MAQUET Cardiopulmonary AG

Premarket Notification Special 510(k) - Change due to recall/corrective action
Modified QUADROX-i, QUADROX-iD

510 (k) Summary
[As required by 21 CFR 807.92(c)]

Date: September 06th, 2013

Submitter: MAQUET Cardiopulmonary AG
Kehler Straße 31
76437 Rastatt
Germany

Contact Person: Whitney Törning
Director of Regulatory
MAQUET Cardiovascular
45 Barbour Pond Drive
Wayne, NJ 07470
Phone: 973-709-7994
Fax: 973-807-9210

OCT 08 2013

Device Trade Names: QUADROX-i Adult / Small Adult / Pediatric / Neonatal Microporous Membrane Oxygenators, with and w/o filter;

QUADROX-iD Adult Diffusion Membrane Oxygenators, with and w/o filter;

QUADROX-iD Pediatric Diffusion Membrane Oxygenators, w/o filter

Common/Usual name: Oxygenator with and without integrated arterial filter

Classification Name: Oxygenator, cardiopulmonary bypass, heat exchanger, cardiopulmonary bypass, filter, blood cardiopulmonary bypass, arterial line, non-roller type blood pump, cardiopulmonary bypass

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Device Modification

The only modification consists of adding a reusable stainless steel holding clamp as an interim protective safeguard / corrective action to prevent the inlet and/or outlet connector from disconnection. The holding clamp is applied by the perfusionist prior to use.

Legally marketed MAQUET Predicate Devices:

QUADROX-i Adult Microporous Membrane Oxygenators K082117 & K090511, QUADROX-i Small Adult Microporous Membrane Oxygenators K090689 & K093522, QUADROX-i Pediatric Microporous Membrane Oxygenator K103191, QUADROX-i Neonatal Microporous Membrane Oxygenator K102464, QUADROX-iD Adult Diffusion Membrane Oxygenator K101153, QUADROX-iD Pediatric Diffusion Membrane Oxygenator K100278

Device Description:

Holding Clamp – Interim protective safeguard and component of the QUADROX-i / -iD

The holding clamp is applicable to all QUADROX-i / -iD oxygenators which are subject to this submission. The following table provides an overview of the holding clamps suitable for QUADROX-i / -iD Oxygenator models.

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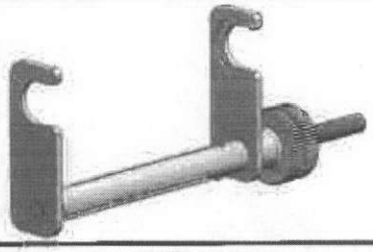
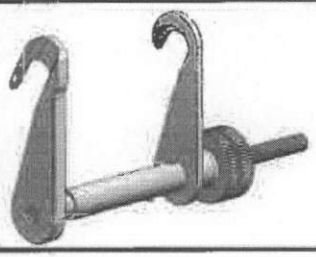
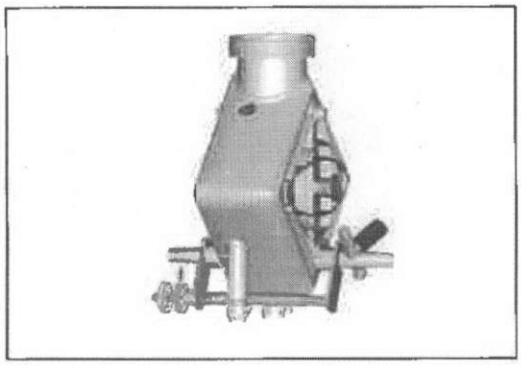
Catalogue number	Holding clamp - picture	suitable for*
HKH 3570		HMO 71000 USA - Quadrox i Adult with filter HMO 70000 USA - Quadrox i Adult w/o filter HMO 51000 USA - Quadrox i Small Adult with filter HMO 50000 USA - Quadrox i Small Adult w/o filter HMOD 71000 USA - Quadrox iD Adult with filter HMOD 70000 USA - Quadrox iD Adult w/o filter
HKH 3571		HMO 30000 USA - Quadrox i pediatric w/o filter HMO 31000 USA- Quadrox i pediatric with filter HMO 10000 USA – Quadrox i neonatal w/o filter HMO 11000 USA - Quadrox i neonatal with filter HMOD 30000 USA - Quadrox iD pediatric w/o filter

* The above listed devices refer to the QUADROX-i / - iD Oxygenator models which may also be provided with BIOLINE Coating and may be sold in combination with other devices as described in the original 510(k) of each device.

The following picture shows exemplarily the holding clamp in combination with the QUADROX-i Oxygenator:



QUADROX-i Adult Microporous Membrane Oxygenator with and without integrated Arterial Filter

The membrane oxygenator Quadrox-i Adult is intended for the use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. Within the specified flow rate range, the device oxygenates the blood, eliminates carbon dioxide and

regulates blood temperature. The Quadrox-i Adult (HMO 71000) 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.

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

QUADROX-i Small Adult Microporous Membrane Oxygenator with and without integrated Arterial Filter

The membrane oxygenator QUADROX-i Small Adult is intended for the 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.

