510 (K) Summary

Submitter:	Maquet Cardiopulmonary AG Hechinger Strasse 38 72145 Hirrlingen Germany
Contact Person:	Kathleen Johnson Phone: 641-472-0775 Fax: 641-472-0241 E-mail: kathleen@mdai.net
Date Prepared:	August 27, 2005
Device Trade Name:	Jostra HLM Tubing Set
Common/Usual Name:	Custom tubing pack
Classification Names: cannula,	Cardiopulmonary bypass pump tubing Cardiopulmonary bypass vascular catheter, or tubing Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting
Predicate Devices:	Tubing and Connectors: Gish Biomedical, Tubing Connectors - K833322 Cobe Cardiovascular, Tubing Sets - K771692 Terumo Cardiovascular Systems, Pump Tubing - K013578 Terumo Cardiovascular Systems, Circuit Connectors - K041697 Tubing Sets: Cobe Cardiovascular, Cobe Heart-Lung Perfusion and Cardioplegia Pack - K881330 Medtronic Perfusion Systems, Intersept Blood Tubing Packs - K800178 Maquet Cardiopulmonary, Jostra MECC Set - K023132

Device Description:
The Jostra HLM Tubing Set is a sterile, non-pyrogenic device for single use only and is not to be re-sterilized by the user. The product consists of tubing and connectors with connected oxygenators, reservoirs, filters, and other cardiopulmonary bypass components assembled into user specified circuits for procedures requiring extracorporeal support up to six hours.

Tubing with a 3/32 inch wall thickness may also be used in a roller type displacement blood pump to propel the blood/fluid through the circuit.
The Maquet tubing is made of polyvinyl chloride (PVC) and ranges in size from 1/8" diameter to ½" diameter.
The following generic types of barbed connectors will be used: straight with or without luer locks, reducer with or without luer port, Y with or without luer port, male or female luer locks. Connectors may range in size from 1/8 to ½ inch.

Indications for Use:
The Jostra HLM Tubing Sets are designed to be used in extracorporeal circulation during cardiopulmonary bypass procedures lasting six hours or less.

Statement of Technical Comparison
The Jostra HLM Tubing Set has the same intended use, design and materials, principle of operation and performance as product that is commercially available.

Non-clinical Testing
The tubing and connectors have undergone biocompatibility and performance testing to demonstrate safety and equivalence for their intended use in the Jostra HLM Tubing Set. All other components in the custom tubing pack are legally marketed devices used in accordance with their intended use.

The following tests have been performed on the tubing and connectors:

1. Bond strength
2. Burst pressure
3. Effects upon cellular components (hemolysis)
4. Spallation

The non-clinical tests have demonstrated that the tubing and connectors used to produce the Jostra HLM Tubing Sets are safe and effective for their intended use.

These data support that Maquet tubing and connectors are substantially equivalent to the tubing and connectors that currently hold market clearance.

The Jostra HLM Tubing Sets are substantially equivalent to the Custom Tubing Packs that currently hold market clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Maquet Cardiopulmonary AG
c/o Mr. Daniel W. Lehtonen
Staff Engineer, Medical Devices
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BoxBorough, MA 01719

Re: K053025
Trade Name: Jostra HLM Tubing Set
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing
Regulatory Class: Class II (two)
Product Code: DWE
Dated: October 26, 2005
Received: October 27, 2005

Dear Mr. Lehtonen:

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,

Diana R. Vachon

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): K053025

Device Name: Jostra HLM Tubing Set

Indications for Use:

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

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 K053025