NOV 0 6 2001

K012617

510 (K) Summary

Submitter:	Jostra AG Hechinger Straße 38 72145 Hirrlingen Germany
Contact Person:	Kathleen Johnson Phone: (610) 932-7738 Fax: (610) 932-7366
Date Prepared:	June 21, 2001
Device Trade Name:	Jostra Pediatric Arterial Cannulae
Common/Usual Name:	Pediatric Arterial Cannulae
Classification Names:	Cardiopulmonary Bypass Vascular Cannula Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting
Predicate Device:	Medtronic DLP Pediatric Arterial Cannulae

Device Description:

The Jostra Pediatric Arterial Cannulae are single, sterile devices for single use only and not to be resterilized by the user. The cannulas are to be used to return arterial blood to the patient via the aortic root or other large artery during extracorporeal circulation. The cannulaer are made from polyvinyl chloride (PVC) and range in size from 8fr. to 16fr. with a variety of tips, with or without attached connectors. The cannulas are specifically designed for pediatric use.

Indications for use:

The Jostra Pediatric Arterial Cannulae are designed to be used as perfusion cannulae to return arterial blood from the extracoproeal circuit to the patient during cardiopulmonary bypass up to 6 hours or less.

Statement of Technical Characteristics Comparison:

The Jostra Pediatric Cannulae have the same intended use as the Medtronic DLP Pediatric Cannulae. The wire-wound 8fr. to 16fr. Sizes from Medtronic are not available with a curved tip, and come with a "Flow-Guard" Style introducer. The Jostra Pediatric Cannulae provide the user with the option of a curved tip, and a vent plug for safe de-airing. Comparative testing has demonstrated that these differences do not affect safety and effectiveness.

Non-Clinical Testing:

Biocompatibility and performance testing was performed to demonstrate substantial equivalency to the predicate device.

Performance testing included:

Flow-Pressure curves
Kink Resistance
Bond Strength
Leakage Test

Additionally, in-vitro testing was performed to determine the effects on cellular components.

Conclusion:

Performance, and in-vitro testing demonstrate that the Jostra Pediatric Arterial Cannulae are "substantially equivalent" to the predicate devices in intended use, principles of operation, materials, design, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 6 2001

Ms. Kathleen Johnson
Regulatory Affairs, Submission Manager
Jostra AG
c/o Jostra-Bentley Corporation
478 Media Road
Oxford, PA 19363

Re: K012617
Trade Name: Jostra Arterial Perfusion Cannulae
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing.
Regulatory Class: Class II (two)
Product Code: DWF
Dated: June 29, 2001
Received: August 13, 2001

Dear Ms. Johnson:

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,

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

Enclosure

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K012617

510(k) Number:

Device Name: Arterial Cannulae (paediatric)

Indications for Use
The Jostra Pediatric Arterial Cannulae are designed to be used as perfusion cannulae to return arterial blood from the extracoproeal circuit to the patient during cardiopulmonary bypass up to 6 hours or less.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Division of Cardiovas...
510(k) Number K012617