DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 16, 2016

Maquet Cardiopulmonary AG
c/o Katrin Schwenkglenks
Hechinger Strasse 38
Hirrlingen, Germany 72145

Re: K061072
Trade/Device Name: RotaFlow Centrifugal Pump System with Safeline Coating
Regulation Number: 21 CFR 870.4360
Regulation Name: Non-Roller Type Cardiopulmonary Bypass Blood Pump
Regulatory Class: Class II
Product Code: KFM
Dated: April 7, 2006
Received: April 17, 2006

Dear Ms. Schwenkglenks:

This letter corrects our substantially equivalent letter of May 23, 2006.

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Eric E. Richardson -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K061072

Device Name

Rotaflow Centrifugal Pump with Safeline

Indications for Use *(Describe)*

The Rotaflow Centrifugal Pump is a device that uses a method other than revolving rollers to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either:

- Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or
- Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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MAQUET

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

Submitter:	Maquet Cardiopulmonary AG Hechinger Strasse 38 72145 Hirrlingen Germany
Contact Person:	Katrin Schwenkglenks Phone: +49 7478 921-151 Fax: +49 7478 921-400 E-mail: katrin.schwenkglenks@maquet-cp.com

Date Prepared:	April 07, 2006
Device Trade Name:	RotaFlow Centrifugal Pump with Safeline Coating
Common/Usual Name:	Centrifugal pump, coated
Classification Names:	Pump, blood, non-roller-type, cardiopulmonary; (21 CFR 870.4360, product code: KFM)
Predicate Devices:	RotaFlow Centrifugal Pump (K991864) Quadrox Hollow Fiber Membrane Oxgenator Safeline (K992559, K030264)

Device Description

The Jostra RotaFlow Centrifugal Pump with Safeline Coating is a sterile, non-pyrogenic device for single use only and is not to be re-sterilized by the user.

The RotaFlow Centrifugal Pump with Safeline Coating is indicated as a component of the extracorporeal circuit and is intended to be used exclusively in conjunction with the RotaFlow-Console, the RotaFlow Drive Unit and the RotaFlow Emergency Drive. The device is not designed or intended for use except as indicated. The centrifugal pump is indicated for single use as a pump for up to 6 hrs.

The RotaFlow is a blood pump that functions on the basis of the centrifugal principle, whereas the drive is based on a magnetic system. A sapphire ball and a PE calotte guarantee low friction bearing.
The centrifugal pump has a spinning rotor with flow channels which impart rotary motion to the incoming blood, directing it through a spiral housing to the outflow port. The Rotor is shrouded. It forms the flow channels with 4 fan-shaped members. The flow is guided from the center of the pump to the periphery of the pump, where it is then forced into the flow channel by means of a spiral flow channel the cross-section of which increases in the direction of flow. The RotaFlow Centrifugal Pump allows for pulsatile and non-pulsatile flow.
The RotaFlow Centrifugal Pump comes with an integrated flow probe connector.

The design principle minimizes blood traumatization and stress with optimum flow guidance. Additionally, the pump design results in no stagnant blood zones and a small priming volume of 32 ml which allows for minimal mean transit time (MTT).

Indications for Use:
The Jostra RotaFlow Centrifugal Pump with Safeline Coating is a prescription device that uses a method other than revolving rollers to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either:

(i) Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or

(ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

Statement of Technical Characteristics Comparison
The two devices differ in that the blood contacting surfaces of the Jostra RotaFlow Centrifugal Pump with Safeline Coating has been treated with the Safeline Coating. Otherwise, indications for use, materials, components, design, performance characteristics and sterilization for the two devices are the same. The safety of the Safeline Coating has been shown with the Quadrox Safeline Oxygenator (K992559). Due to equivalence of indications for use, materials, design and functional characteristics, the device raises no new safety or effectiveness issues.

Determination of Substantial Equivalence
Evaluation and testing on safety and effectiveness was executed to demonstrate that the Jostra RotaFlow Centrifugal Pump with Safeline Coating described in this submission is substantially equivalent to the Jostra RotaFlow Centrifugal Pump as a pump and to the Quadrox Safeline Hollow Fiber Membrane Oxygenator regarding the Safeline coating.

The following areas have been tested and / or evaluated:

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

Conclusion
The data given demonstrate that the Jostra RotaFlow Centrifugal Pump with Safeline Coating is substantially equivalent to the named predicate devices which hold currently market clearance.