AUG 19 1999

K984338

SUBSTANTIAL EQUIVALENCE SUMMARY

This summary follows the format of the FDA 510(k) Substantial Equivalence Decision-Making Process document.

EQUIVALENT (PREDICATE) DEVICE: **K943803**
Jostra HL-20 Single Head Roller Pump

MANUFACTURED BY: **Jostra, AB**
Lund, Sweden

A. Does the Jostra HL-20 Twin Pump have the same indications statements?

Yes, the Jostra HL-20 Twin Pump and the Jostra HL-20 Single Head Roller Pump have the same intended use which is for use as an extra corporeal circulation device for perfusion appropriate to cardiopulmonary bypass procedures of six hours or less.

B. Does the Jostra HL-20 Twin Pump have the same technological characteristics, e.g., design, materials, etc.?

Yes, both products have the same technological characteristics. The materials are the same and essentially, the HL-20 Twin Pump is two half-scale predicate pumps in the same size module as the predicate device.

C. Could the new characteristics affect safety and effectiveness?

The safety and effectiveness are not affected due to the modification to the predicate device. If anything, the new product is more effective, due to its capacity of lower flow rates which are necessary during procedures such as pediatric perfusion, cardioplegia delivery, suction or venting.

The occlusion locking mechanism on the Twin Pump model does not have a stop to hold it in the open position (for adjusting occlusion) as on the predicate device. This is due to size limitations on the smaller pump head, but this change is not deemed to have an adverse effect on safety and efficacy.

D. Do the new characteristics raise new types of safety or effectiveness questions?

No, none of the changes to the predicate device are deemed to have an adverse effect on safety or efficacy.

E. Do acceptable scientific methods exist for assessing effects of the new characteristics?

N/A

F. Are performance data available to assess the effects of new characteristics?

Yes, performance data is included in Attachment # 5.

G. Do performance data demonstrate equivalence?

Yes, it is evident from the data provided that the Twin Pump performs within its specifications and also within acceptable limits for performance standards such as

General:	EN93/42:	EU Council Directive 93/42/EEC concerning Medical Devices
Constructional Safety:	IEC 601-1:	IEC 601-1, 2nd Edition: 1988 Safety of Medical Electircal Equipment, Part 1: General Requirement (Identical with DIN VDE 0750 Part 1)
Electromagnetic Compatibility:	EU 89/336: IEC 601-1-2:	EMC Directive 89/336/EEC 1993 Electromagnetic Compatibility (Identical with DIN VDE 0750, Part 1-2)

CONCLUSION:

Jostra AB has provided data in this pre-market notification submission, which demonstrate that the HL-20 Twin Pump model is similar in materials, design and function to that of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 1999

Ms. Kathy Johnson
Product Manager
Jostra USA
478 Media Road
Oxford, PA 19363

Re: K984338
Jostra HL-20 Twin Pump
Regulatory Class: II (TWO)
Product Code: DPW
Dated: August 4, 1999
Received: August 6, 1999

Dear Ms. Johnson:

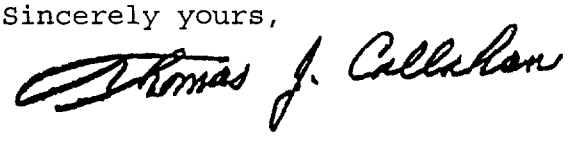
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K984338

Device Name: Jostra HL-20 Twin Pump

Indications for Use:

The Jostra HL-20 Twin Pump is intended for use as an extra corporeal circulation device for perfusion appropriate to cardiopulmonary bypass procedures of six hours or less. It is only intended for use with the Jostra HL-20 Heart Lung Machine.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K984338

(Optional Format 3-10-98)