K022022

510 (K) Summary

SEP 11 2002

Submitter:	Jostra AG Hechinger Straße 38 72145 Hirrlingen Germany
Contact Person:	Kathleen Johnson P. O. Box 218 Oxford, PA 19363 Phone: (610) 932-7738 Fax: (610) 932-7366
Date Prepared:	May 29, 2002
Device Trade Name:	Jostra Vent Catheter
Common/Usual Name:	Cardiac Vent Catheter
Classification Names:	Cardiopulmonary Bypass Vascular Catheter, Cannula and Tubing
Predicate Device:	Medtronic DLP Left Heart Vent Catheters Edwards Lifesciences Research Medical Vent Catheters

Device Description:

The Jostra Vent Catheters are sterile devices for single use only and are not to be resterilized by the user. They are designed for use in venting the left ventricle during cardiopulmonary bypass surgery. The catheter is inserted into the left ventricle via the pulmonary vein, cardiac auricle or cardiac apex. The catheters are made of polyvinyl chloride and are available in a variety of sizes. They are also available in a variety of configurations (straight or bent tip, with or without wire reinforcement, with or without an integrated stylet, with or without a vacuum valve, malleable and non malleable). The catheters range from 8 to 18 French and are offered in lengths from 23 to 40 cm.

Indications for use:

The Jostra Vent Catheters are used to drain blood or fluid from the left ventricle during cardiopulmonary bypass surgery up to 6 hours or less.

Statement of Technical Characteristics Comparison:

The Jostra Vent Catheters have the same intended use and similar design as the Medtronic DLP and Edwards Lifesciences Research Medical Vent Catheters. The Jostra Vent Catheters range from 8 to 18 French and are 23 to 40 cm in length. The Medtronic DLP Vent Catheters range from 10 to 20 French and are 33 and 41 cm in length. The Edwards Lifesciences Research Medical device is a 20Fr. O.D. and 36.8 cm long. Comparative testing has demonstrated that the 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 of the smallest and largest models included:

Kink stability
Leak testing
Tensile strength testing

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

Conclusion:

Performance and in-vitro testing demonstrate that the Jostra Vent Catheters 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

SEP 11 2002

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

Re: K022022
Trade Name: Vent Catheters
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing
Regulatory Class: Class II (two)
Product Code: DWF and DRA
Dated: May 29, 2002
Received: June 20, 2002

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,

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

Enclosure

510(k) Number:

Device Name: Vent Catheters

Indications for Use

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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)

(Optional Format 3-10-98)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022022

Prescription Use X
(Per 21 CFR 801.109)