K070605

JAN - 4 2008

MAQUET

510 (K) Summary [as required by 21 CFR 807.92(c)]

Submitter:	Maquet Cardiopulmonary AG Hechinger Strasse 38 72145 Hirrlingen Germany
Contact Person:	Katrin Schwenkglenks Phone: +49 7478 921-151 Fax: +49 7478 921-400 E-mail: katrin.schwenkglenks@maquet-cp.com
Date Prepared:	February 28, 2007
Device Trade Name:	Jostra Venous Softbag Reservoirs with and without Safeline Coating
Common/Usual Name:	Venous Reservoir Bag
Classification Names:	Reservoir, Blood, Cardiopulmonary Bypass (21 CFR 870.4400, product code: DTN)
Predicate Devices:	BMR 1900 Soft-Shell Venous Reservoir, Cobe Cardiovascular Inc. (K050111), MVR 800 Collapsible Venous Reservoir Bag, Medtronic Inc. (K920774) RotaFlow Centrifugal Pump with Safeline Coating (K061072)

Device Description

The Venous Softbag Reservoir is used in extracorporeal circuits during cardiopulmonary bypass surgery and serves as container for a certain blood volume. It consists of plastic foils which are welded together and between which tubes of different diameters and a polyester mesh are sandwiched. The polyester mesh serves for an improved air removal. Application duration: The utilization period of this device is restricted to six hours. The softbag reservoir is delivered sterile and is determined for single use only.

The group of Venous Softbag Reservoirs consists of a variety of models which differ in size (filling volume) and in the port sizes. The filling volumes of the reservoirs range from 650 ml to 1900 ml depending on the model and the ports are either 3/8" or ½" in size.

Statement of Indications for Use

The Jostra Venous Softbag Reservoirs are indicated for use in extracorporeal circuits during cardiopulmonary bypass procedures in the field of open-heart-surgery. The utilization period of this device is restricted to six hours. Blood contact longer than 6 hours is not recommended. Application and use of the softbag reservoir is in the sole responsibility of the respective physician.

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Statement of Technical Characteristics Comparison
Maquet Cardiopulmonary AG has compared indications for use, design, specifications, performance characteristics and safety of the Jostra Venous Softbag Reservoirs with and without Safeline Coating and of the predicate devices.

In-vitro testing on safety and effectiveness was executed to demonstrate that the Jostra Venous Softbag Reservoirs with and without Safeline Coating described in this submission are substantially equivalent to the named predicate devices.

The following areas have been tested:

- Integrity
- Performance
- Stability of the coating
- Biocompatibility
- Sterility

Conclusion
The Jostra Venous Softbag Reservoirs with and without Safeline Coating are substantially equivalent to the named predicate devices that currently hold market clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 2008

Maquet Cardiopulmonary AG
c/o Ms. Katrin Schwenkglenks
Regulatory Affairs Manager
Hechinger Strasse 38
72145 Hirrlingen, Germany

Re: K070605
Jostra Venous Softbag Reservoirs with and without Safeline
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary bypass blood reservoir
Regulatory Class: Class II (two)
Product Code: DTN
Dated: December 20, 2007
Received: December 26, 2007

Dear Ms. Schwenkglenks:

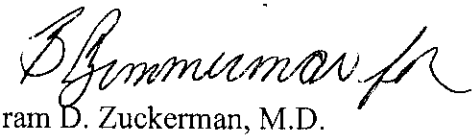
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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): K070605

Device Name: Jostra Venous Softbag Reservoir with and without Safeline Coating __

Indications for Use:

The Jostra Venous Softbag Reservoirs are indicated for use in extracorporeal circuits during cardiopulmonary bypass procedures in the field of open-heart-surgery. The utilization period of this device is restricted to six hours. Blood contact longer than 6 hours is not recommended. Application and use of the softbag reservoir is in the sole responsibility of the respective physician.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070605

(Posted November 13, 2003)