K130300

HCU 40
510(k) Summary
Prepared in accordance with 21 CFR Part 807.92

JUL 0 1 2013

GENERAL INFORMATION

Submitter's name and address:

MAQUET Cardiopulmonary AG
Kehler Straße 31
D-76437 Rastatt
Germany

Contact person and telephone number:

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Regulatory Affairs Program Manager
MAQUET Cardiovascular
45 Barbour Pond Drive
Wayne, NJ 07470
USA

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Date prepared: January 25, 2013

DEVICE INFORMATION:

Trade Name:	HCU 40 Heater-Cooler Unit
Common/Generic Name:	Heater-Cooler Unit
Classification Name:	Heater-Cooler Unit
Regulation Number:	21 CFR 870.4250
Product Code:	DWC

PREDICATE DEVCE INFORMATION:

The Heater-Cooler Unit HCU 40 is substantially equivalent in function and intended use to the Heater-Cooler Unit HCU 30 (K031544).

DEVICE DESCRIPTION AND INTENDED USE:

The Heater-Cooler Unit HCU 40 is used to supply temperature-controlled water to regulate the patient temperature during extracorporeal circulation (ECC). Further application areas are warming and/or cooling therapies. The device can also be used to control the temperature of a cardioplegia solution. Therefore the Heater-Cooler Unit HCU 40 contains two independent water circuits.

One circuit (main circuit) can be connected to the blood heat exchanger (part of the oxygenator) and/or to the warming/cooling blanket. The other circuit (cardioplegia circuit) can be connected to the cardioplegia heat exchanger.
The use of an UV treatment does significantly enhance the water quality between the water change intervals.

The heat exchange with the patient and the cardioplegia fluid occurs when the water passes the heat exchangers and/or the blanket. The water temperature of the main and the cardioplegia circuit can be regulated independently from each other.

The HCU 40 is intended to circulate water through heat exchange circuits to warm or cool a patient during short duration cardiopulmonary bypass procedures lasting 6 hours or less.

TECHNOLOGICAL CHARACTERISTICS:

The HCU 40 is substantially equivalent to the HCU 30 (K031544). The modifications essentially consist of a polished stainless steel housing, full color touch screen with rotary knob, two tank construction for faster body temperature adjustment and cold cardioplegia, more effective ice-building, improved heating performance, independent and precise flow regulation of the patient and cardioplegia circuit, and permanent working UV lamp.

NON-CLINICAL TESTS:

The HCU 40 complies with the voluntary standards identified in Section 3 of this submission. MAQUET's development process required that the following activities be completed during the development of the HCU 40:

- Requirements specification review
- Hardware and software testing
- Code design and code reviews
- Environmental testing
- Safety testing
- Performance testing
- Hardware and software validation

CLINICAL TESTS:

No clinical evaluation of the modified device was conducted or required.

CONCLUSION:

Based upon the information submitted in this Special 510(k) premarket notification, MAQUET's HCU 40 is substantially equivalent to the currently marketed HCU 30 (K031544). The HCU 40 is similar to the predicate device in the intended use, the fundamental scientific technology of the device, and does not raise new issues of safety and effectiveness.

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 1, 2013

MAQUET Cardiopulmonary AG
C/O Helder A. Sousa
Regulatory Affairs Program Manager
45 Barbour Pond Dr.
Wayne, NJ 07470

Re: K130300
Trade/Device Name: Heater-Cooler Unit HCU 40
Regulation Number: 21 CFR 870.4250
Regulation Name: Cardiopulmonary bypass temperature controller
Regulatory Class: Class II
Product Code: DWC
Dated: May 22, 2013
Received: May 23, 2013

Dear Mr. Sousa:

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 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. 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,

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): K130300

Device Name: Heater-Cooler Unit HCU 40

Indications For Use:

The HCU 40 is intended to circulate water through heat exchange circuits to warm or cool a patient during short duration cardiopulmonary bypass procedures lasting 6 hours or less.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)