K080592

SEP 1 1 2008

510(k) SUMMARY

SUBMITTER: Maquet Cardiopulmonary AG
Hechinger Strasse 38
72145 Hirrlingen, Germany

CONTACT PERSON: Katrin Schwenkglenks
Phone: (011) 49 7478 921- 151
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DATE PREPARED: February 22, 2008

DEVICE TRADE NAME: HLM Tubing Sets with Bioline Coating

COMMON/USUAL NAME Custom Tubing Pack

CLASSIFICATION NAME Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing;
Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting;
Cardiopulmonary Bypass Pump Tubing.

PREDICATE DEVICES OR LEGALLY MARKETED DEVICES

Jostra HLM Tubing Sets (K053025)

Quadrox D Diffusion Membrane Oxygenator with Bioline Coating (K071774)

DEVICE DESCRIPTION / INDICATONS FOR USE STATEMENT

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

The Bioline Coating improves the physical surface properties of products for the extracorporeal circulation system.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The HLM Tubing Set – Bioline Coated has the same intended use, design, principals of operation, and performance as the uncoated Jostra HLM Tubing Set. The only difference is the application of the Bioline Coating to the tubing and connectors.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Evaluation on safety and effectiveness was executed to demonstrate that the HLM-Tubing Set with Bioline Coating described in this submission is substantially equivalent to the Jostra HLM-Tubing Set as a custom tubing pack and to the Quadrox D Diffusion Membrane Oxygenator with Bioline Coating with regards to the Bioline Coating.

The following areas have been evaluated:

- Integrity
- Performance
- Biocompatibility
- Sterility

CONCLUSION

The data given demonstrate that the HLM-Tubing Set with Bioline Coating is 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

SEP 1 1 2008

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

Re: K080592
HLM Tubing Set with Bioline Coating
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing
Regulatory Class: Class II (two)
Product Code: DWE, DWF, DTL
Dated: August 29, 2008
Received: September 4, 2008

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): K080592

Device Name: HLM Tubing Set with Bioline Coating

Indications for Use:

The HLM Tubing Sets with Bioline Coating are designed to be used in extracorporeal circulation during cardiopulmonary bypass procedures lasting six hours or less.

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)

Donna R. Vedrnes

(Division Sign-Off)

Division of Cardiovascular Devices

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(Posted November 13, 2003)