

AUG 22 2006

MAQUET

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

Submitter: Maquet Cardiopulmonary AG  
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Date Prepared: June 09, 2006

Device Trade Name: Jostra Quadrox D Safeline Diffusion Membrane  
Oxygenator

Common/Usual name: Quadrox D

Classification names: Oxygenator, cardiopulmonary bypass  
Heat Exchanger, cardiopulmonary bypass

Predicate Devices: Jostra Quadrox Safeline Hollow Fiber Membrane  
Oxygenator (K992559, K030264)

Device Description:

The Quadrox D Safeline is a sterile and non-pyrogenic device, for single use only and is not to be re-sterilized by the user.

In open heart surgery it is used in combination with the heartlung machine for the oxygenation of blood and removal of carbon dioxide. The Quadrox D Safeline is therefore a component in the extracorporeal perfusion circulation system, for oxygenation of blood and removal of carbon dioxide. The utilization period of this device is restricted to six hours.

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The Jostra Quadrox D Safeline Diffusion Membrane Oxygenator is a model of the Quadrox Safeline Hollow Fiber Membrane Oxygenator. In contrast to the Quadrox, a tight diffusive membrane instead of a microporous membrane is used for the gas exchange.

With this diffusive membrane the gas exchange takes place by diffusion through the membrane wall. This membrane has no pores, therefore a passover of air bubbles or plasma leakage is not possible.

The diffusive membrane has the same outer diameter as the open-pored membrane. The outer diameters are 1.8 m<sup>2</sup> gas exchange surface and 0.6 m<sup>2</sup> heat exchanger surface available.

The performance data of the Quadrox D Safeline are comparable with the performance data of the Quadrox Safeline Oxygenator.

The complete construction, priming volume and the connections are the same for the Quadrox D Safeline as well as for the Quadrox Safeline Oxygenator.

It may be marketed both as single product and pre-mounted with the venous hardshell cardiotomy reservoir (K003551, K982136), equivalent to Jostra Quadrox Safeline Oxygenator (K992559). The Jostra Quadrox D Safeline Diffusion Membrane Oxygenator will be provided with a Jostra Manifold Sampling Line.

## Indications for Use:

The Jostra Quadrox D Safeline Diffusion Membrane Oxygenator is used for extracorporeal circulation during cardiopulmonary bypass in the field of open-heart surgery. Within the indicated flow rates blood is oxygenated and carbon dioxide is removed. The utilization period of this device is restricted to six hours.

The application and use of the oxygenator is the sole responsibility of the attending physician.

## Statement of Technical Comparison:

The Jostra Quadrox D Safeline Diffusion Membrane Oxygenator has the same intended use, design, principals of operation, and performance as the Jostra Quadrox Safeline Oxygenator. The only difference is that the Jostra Quadrox D Safeline Diffusion Membrane Oxygenator uses a tight diffusive membrane instead of a microporous membrane for the gas exchange.

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## Non-clinical Testing:

The Jostra Quadrox D Safeline Diffusion Membrane Oxygenator has been tested to and met the requirements of ISO 10993-1 Biologic Evaluation of Medical Devices as well as the requirements of ISO 7199: 1996 "Cardiovascular implants and artificial organs – blood gas exchangers (oxygenators).

## Determination of Substantial Equivalence

Testing and evaluation on safety and effectiveness was executed to demonstrate that the Jostra Quadrox D Safeline Diffusion Membrane Oxygenator described in this submission is substantially equivalent to the Jostra Quadrox Safeline Membrane Oxygenator.

The following areas have been tested:

- Integrity
- Performance
- Stability of the Coating
- Biocompatibility
- Sterility

## Conclusion

The data given demonstrate that the Jostra Quadrox D Safeline Diffusion Membrane Oxygenator is substantially equivalent to the named predicate device which holds currently market clearance.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 22 2006

Maquet Cardiopulmonary AG  
c/o Mr. James R. Collie  
J.R. Collie Associates, Inc.  
414 Maryjoe Way  
Warrington, PA 18976

Re: K061628  
Quadrox D Safeline Diffusion Membrane Oxygenator  
Regulation Number: 21 CFR 870.4350  
Regulation Name: Cardiopulmonary Bypass Oxygenator  
Regulatory Class: Class II (two)  
Product Code: DTZ  
Dated: August 7, 2006  
Received: August 8, 2006

Dear Mr. Collie:

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.

Page 2 – Mr. James R. Collie

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 (301) 443-6597 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): K061628

Device Name: Jostra Quadrox D Safeline Diffusion Membrane Oxygenator \_\_\_\_\_

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Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (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 Cardiac Devices

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