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# 510 (K) Summary [as required by 21 CFR 807.92(c) ]

K102464


Submitter: Maquet Cardiopulmonary AG
Hechinger Strasse 38
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Germany

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Date Prepared: March 3, 2011

Device Trade Name: QUADROX-i Neonatal Microporous Membrane Oxygenator with and without integrated Arterial Filter with SOFTLINE Coating and with BIOLINE Coating

Common/Usual name: Oxygenator with integrated heat exchanger and optional integrated arterial filter

Classification names: Oxygenator, cardiopulmonary bypass
Heat Exchanger, cardiopulmonary bypass
Filter, blood, cardiopulmonary bypass, arterial line

Predicate Devices:

Capiox RX 05 Baby Hollow Fiber Oxygenator, Terumo Cardiovascular Systems Corp., cleared under K022115,

Capiox Arterial Filter, CX*AF02, Terumo Cardiovascular Systems Corp., cleared under K943917,

QUADROX-i Adult microporous membrane oxygenator with and without integrated arterial filter with SOFTLINE coating, MAQUET Cardiopulmonary AG, cleared under K082117,

QUADROX-i Adult Microporous Membrane Oxygenator with and without Arterial Filter with Bioline Coating, MAQUET Cardiopulmonary AG, K090511.

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QUADROX-iD Pedatric Diffusion Membrane Oxyenator with BIOLINE Coating, MAQUET Cardiopulmonary AG, K100278

Medos Hilte Infant Oxygenator, model 1000, 800 LT, Gish Biomedical Inc. K 090449

Device Description:

The QUADROX-i Neonatal Oxygenator is a blood-gas exchanger with integrated heat exchanger and optional integrated arterial filter, intended for the treatment of neonate and infant patients. The Oxygenator is designed for a blood flow range from 0.2 to 1.5 l/min. Since these patients have a very small blood volume of their own, the small priming volume of the oxygenator is an important parameter. The priming volume is 38 ml for the version without integrated arterial filter. The version with integrated arterial filter has a priming volume of 40 ml.
The effective gas exchange surface is 0.38 $m^2$; the one for the heat exchanger is 0.07 $m^2$. The integrated arterial filter is composed of a planar area from a woven 33 micron filter. The filter surface is 20 $cm^2$.

The blood contacting surfaces are coated with SOFTLINE coating or with BIOLINE Coating.

The QUADROX-i Neonatal oxygenator is a sterile and non-pyrogenic device, for single use only and is not to be re-sterilized by the user.

Indications for Use:

The membrane oxygenator QUADROX-i Neonatal is intended for use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. It is designed for a blood flow rate of 0.2 – 1.5 l/min and is intended for the treatment of pediatric (neonate and infant) patients. Within the specified flow rate range, the device oxygenates the blood, removes carbon dioxide and regulates the blood temperature.
The QUADROX-i Neonatal (HMO 11000) model with integrated arterial filter also filters air bubbles and particles larger than 33 µm.
The utilization period of this device is restricted to six hours.

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

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Statement of Technical Comparison:

The QUADROX-i Neonatal Microporous Membrane Oxygenator is comparable to the QUADROX-i Adult Microporous Membrane Oxygenator regarding the design principles, biocompatibility and sterility process. Both products come with and without an Integrated Arterial Filter with Softline Coating. The Softline Coating and the BIOLINE Coating are the same coatings contained in the QUADROX-i Adult Oxygenator.

Non-clinical Testing:

The QUADROX-i Neonatal Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating and with BIOLINE Coating have been tested or evaluated for compliance to ISO 10993-1 Biologic Evaluation of Medical Devices, ISO 7199 "Cardiovascular implants and artificial organs – blood gas exchangers (oxygenators) as well as the requirements of ISO 15675 "Cardiovascular implants and artificial organs – Cardiopulmonary Bypass – Arterial line blood filters". The products met these requirements.

Determination of Substantial Equivalence

Testing and evaluation on safety and effectiveness was conducted to demonstrate that the QUADROX-i Neonatal Microporous Membrane Oxygenator with and without Integrated Arterial Filter with SOFTLINE Coating and BIOLINE Coating is substantially equivalent to the Capiox RX 05 Baby Hollow Fiber Oxygenator from Terumo as well as to the Capiox Arterial Filter, CX*AF02 from Terumo.

The following areas have been tested or evaluated:

- Indications for Use
- Integrity
- Performance
- Biocompatibility
- Sterility

Conclusion

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

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Re: K102464

Trade/Device Name: QUADROX-i Neonatal Microporous Membrane Oxygenator with SOFTLINE COATING (HMO 10000), QUADROX-i Neonatal Microporous Membrane Oxygenator with integrated Arterial Filter with SOFTLINE COATING (HMO 11000), QUADROX-i Neonatal Microporous Membrane Oxygenator with BIOLINE COATING (BE-HMO 10000, BEQ-HMO 10000), and QUADROX-i Neonatal Microporous Membrane Oxygenator with integrated Arterial Filter with BIOLINE COATING (BEQ-HMO 11000, BE-HMO 11000)
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary bypass oxygenator
Regulatory Class: II
Product Code: DTZ, DTR, DTM
Dated: February 21, 2011
Received: February 24, 2011

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,

Donna R. Vuchmes

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): K102464

Device Name: **QUADROX-i Neonatal Microporous Membrane Oxygenator with and without integrated Arterial Filter**

Indications for Use:

The membrane oxygenator QUADROX-i Neonatal is intended for use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. It is designed for a blood flow rate of 0.2 – 1.5 l/min and is intended for the treatment of pediatric (neonate and infant) patients. Within the specified flow rate range, the device oxygenates the blood, removes carbon dioxide and regulates the blood temperature.

The QUADROX-i Neonatal (HMO 11000) model with integrated arterial filter also filters air bubbles and particles larger than 33 µm.

The utilization period of this device is restricted to six 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kelner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102464