510 (K) Summary

DEC 1 4 2001

K013939

Submitter: Jostra AG
Hechinger Straße 38
72145 Hirrlingen
Germany

Contact Person: Kathleen Johnson
Phone: (610) 932-7738
Fax: (610) 932-7366

Date Prepared: October 15, 2001

Device Trade Name: Jostra Flowprobe FP-32E

Common/Usual Name: Flowprobe

Classification Names: Extracorporeal Blood Flow Probe

Predicate Device: Medtronic-BioMedicus DP-38 Bio-Probe

Device Description:

The Jostra Flowprobe FP-32E is a single, sterile device for single use only and not to be resterilized by the user. The flowprobe is to be used to measure blood flow during extracorporeal circulation. The flowprobe is made from polycarbonate and is available in a 3/8" size.

Indications for use:

The Jostra Flowprobe FP-32E is intended to be used as a flow measuring device in procedures requiring extracorporeal circulation for 6 hours or less.

Statement of Technical Characteristics Comparison:

The Jostra Flowprobe FP-32E has the same intended use as the Medtronic BioMedicus DP-38 flow probe. The Flowprobe FP-32E is a 3/8" polycarbonate probe. The Medtronic BioMedicus DP-38 flow probe is a 3/8" acrylic probe. Comparative testing has demonstrated that this difference does 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:

Functional testing
Flow measurement accuracy
Pressure testing
Electrical safety

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

Conclusion:

Performance, and in-vitro testing demonstrate that the Jostra Flowprobe FP-32E is "substantially equivalent" to the predicate device 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

DEC 1 4 2001

Jostra AG
c/o Mr. Ned E. Devine, Jr.
Entala, Inc.
3033 Madison Avenue SE
Grand Rapids, MI 49548

Re: K013939
Trade Name: Jostra Flowprobe FP-32E
Regulation Number: 21 CFR 870.2120
Regulation Name: Extravascular Blood-Flow Probe
Regulatory Class: Class II (two)
Product Code: DPT
Dated: October 15, 2001
Received: November 29, 2001

Dear Mr. Devine:

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,

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

Enclosure

510(k) Number (if known):

Device Name: Flowprobe FP-32E

Indications for Use:

The Jostra Flowprobe FP-32E is indicated for use as a flow measuring device to be used in conjunction with an electromagnetic blood flow transducer as a direct product substitution for the Medtronic BioMedicus flowprobe DP-38 in extracorporeal circuits for up to 6 hours.

(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 K013957

(Optional Format 3-10-98)

Prescription Use ✓
(Per 21 CFR 801.109)