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

QUADROX-i Pediatric Microporous Membrane Oxygenator with and without integrated Arterial Filter

The membrane oxygenator QUADROX-i Pediatric is intended for use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. It is designed for a blood flow rate of 0.2 – 2.8 l/min and is intended for the treatment of pediatric patients. Within the specified flow rate range, the device oxygenates the blood, removes carbon dioxide and regulates the blood temperature.

The QUADROX-i Pediatric (HMO 31000) 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.

QUADROX-i Neonatal Microporous Membrane Oxygenator with and without integrated Arterial Filter

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 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.

QUADROX-iD Adult Diffusion Membrane Oxygenator

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.

QUADROX-iD Pediatric Diffusion Membrane Oxygenator

The Diffusion Membrane Oxygenator QUADROX-iD Pediatric is intended for use in an extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. The oxygenator is designed for a blood flow rate of 0.2 – 2.8 l/min and is intended for the treatment of pediatric patients. Within the specified flow rate range, the device oxygenates the blood, removes carbon dioxide and regulates the blood temperature.

The utilization period for this device is restricted to six hours.

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

Technological Characteristics:

The modified devices as mentioned above are identical to the originally cleared devices, with the exception that an added reusable stainless steel holding clamp is applied by the perfusionist prior to use as an interim protective safeguard in the unlikely event that the inlet and/or outlet connector would become loose. Besides this difference, the proposed devices are the same in design, intended use, method of operation, components, packaging, and fundamental scientific technology as the predicate devices.

Non-clinical Tests:

The modified devices were subjected to **design verification** tests which are based on the risk assessment. The tests are designed to show that the clamp can be mounted on the Oxygenator, so that the clamp will stay in place during its use, and in the unlikely event that the bonding of the connectors to the housing would fail the connector would not detach from the housing.

The tests simulate relevant mechanical conditions in the use of the Oxygenators. The following mechanical tests were performed:

- **Holding Forces** – Force applied to the connectors to hold the clamp in place
- **Pull off Forces** – Force to remove the holding clamp from the housing perpendicular to the clamping force.
- **Vibration Test with Shaker** — Simulate impact forces up to 3G and confirm the secure attachment of the clamp under repeated impact.
- **Vibration Test with Roller Pumps** – Relevant for QUADROX-i / - iD products to simulate the influence of repeated motions of the tubing.
- **Leakage Test with Reduction Adapter** – Relevant only to the Quadrox-i pediatric/neonatal products used in combination with 1/4" x 3/16" reduction adapters 09844-s. The test confirmed that the clamp can be used with the pediatric/neonatal reduction adapters.
- **Usability test** – This test was performed in three hospitals and evaluated as to whether the clamp could be mounted using the Instruction for Use.

The holding clamp as an external component of the cleared QUADROX-i does not affect the performance specifications related to the intended use.

Based on the tests listed above, the modified devices are safe and effective according to the intended use and are substantially equivalent to the originally cleared device.

Clinical Tests:

Clinical results are not required for this submission to support substantial equivalence.

Conclusion:

Based on the risk analysis, MAQUET Cardiopulmonary AG has conducted the appropriate design verification activities and believes that the modified devices are substantially equivalent to the cleared MAQUET predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 8, 2013

MAQUET Cardiopulmonary AG
Whitney Törning
Director of Regulatory
45 Barbour Pond Drive
Wayne, ND 07470

Re: K132829
Trade/Device Name: QUADROX-i Microporous Membrane Oxygenators
QUADROX-iD Diffusion Membrane Oxygenators
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ, DTR, DTM
Dated: September 6, 2013
Received: September 9, 2013

Dear Ms. Törning:

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 contact 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. 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,

for 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): K132829

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

Indications for Use:
The membrane oxygenator Quadrox-i Adult is intended for the use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. Within the specified flow rate range, the device oxygenates the blood, eliminates carbon dioxide and regulates blood temperature. The Quadrox-i Adult (HMO 71000) 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.
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)

Indications for Use

510(k) Number (if known): K132829

Device Name: QUADROX-i Small Adult Microporous Membrane Oxygenator with and without integrated Arterial Filter

Indications for Use:

The membrane oxygenator QUADROX-i Small Adult is intended for the 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.

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)

Indications for Use

510(k) Number (if known): K132829

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

Indications for Use:

The membrane oxygenator QUADROX-i Pediatric is intended for use in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. It is designed for a blood flow rate of 0.2 – 2.8 l/min and is intended for the treatment of pediatric patients. Within the specified flow rate range, the device oxygenates the blood, removes carbon dioxide and regulates the blood temperature.

The QUADROX-i Pediatric (HMO 31000) 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K132829

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 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K132829

Device Name: QUADROX-iD Adult Diffusion Membrane Oxygenator

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)

Indications for Use

510(k) Number (if known): K132829

Device Name: QUADROX-iD Pediatric Diffusion Membrane Oxygenator

Indications for Use:

The Diffusion Membrane Oxygenator QUADROX-iD Pediatric is intended for use in an extracorporeal circulation during cardiopulmonary bypass in cardiac surgery. The oxygenator is designed for a blood flow rate of 0.2 – 2.8 l/min and is intended for the treatment of pediatric patients. Within the specified flow rate range, the device oxygenates the blood, removes carbon dioxide and regulates the blood temperature.

The utilization period for 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)

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