K061743

JUL 21 2006

MAQUET

Special 510(k): Device Modification: Venous Hardshell Cardiotomy Reservoirs with Safeline Coating

510(k) SUMMARY

SUBMITTER:	Maquet Cardiopulmonary AG Hechinger Strasse 38 72145 Hirrlingen, Germany
CONTACT PERSON:	Katrin Schwenkglenks Phone: (011) 49 7478 921- 151 Fax: 011 49 7478 921- 400
DATE PREPARED:	June 16, 2006
DEVICE TRADE NAME:	Jostra Venous Hardshell Cardiotomy Reservoirs with Safeline Coating
COMMON/USUAL NAME	Venous Reservoirs
CLASSIFICATION NAME	Cardiopulmonary bypass blood reservoir Cardiopulmonary bypass defoamer Cardiopulmonary bypass cardiotomy suction line blood filter
PREDICATE DEVICES OR LEGALLY MARKETED DEVICES	Jostra Venous Hardshell Cardiotomy Reservoirs (K982136, K003551) Jostra RotaFlow Centrifugal Pump with Safeline Coating (K061072)

DEVICE DESCRIPTION/INDICATONS FOR USE STATEMENT

The Jostra Venous Hardshell Cardiotomy Reservoir (non-vacuum-tight model) is designed to collect, store and filter the blood in an extracorporeal circuit during cardiopulmonary bypass procedures up to six hours in adult surgery . It can be integrated into almost all perfusion systems. The Jostra Venous Hardshell Cardiotomy Reservoir is designed and sold for use only as indicated.

The Jostra Venous Hardshell Cardiotomy Reservoir (vacuum-tight model) is designed to collect, store and filter the blood in an extracorporeal circuit during cardiopulmonary bypass procedures with or without vacuum assisted venous return up to six hours in adult surgery . It can be integrated into almost all perfusion systems. The Jostra Venous Hardshell Cardiotomy Reservoir is designed and sold for use only as indicated. This reservoir is also designed to be used postoperatively as a drainage and autotransfusion reservoir (e.g. for chest drainage) to return autologous blood shed from the chest to the patient for volume replacement.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The Jostra Venous Hardshell Cardiotomy Reservoirs (vacuum-tight and non-vacuum-tight model) with Safeline Coating are identical to the Jostra Venous Hardshell Cardiotomy Reservoirs with the only exception that the Venous Hardshell Cardiotomy Reservoirs with Safeline Coating have been coated with Safeline. The Safeline Coating is the same as with the Jostra RotaFlow Centrifugal Pump with Safeline Coating. Besides this difference the Venous Hardshell Cardiotomy Reservoirs with Safeline Coating are the same in design, intended use, method of operation, components, packaging, and fundamental scientific technology as compared to the uncoated Venous Hardshell Cardiotomy Reservoirs.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Evaluation and testing on safety and effectiveness was executed to demonstrate that the Jostra Venous Hardshell Cardiotomy Reservoirs with Safeline Coating described in this submission are substantially equivalent to the Jostra Venous Hardshell Cardiotomy Reservoirs as reservoirs and to the RotaFlow Centrifugal Pump with Safeline Coating regarding the Safeline coating.

The following areas have been tested and / or evaluated:

- Integrity
- Performance
- Biocompatibility
- Sterility

Conclusion

The data given demonstrate that the Jostra Venous Hardshell Cardiotomy Reservoirs (sealed and non-sealed model) with Safeline Coating are substantially equivalent to the named predicate devices which hold currently market clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2006

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

Re: K061743
Trade Name: Venous Hardshell Cardiotomy Reservoir with Safeline Coating
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiotomy Reservoir
Regulatory Class: Class II (two)
Product Code: DTN
Dated: June 16, 2006
Received: June 21, 2006

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Volmer

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): K061743

Device Name: Venous Hardshell Cardiotomy Reservoirs with Safeline Coating

The Jostra Venous Hardshell Cardiotomy Reservoir (non-vacuum-tight model) is designed to collect, store and filter the blood in an extracorporeal circuit during cardiopulmonary bypass procedures up to six hours in adult surgery . It can be integrated into almost all perfusion systems. The Jostra Venous Hardshell Cardiotomy Reservoir is designed and sold for use only as indicated.

The Jostra Venous Hardshell Cardiotomy Reservoir (vacuum-tight model) is designed to collect, store and filter the blood in an extracorporeal circuit during cardiopulmonary bypass procedures with or without vacuum assisted venous return up to six hours in adult surgery . It can be integrated into almost all perfusion systems. The Jostra Venous Hardshell Cardiotomy Reservoir is designed and sold for use only as indicated. This reservoir is also designed to be used postoperatively as a drainage and autotransfusion reservoir (e.g. for chest drainage) to return autologous blood shed from the chest to the patient for volume replacement.

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)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061743