510(K) Summary

K061832
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Submitter: Maquet Cardiopulmonary AG
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AUG 11 2006

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Date Prepared: June 30, 2006

Device Trade Name: Jostra HLM Tubing Sets with Safeline Coating

Common/Usual name: Custom Tubing Pack

Classification names: Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing

Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting

Cardiopulmonary Bypass Pump Tubing

Predicate Devices: Jostra HLM Tubing Sets – 510(k) number K053025

RotaFlow Centrifugal Pump with Safeline Coating, K061072, (with regards to the Safeline Coating only)

Device Description:

The Jostra HLM Tubing Sets with Safeline Coating are for single use only. They may be sold sterile, non-sterile, and bulk packed. Tubing sets that are sold sterile are not to be re-sterilized by the user.

In open heart surgery the Jostra HLM Tubing Sets with Safeline Coating are used in combination with the heartlung machine for the oxygenation of blood and removal of carbon dioxide. The main purpose of the Jostra HLM Tubing Sets with Safeline Coating is to connect the patient to the heartlung machine and it's components. The Jostra HLM Tubing Sets with Safeline Coating are therefore a component in the extracorporeal perfusion circulation system, for the oxygenation of blood and the removal of carbon dioxide. The utilization period of the use of the tubing sets is restricted to six hours.

The performance data of the Jostra HLM Tubing Sets with Safeline Coating are comparable with the performance data of the Jostra HLM Tubing Sets without the Safeline Coating.

Indications for Use:

Jostra HLM Tubing Set – Safeline coated

The Jostra HLM Tubing Set with Safeline Coating is indicated for use in surgical procedures requiring extracorporeal support for periods of up to six hours.

Indications for use Jostra Safeline Coating

To reduce the surface tension on blood contact surfaces.

The above tubing set indications for use has been cleared with the Jostra HLM Tubing Set 510(k) number K0503025. The intended use of the modified devices, as described in its labeling, has not changed as a result of the modification.

Statement of Technical Comparison:

The Jostra HLM Tubing Set – Safeline Coated has the same intended use, design, principals of operation, and performance as the Jostra HLM Tubing Set without the Safeline Coating. The only difference is the application of the Safeline Coating to the tubing and connectors.

Non-clinical Testing:

All of the Jostra HLM Tubing Set tests in 510(k) number K0503025 are applicable to the Jostra HLM Tubing Set – Safeline Coated product.

Risk analysis

The risk analysis method used to assess the impact of the modification was done according to the logic of a Failure Modes and Effects Analysis (FMEA). Design verification tests were performed as a result of this risk analysis assessment.

All possible risks for the user and the patient related to the design change (combination of the existing Jostra HLM Tubing Set with the existing Safeline Coating) have been assessed by evaluation or testing acc. to the risk analysis for the Jostra HLM Tubing Set with Safeline Coating. As a result of this analysis the following hazards were addressed:

Biological Hazards related to

- pyrogenicity
- ETO-degassing
- Biocompatibility

Functional Hazards related to

- device integrity

Hazards due to wrong application

- interaction between Safeline and other coatings

The evaluation and test results do not show any kind of risk potential for the user and/or the patient. The modification does not alter the fundamental scientific technologies of the Jostra HLM Tubing Set.Based on the test results and the evaluation the Jostra HLM Tubing Set with Safeline Coating are safe and effective for their intended use and are substantially equivalent to the named predicate devices, the uncoated Jostra HLM Tubing Set and the RotaFlow Centrifugal Pump with Safeline Coating (regarding the Safeline Coating).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2006

Maquet Cardiopulmonary AG
c/o Mr. James Collie
President
414 Maryjoe Way
Warrington, PA 18976

Re: K061832
Jostra HLM Tubing Sets with Safeline Coating
Regulation Number: 21 CFR 870.4210
Regulation Name: Catheter, Cannula and Tubing, Vascular
Regulatory Class: Class II (two)
Product Code: DWF
Dated: June 30, 2006
Received: June 29, 2006

Dear Mr. Collie:

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,

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): K061832

Device Name: Jostra HLM Tubing Set with Safeline Coating

Indications For Use:

The Jostra HLM Tubing Set with Safeline Coating is indicated for use in surgical procedures requiring extracorporeal support for up to six hours

The Safeline coating is used to reduce the surface tension on blood contact surfaces.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Chung

(Division Sign-Off)
Division of Cardiovascular Devices

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