis and advanced into the right atrium, allowing blood from the systemic circulation to enter the extracorporeal circuit. Insertion of the cannula into the vena femoralis during cardiopulmonary bypass surgery is an alternative method for insertion of a cannula into the superior or inferior vena cava.

The Stöckert V172-28 Cannula is 28 Fr and 90 cm in length, with a flexible proximal end that can accommodate a 1/2" connector. The cannula tube contains two sets of side holes, one set for drainage from the right atrium and one set for drainage from the inferior vena cava and hepatic veins. An obturator is provided with each cannula, which seals the inside of the cannula tube in the areas of the side holes to prevent blood leakage from the cannula during insertion. After insertion, the obturator is removed and discarded by the user.

INDICATIONS FOR USE

The Stöckert V172-28 Venous Femoral Cannula is intended to be used to cannulate the inferior vena cava and the right atrium via femoral access during cardiopulmonary bypass surgery for periods up to six hours.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The Stöckert V172-28 Venous Femoral Cannula are substantially equivalent to the Medtronic DLP Venous Femoral Cannula. The following tests were performed to demonstrate substantial equivalency of the devices:

1. Pressure Drop
2. Blood Trauma
3. Leak
4. Kink Resistance

TRUTHFUL AND ACCURATE STATEMENT

A statement attesting to the truthfulness and accuracy of the information contained in this submission is attached as Appendix 11.

FURTHER INFORMATION

In the event that additional information is required, please contact the following individual at COBE Cardiovascular, Inc. the applicant of this 510(k) notification, submitting on behalf of the manufacturer and specification holder of the product, Stöckert Instrumente GmbH, Munich, Germany:

Shawn Riedel
Manager, Regulatory and Quality Assurance
COBE Cardiovascular, Inc.
14401 West 65th Way
Arvada, Colorado 80004-3599 USA
Phone: (303) 467-6521
Fax: (303) 467-6525
Email: shawn.riedel@cobecv.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 9 2002

Stöckert Instrumente GmbH
c/o Mr. Shawn Riedel
COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, CO 80004-3599

Re: K022321
Stöckert V172-28 Venous Femoral Cannula
Regulation Number: 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, and Tubing
Regulatory Class: II (two)
Product Code: DWF
Dated: July 12, 2002
Received: July 17, 2002

Dear Mr. Riedel:

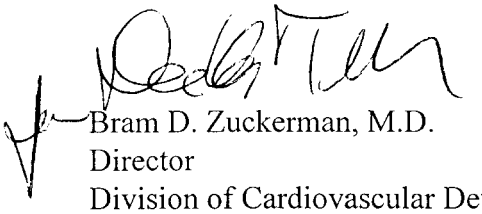
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022321

Indications For Use

510(k) Number (If known): K022321

Device Name:

Stöckert V172-28 Venous Femoral Cannula

Indications For Use:

The Stöckert V172-28 Venous Femoral Cannula is intended to be used to cannulate the inferior vena cava and the right atrium via femoral access during cardiopulmonary bypass surgery for periods 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)

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

Division of Cardiovascular & Respiratory Devices
510(k) Number K022321