K093522

MAQUET
GETINGE GROUP

510(k) Summary

[as required by 21 CFR 807.92(c)]

Submitter	**MAQUET Cardiopulmonary AG** Hechinger Strasse 38 72145 Hirrlingen Germany
Contact Person	Frank Moehrke Phone: 011 49 7478 921 229 Fax: 011 49 7478 921 8667
Date Prepared	November 10, 2009
Device Trade Name	**QUADROX-i Small Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with BIOLINE Coating**
Common/Usual Name	Oxygenator with integrated heat exchanger and optional integrated arterial filter
Classification Names	Cardiopulmonary bypass oxygenator *(21 CFR 870.4350 – Product Code: DTZ)* Cardiopulmonary bypass heat exchanger *(21 CFR 870.4240 – Product Code: DTR)* Cardiopulmonary bypass arterial line blood filter *(21 CFR 870.4260 – Product Code: DTM)*
Legally Marketed Devices	QUADROX-i Small Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating (K090689), QUADROX-i Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with BIOLINE Coating (K090511).

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Device Description

The QUADROX-i Small Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with BIOLINE Coating is a blood-gas exchanger with integrated heat exchanger and optional integrated arterial blood filter.

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Indications for Use

The membrane oxygenator QUADROX-i Small Adult is intended for use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. The blood flow rate is defined from 0.5 – 5 l/min. Within the specified flow rate range, the device oxygenates the blood, eliminates carbon dioxide and regulates blood temperature.

The QUADROX-i Small Adult (HMO 51000) version with integrated arterial filter also filters out air bubbles and particles larger than 40 µm.

The device's utilization period is limited to six hours. The oxygenator is suitable for delivery of the volatile anesthetics isoflurane and sevoflurane. The anesthetic gas is administered through the oxygenator's gas inlet by means of a suitable anesthetic gas vaporizer. Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

Statement of Technical Comparison

The QUADROX-i Small Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with BIOLINE Coating is identical to the QUADROX-i Small Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating with the only exception that the QUADROX-i Small Adult Oxygenators with BIOLINE Coating have been coated with BIOLINE Coating instead of Softline Coating. However, the BIOLINE Coating is the same as with the QUADROX-i Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with BIOLINE Coating. Besides this difference the QUADROX-i Small Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with BIOLINE Coating is the same in design, intended use, method of operation, components, packaging, and fundamental scientific technology as compared to the QUADROX-i Small Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating.

Determination of Substantial Equivalence

Evaluation and testing on safety and effectiveness was executed to demonstrate that the QUADROX-i Small Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with BIOLINE Coating described in this submission is substantially equivalent to the QUADROX-i Small Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating as oxygenator and to the QUADROX-i Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with BIOLINE Coating regarding the BIOLINE Coating.

The following areas have been tested and / or evaluated:

- Integrity
- Performance
- Biocompatibility
- Sterility

Conclusion

The data given demonstrate that the QUADROX-i Small Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with BIOLINE Coating is substantially equivalent to the named predicate devices which hold currently market clearance.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC - 7 2009

Maquet Cardiopulmonary AG
c/o Mr. Frank Moehrke
Regulatory Affairs Manager
Hechinger Strasse 38
72145 Hirrlingen
Germany

Re: K093522
QUADROX-i Small Adult Microporous Membrane Oxygenator
With and without Integrated Arterial Filter with BIOLINE Coating
Regulation Number: 21 CFR 870.4350
Regulation Name: Oxygenator Cardiopulmonary Bypass
Regulatory Class: Class II (two)
Product Code: DTZ, DTR, DTM
Dated: November 10, 2009
Received: November 13, 2009

Dear Mr. Moehrke:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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): K093522

Device Name:

QUADROX-i Small Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with BIOLINE Coating

Indications for Use:

The membrane oxygenator QUADROX-i Small Adult is intended for use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. The blood flow rate is defined from 0.5 – 5 l/min. Within the specified flow rate range, the device oxygenates the blood, eliminates carbon dioxide and regulates blood temperature.

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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. Lechner

(Division Sign-Off)
Division of Cardiovascular Devices

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