K102726

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APR - 4 2011

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


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Date Prepared: September 13, 2010

Device Trade Name: CARDIOHELP System

Common/Usual name: Cardiopulmonary Support System

Classification names:
Cardiopulmonary bypass heart/lung machine console (21CFR 870.4220)
Non-roller type cardiopulmonary bypass blood pump (21CFR 870.4360)
Cardiopulmonary bypass level sensing monitor and /or control (21CFR 870.4340)
Cardiopulmonary bypass bubble detector (21CFR 870.4205)
Cardiopulmonary bypass pump speed control (21CFR 870.4380)
Cardiopulmonary bypass oxygenator (21CFR 870.4350)
Cardiopulmonary bypass heat exchanger (21CFR 870.4240)
Cardiopulmonary bypass arterial line blood filter (21CFR 870.4260)
Cardiopulmonary bypass vascular catheter, cannulae, or tubing (21CFR 870.4210)
Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting (21CFR 870.4290)
Cardiopulmonary bypass accessory equipment (21CFR 870.4200)
Cardiopulmonary bypass on-line blood monitor (21CFR 870.4330)

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Predicate Devices:

Systems:
Jostra HL20 Integrated Perfusion System, K943803
RotaFlow Centrifugal Pump System, K991864
LIFEBRIDGE B2T, K090006
Impella 5.0 Catheters, K083111
Levitronix CentriMag Extracorporeal Blood Pumping System, K020271
TandemHeart Escort Controller, K061369

Disposables:
RotaFlow Centrifugal Pump with Bioline Coating, K080470
Jostra QuadroxD Diffusion Membrane Oxygenator with Bioline Coating, K071774
Quadrox-i Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating, K082117
Quadrox-i Small Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Bioline Coating, K093522
HLM- Tubing Set with BIOLINE Coating, K080592
HLM- Tubing Set with SOFTLINE Coating, K090533

Accessory:
Venous Probe accessory (Blood Monitoring Unit BMU40), K090147

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Device Description:

The CARDIOHELP System is a compact perfusion system consisting of the following components:

- the CARDIOHELP-i drives suitable disposables using an integrated pump, controls and monitors the extracorporeal circulation and can communicate with other devices
- the CARDIOHELP Emergency Drive is used in emergencies to manually drive the disposable if the CARDIOHELP-i fails
- different accessories:
    - flow/bubble sensor
    - level sensor including level sensor pad
    - venous probe for blood gas monitoring and measurement of venous temperature
    - external sensors for temperature and pressure
    - different holders
    - connection cables
- various disposables, that can be driven by CARDIOHELP-i
    - HLS/ HIT Set Advanced are tubing sets, that contain the HLS Module Advanced oxygenator with integrated centrifugal pump, which fits into the CARDIOHELP-i. These sets are available in different configurations and will be compiled as customized tubing sets
    - QUADROX–iR is an oxygenator with integrated centrifugal pump and will be provided with or without integrated arterial filter

Indications for Use:

The CARDIOHELP System is a blood oxygenation and carbon dioxide removal system used to pump blood through the extracorporeal bypass circuit for circulatory and/or pulmonary support during procedures requiring cardiopulmonary bypass (for periods up to six hours). It is also intended to provide circulatory and/or pulmonary support during procedures not requiring cardiopulmonary bypass (for periods up to six hours).

The CARDIOHELP System in configuration with the HLS/HIT Set Advanced is intended to be used within the hospital environment and outside the hospital environment (for periods up to six hours), e.g. for intra- and inter-hospital transport.

The CARDIOHELP System in configuration with the QUADROX-iR is intended to be used in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery (for periods for up to six hours).

Comparison of Technical Characteristics to Predicates:

The CARDIOHELP System has indications for use which are substantially equivalent to those of the predicate devices. The predicate devices with a clearance as a system (HL20, Rotaflow, Impella 5.0, Lifebridge B2T, Centrimag, TandemHeart) are designed as extracorporeal circulation systems for perfusion appropriate to cardiopulmonary bypass procedures of six hours or less. The predicate devices Impella 5.0, Centrimag and TandemHeart are also intended to be used to provide circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.

The CARDIOHELP System has similar technical characteristics, performance specifications and materials as the following predicates: Lifebridge B2T (K090006), CentriMag (K020271), Rotaflow (K991864).

