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

K102919

Submitter: Maquet Cardiopulmonary AG
Hechinger Strasse 38
72145 Hirrlingen
Germany

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Date Prepared: September 28, 2010

Device Trade Name: Neonatal Venous Hardshell Cardiotomy Reservoir and Pediatric Venous Hardshell Cardiotomy Reservoir, with and without SOFTLINE Coating

Common/Usual name: Venous Hardshell Cardiotomy Reservoir

Classification names: Cardiopulmonary bypass blood reservoir,
Cardiopulmonary bypass defoamer,
Cardiopulmonary bypass cardiotomy suction line

Predicate Devices:

Capiox Resevoir RX 05R Baby, Terumo Cardiovascular Systems Corp (K022115),

Resevoir D101 Dideco Kids Infant with Ph.I.S.I.O. Coating, Sorin (K072091),

Venous Hardshell Cardiotomy Reservoir with SOFTLINE Coating (K090534), MAQUET Cardiopulmonary AG.

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Device Description:

The Neonatal and Pediatric Venous Hardshell Cardiotomy Reservoirs are developed for the use in the field of cardiopulmonary bypass operation. They are used as blood buffer in the extracorporeal circuit and as collecting and defoaming device for sucked blood.

The Neonatal and Pediatric Reservoirs may be applied during the surgery in the extracorporeal circulation for collecting venous blood by gravitation or vacuum assist venous drainage (VAVD), air removal in venous blood, as a volume depot of blood, for collecting, defoaming and filtering cardiotomy blood.
The Reservoirs may also be applied after the surgery on the intensive care unit for vacuum operated thoracic drainage and for the autotransfusion of autologous blood. If the application occurs in the intensive care unit the reservoir which was employed in the operation is usually used.

The blood contacting surfaces are coated optionally with SOFTLINE Coating.

The Neonatal and Pediatric Reservoirs are sterile and non-pyrogenic devices, for single use only and are not to be re-sterilized by the user.

Indications for Use:

The venous hardshell cardiotomy reservoir is used to collect, store and filter blood in extracorporeal circulation in cardiopulmonary bypass operations on pediatric patients for up to 6 hours.
The reservoir can also be employed postoperatively as drainage and autotransfusion reservoir (e.g., for thorax drainage) to return the autologous blood to the patient which was removed from the thorax for the volume exchange.

Statement of Technical Comparison:

The Neonatal Venous Hardshell Cardiotomy Reservoir and Pediatric Venous Hardshell Cardiotomy Reservoir, with and without SOFTLINE Coating is comparable to the above named predicate devices which are also designed and intended to be used with neonate and pediatric patients. The Softline Coating is the same coating contained in the Venous Hardshell Cardiotomy Reservoir with SOFTLINE Coating.

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Non-clinical Testing:

The Neonatal Venous Hardshell Cardiotomy Reservoir and Pediatric Venous Hardshell Cardiotomy Reservoir, with and without SOFTLINE Coating have been tested or evaluated for compliance to ISO 10993-1 Biologic Evaluation of Medical Devices and ISO 15674 "Cardiovascular implants and artificial organs – Hard-shell cardiotomy / venous reservoir systems (with/without filter) and softbag venous reservoir bags" The products met these requirements.

Determination of Substantial Equivalence

Testing and evaluation on safety and effectiveness was conducted to demonstrate that the Neonatal Venous Hardshell Cardiotomy Reservoir and Pediatric Venous Hardshell Cardiotomy Reservoir, with and without SOFTLINE Coating is substantially equivalent to the Capiox Reservoir RX 05 Baby from Terumo (K022115) as well as to the Resevoir D101 Dideco Kids Infant with Ph.I.S.I.O. Coating from Sorin (K072091).

The following areas have been tested or evaluated:

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

Conclusion

The data given demonstrate that the Neonatal Venous Hardshell Cardiotomy Reservoir and Pediatric Venous Hardshell Cardiotomy Reservoir, with and without SOFTLINE 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

MAR 1 1 2011

Re: K102919
Trade/Device Name: Neonatal Venous Hardshell Cardiotomy Reservoir (VHK11000), Neonatal Venous Hardshell Cardiotomy Reservoir with SOFTLINE Coating (BO-VHK 11000), Pediatric Venous Hardshell Cardiotomy Reservoir (VHK31000), and Pediatric Venous Hardshell Cardiotomy Reservoir with SOFTLINE Coating (BO-VHK 31000)
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary bypass blood reservoir
Regulatory Class: II
Product Code: DTN, DTP, JOD
Dated: March 1, 2011
Received: March 4, 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,

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): K102919

Device Name: Neonatal Venous Hardshell Cardiotomy Reservoir and Pediatric Venous Hardshell Cardiotomy Reservoir, with and without SOFTLINE Coating

Indications for Use:

The venous hardshell cardiotomy reservoir is used to collect, store and filter blood in extracorporeal circulation in cardiopulmonary bypass operations on pediatric patients for up to 6 hours.

The reservoir can also be employed postoperatively as drainage and autotransfusion reservoir (e.g., for thorax drainage) to return the autologous blood to the patient which was removed from the thorax for the volume exchange.

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)

Donna R. Vorhees

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102919