K082544

OCT 3 - 2008

MAQUET

Special 510(k): Device Modification: Quart Arterial Filter with Bioline Coating

510(k) SUMMARY

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- 400
DATE PREPARED:	August 27, 2008
DEVICE TRADE NAME:	Quart Arterial Filter with Bioline Coating
COMMON/USUAL NAME	Arterial Filter, coated
CLASSIFICATION NAME	Filter, Blood, Cardiopulmonary Bypass, Arterial Line
PREDICATE DEVICES OR LEGALLY MARKETED DEVICES	Quart Arterial Filter (K001787) Quadrox D Diffusion Membrane Oxygenator with Bioline Coating (K071774)

DEVICE DESCRIPTION / INDICATONS FOR USE STATEMENT

The Quart Arterial Filter with Bioline Coating is designed for use in an extracorporeal circulation system during surgical procedures involving a cardiopulmonary bypass. Within the cited flow rates, the arterial filter removes particulate and gaseous micro-embolisms from the extracorporeal circulation system. The eliminated gas can be removed via the purge line.

The decision regarding the method in which the arterial filter is to be employed rests solely with the treating physician.

The unit may not be continuously employed for more than 6 hours. We do not recommend longer contact with the blood.

The Bioline Coating improves the physical surface properties of products for the extracorporeal circulation system.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The Quart Arterial Filter with Bioline Coating is identical to the Quart Arterial Filter, uncoated with the only exception that the Quart Arterial Filter with Bioline Coating has been coated with Bioline. The Bioline Coating is the same as with the Quadrox D Diffusion Membrane Oxygenator with Bioline Coating. Besides this difference the both Quart Arterial Filters are the same in design, indications for use, method of operation, components, packaging, and fundamental scientific technology.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Evaluation and testing on safety and effectiveness was executed to demonstrate that the Quart Arterial Filter with Bioline Coating described in this submission is substantially equivalent to the Quart Arterial Filter as an arterial filter and to the Quadrox D Diffusion Membrane Oxygenator 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 Quart Arterial Filter with Bioline Coating is substantially equivalent to the named predicate devices which hold currently market clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 - 2008

Maquet Cardiopulmonary AG
Ms. Katrin Schwenkglenks
Regulatory Affairs Manager
Hechinger Strasse 38
72145 Hirrlingen, Germany

Re: K082544
Trade/Device Name: Quart Arterial Filter with Bioline Coating
Regulation Number: 21 CFR 870.4260
Regulation Name: Cardiopulmonary Bypass Arterial Line Blood Filter
Regulatory Class: Class II (two)
Product Code: DTM
Dated: August 27, 2008
Received: September 3, 2008

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.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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): K082544

Device Name: Quart Arterial Filter with Bioline Coating

Indications for Use:

The Quart Arterial Filter is designed for use in an extracorporeal circulation system during surgical procedures involving a cardiopulmonary bypass. Within the cited flowrates, the Quart Arterial Filter removes particulate and gaseous micro-embolisms from the extracorporeal circulation system. The eliminated gas can be removed via the purge line. The max. flow rate of the Quart Arterial Filter is 7 l/min.
The decision regarding the method in which the arterial filter is to be employed rests solely with the treating physician.
The unit may not be continuously employed for more than 6 hours. We do not recommend longer contact with the blood.

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)

(Posted November 13, 2003)

Donna R. Lachman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082544