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K101153

510(k) Summary

[as required by 21 CFR 807.92(c)]

DEC - 8 2010

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 8667
Date Prepared	April 19, 2010
Device Trade Name	QUADROX-iD Adult diffusion membrane oxygenator with BIOLINE Coating and with SOFTLINE Coating
Common/Usual Name	Oxygenator with integrated heat exchanger
Classification Names	Cardiopulmonary bypass oxygenator *(21 CFR 870.4350 – Product Code: DTZ)* Cardiopulmonary bypass heat exchanger *(21 CFR 870.4240 – Product Code: DTR)*
Legally Marketed Devices	QUADROX-i Adult microporous membrane Oxygenator with SOFTLINE Coating (K082117), QUADROX-i Adult microporous membrane Oxygenator with BIOLINE Coating (K090511), QUADROX-D diffusion membrane oxygenator with SAFELINE Coating (K061628) and with BIOLINE Coating (K071774).

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Device Description

The QUADROX-iD Adult diffusion membrane oxygenator with BIOLINE Coating and with SOFTLINE Coating is a blood-gas exchanger with integrated heat exchanger.

Indications for Use

The QUADROX-iD Adult diffusion membrane oxygenator is intended for use in an extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. Within the specified flow rate range, the device oxygenates the blood, removes carbon dioxide from the blood and regulates the blood temperature. The application duration is limited to 6 hours.
Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

Statement of Technical Comparison

The QUADROX-iD Adult diffusion membrane oxygenator with BIOLINE Coating and with SOFTLINE Coating is comparable to the QUADROX-i Adult microporous membrane oxygenator with BIOLINE Coating and with Softline Coating with the only exception that the QUADROX-iD Adult diffusion membrane oxygenator has a diffusive oxygenation membrane instead of a microporous oxygenation membrane. However, the diffusion membrane is the same as with the QUADROX-D diffusion membrane oxygenator. Besides this difference the QUADROX-iD Adult diffusion membrane oxygenator with SOFTLINE Coating and with BIOLINE Coating is comparable in design, method of operation, components, packaging, and fundamental scientific technology as compared to the QUADROX-i Adult microporous membrane oxygenator with Softline Coating and with BIOLINE Coating.

Non-clinical Testing

The QUADROX-iD Adult Diffusion Membrane Oxygenator with BIOLINE COATING and SOFLTINE Coating has been tested to and met the requirements of ISO 10993-1 Biological evaluation of medical devices - Padt 1: Evaluation and testing as well as the requirements of ISO 7199 Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators).

Determination of Substantial Equivalence

Evaluation and testing on safety and effectiveness was executed to demonstrate that the QUADROX-iD Adult diffusion membrane oxygenator with SOFTLINE Coating and with BIOLINE Coating described in this submission is substantially equivalent to the QUADROX-i Adult microporous membrane Oxygenator with Softline Coating and with BIOLINE Coating.

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The following areas have been tested and / or evaluated:

- Integrity
- Performance
- Biocompatibility
- Sterility

Conclusion

The data given demonstrate that the QUADROX-iD Adult diffusion membrane oxygenator with SOFLTINE Coating and with BIOLINE Coating is substantially equivalent to the named predicate devices which currently hold market clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Maquet Cardiopulmonary AG
c/o Ms. Katrin Schwenkglenks
Hechinger Straße 38
D-72145 Hirrlingen, Germany

DEC - 8 2010

Re: K101153
Trade/Device Name: QUADROX-iD Adult diffusion membrane oxygenator with BIOLINE Coating, art. codes: BE-HMOD 70000-USA, BEQ-HMOD 70000-USA; and QUADROX-iD Adult diffusion membrane oxygenator with SOFTLINE Coating, art. codes: HMOD 70000-USA
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary bypass oxygenator
Regulatory Class: II
Product Code: DTZ, DTR
Dated: November 30, 2010
Received: December 2, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

DEC - 8 2010

510(k) Number (if known): K101153

Device Name: **QUADROX-iD Adult diffusion membrane oxygenator with BIOLINE Coating and with SOFTLINE Coating**

Indications for Use:

The QUADROX-iD Adult diffusion membrane oxygenator is intended for use in an extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. Within the specified flow rate range, the device oxygenates the blood, removes carbon dioxide from the blood and regulates the blood temperature. The application duration is limited to 6 hours.

Responsibility for deciding whether to use an oxygenator rests solely with the attending physician.

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 K101153