 K023622

NOV 21 2002

510(k) Summary

SUBMITTER: Stöckert Instrumente GmbH
Lindberghstrasse 25
D-80939 Munich Germany

CONTACT PERSON: Mr. Helmut Höfl
Director, Quality and Regulatory Affairs
Phone: 49-89-323-010
Fax: 49-89-323-01100

DATE PREPARED: September 5, 2002

DEVICE TRADE NAME: Stöckert Pediatric Aortic Cannulae, A272-15 through A272-35

COMMON/USUAL NAME: Cardiovascular Aortic Cannulae

CLASSIFICATION NAME: Cardiopulmonary Bypass Vascular Catheter, Cannula or Tubing

PREDICATE DEVICE: Jostra Arterial Perfusion Cannulae

DEVICE DESCRIPTION:

The Stöckert Pediatric Aortic Cannulae, A272-15 through A272-35 are sterile, non-pyrogenic devices, for single use only, and are not to be resterilized by the user. The devices are wire reinforced aortic cannulae with a curved distal tip.

The cannulae are comprised of two components, the cannula tube and the curved tip. Encapsulated within the cannula outer wall is a helically wound stainless steel wire which allows the cannula tube to resist kinking. The devices range in diameter from 4.5 to 10.5 Fr and have an overall length of 22 cm.

INDICATIONS FOR USE

The Stöckert Pediatric Aortic Cannulae are designed to be used as perfusion cannulae to return arterial blood from the extracorporeal circuit to the patient during cardiopulmonary bypass up to six hours or less.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

In-vitro performance and biocompatibility tests demonstrate substantial equivalence of the Stöckert Pediatric Aortic Cannulae to the Research Medical Inc. Pediatric Aortic Cannula. The devices share the same intended use and overall design features (flexible tapered aortic cannula with a distal tip including suture ring, and without an attached connector).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2002

Stöckert Instrumente GMBH
c/o Ms. Lynne Leonard
Leonard Regulatory Consulting
20193 Goins Drive
Morrison, CO 80465

Re: K023622
Stöckert Pediatric Aortic Cannulae (Models A272-15 through A272-35)
Regulation Number: 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, and Tubing
Regulatory Class: Class II (two)
Product Code: DWF
Dated: October 28, 2002
Received: October 29, 2002

Dear Ms. Leonard:

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), please contact the Office of Compliance at (301) 594-4548. 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

Indications For Use

510(k) Number (If known): K023622

Device Name:

Stöckert Pediatric Aortic Cannulae (Models A272-15 through A272-35)

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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 of Cardiovascular & Respiratory Devices
510(k) Number K023622

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