MAQUET Cardiopulmonary AG

Premarket Notification Special 510(k) – Device Modification;
Modified Neonatal and Pediatric Venous Hardshell Cardiotomy Reservoirs with and without SOFTLINE Coating

JUL 07 2014

510(k) Summary

[As required by 21 CFR 807.92(c)]

Submitter Information	MAQUET Cardiopulmonary AG Kehler Strasse 31 76437 Rastatt Germany
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Summary Date:	May 23, 2014

Device Name

Proprietary name:	Neontal Venous Hardshell Cardiotomy Reservoir with and without SOFTLINE Coting Pediatric Venous Hardshell Cardiotomy Reservoir with and without SOFTLINE Coating
Common/Usual name:	Venous Hardshell Reservoir
Classification:	Class II
CFR Sections:	21 CFR 870.4400; 21 CFR 870.4230; 21 CFR 870.4270

Predicate Device: Neonatal and Pediatric Venous Hardshell Cardiotomy Reservoirs with and without SOFTLINE Coating (K102919).

Device Modification

The modifications subject of this submission comprise the material change of the defoamer coating from ASC to MACE coating combined with a change of the specifications - the increase of the maximum blood flow of the cardiotomy part and thus an increase in the dynamic hold-up volume of the cardiotomy part, as well as a change of the specifications of the break through volume of the venous and of the cardiotomy part.

Device Description

The Neonatal and Pediatric Venous Harshell Cardiotomy Reservoirs with and without SOFTLINE Coating are developed for surgical procedures requiring cardiopulmonary bypass for pediatric patients. They are used as a blood buffer in the extracorporeal circuit and are used as a collecting and defoaming device for sucked blood. The device is supplied sterile and non-pryogenic.

Intended 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.

Comparison of Technological Characteristics to Predicate Device

The modified Venous Hardshell Cardiotomy Reservoirs have the following similarities to the Venous Hardshell Cardiotomy Reservoirs, which previously received 510(k) clearance:

- have the same intended use,
- use the same operating principle,

- incorporate the same reservoir design,
- have the same shelf life,
- are packaged and sterilized using the same processes and
- have the same SOFTLINE Coating

There is no change in the fundamental scientific technology and the product change does not affect the intended use.

In summary, the Neonatal and Pediatric Venous Hardshell Cardiotomy Reservoirs with and without SOFTLINE Coating described in this submission are, in our opinion, substantially equivalent to the predicate devices.

Nonclinical Data

The modified devices were subjected to design verification tests which are based on the risk assessment. The tests are designed to show that the Neonatal and Pediatric Venous Hardshell Cardiotomy Reservoirs with and without SOFTLINE Coating with the proposed modifications are as safe and effective as the originally cleared devices.

The following design verification tests / evaluations were performed:

- Air handling
- Defoaming
- Break Through Volume, cardiotomy part and venous part
- Dynamic Priming Volume, cardiotomy part
- Functional Test, cardiotomy part
- BioBurden
- LAL
- Biocompatibility

The evaluation and test results do not show any kind of risk potential for the health or security of the patient or user. Based on the test results and evaluation, the Neonatal and

Pediatric Venous Hardshell Cardiotomy Reservoirs with and without SOFTLINE Coating are safe and effective for their intended use.

Clinical Data

Clinical results were not submitted to support substantial equivalence.

Conclusions

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

July 7, 2014

MAQUET Cardiopulmonary, AG
Katrin Schwenkglenks
Regulatory Affairs Manager
Neue Rottenburger Strasse 37
72379 Hechingen, Germany

Re: K141432
Trade/Device Name: Neonatal and Pediatric Venous Hardshell Cardiotomy Reservoir with and without SOFTLINE Coating
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary Bypass Blood Reservoir
Regulatory Class: Class II
Product Code: DTN, DTP
Dated: May 23, 2014
Received: June 9, 2014

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 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,

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): K141432

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)

(Posted November 13, 2003)