CARDIOHELP-i:
The CARDIOHELP-i is a microprocessor based device. The CARDIOHELP-i acts as a drive unit for a suitable disposable (HLS Set Advanced, HIT Set Advanced or QUADROX-iR) by electronically creating a rotating magnetic field. The CARDIOHELP-i provides a user interface including a touch screen, a rotary knob, illuminated push buttons and LED indicator lights to control and display the various parameters. The information can be displayed in various ways to optimize the handling of CARDIOHELP for the user.
The CARDIOHELP-i provides various interconnection possibilities for external sensors and data communication ports for external data acquisition devices. The CARDIOHELP-i also provides an internal battery backup.

Venous Probe:
The Venous Probe as accessory for the CARDIOHELP-i is identical to the Venous Probe accessory of the Blood Monitoring Unit BMU40 (K090147). The Venous Probe measures the venous blood parameters $S_vO_2$ (Oxygen Saturation), Hb (Hemoglobin), Hct (Hematocrit) and temperature. For the blood gas measurements, the probe is connected to the disposables measuring cell.

Flow-Bubble Sensor:
The Flow-Bubble Sensor as an accessory for the CARDIOHELP-i is identical in function and technology to the Flow-Bubble Sensor in the Rotaflow Centrifugal Pump System (K991864). The Flow Bubble Sensor must be clamped on a tubing system for contact less volumetric measurement of the flow. The measurement principle is the ultrasonic transit time technique (UST) which guarantees a safe and precise blood flow measurement. The sensor is also used for bubble monitoring.

External Level Sensors:
The external capacitive level sensor kit for the CARDIOHELP-i is identical to the established external capacitive level sensor kit for the HL20 Integrated Perfusion System (K943803) and the Rotaflow Centrifugal Pump System (K991864).

External Temperature Sensors:
The external temperatures probe for oxygenators as an accessory for the CARDIOHELP-i is identical in function and technology to the external temperature probe for oxygenators of the HL20 Integrated Perfusion System (K943803).

External Pressure Sensors:
The external pressure sensor kit as an accessory for the CARDIOHELP-i is identical to the external pressure sensors of the HL20 Integrated Perfusion System (K943803).

Disposables:

HLS Set Advanced:
The HLS Set Advanced consists of the following components: HLS Module Advanced, Tube Connections and Priming set. The HLS Set Advanced has a BIOLINE Coating which is identical to the HLM Tubing Set with BIOLINE Coating (K080592).

HIT Set Advanced:
The HIT Set Advanced consists of the following components: HLS Module Advanced, Tube Connections and Priming set. The HIT Set Advanced has a SOFTLINE Coating which is identical to the HLM Tubing Set with SOFTLINE Coating (K090533).

HLS Module Advanced (component of HLS/HIT Set Advanced):
The HLS Module Advanced consists of the following three subassemblies: Oxygenator, Heat Exchanger and Centrifugal Pump.
The design of the oxygenator part and heat exchanger part of the HLS Module Advanced is equivalent to the one of the QUADROX-i (K082117 and K093522). The oxygenator part of the HLS Module Advanced has a diffusion membrane identical to the membrane of the QuadroxD (K071774). The heat exchanger is made from Polyurethane hollow fiber. The HLS Module Advanced is equipped with an integrated centrifugal pump, which

will be driven by CARDIOHELP-i in order to pump the blood through the extracorporeal circuit. The integrated centrifugal blood pump is based on the established Rotaflow centrifugal pump RF-32 (K080470). The HLS Module Advanced provides three integrated pressure sensors and two integrated temperature sensors which can be connected to the CARDIOHELP-i. Similar to the QUADROX-i the HLS Module Advanced is available in the sizes "Adult" and "Small Adult".

QUADROX-iR:

The QUADROX-iR consists of the following subassemblies: Oxygenator, Heat Exchanger, Centrifugal Pump and an optional arterial filter.

The design of the oxygenator part and heat exchanger part of the QUADROX-iR is equivalent to QUADROX-i (K082117 and K093522). The oxygenator part of the QUADROX-iR has a microporous membrane identical to the membrane of the QUADROX-i. The heat exchanger is made from Polyurethane hollow fiber. The QUADROX-iR is equipped with an integrated centrifugal pump, which will be driven by CARDIOHELP-i in order to pump the blood through the extracorporeal circuit. The integrated centrifugal blood pump is based on the established Rotaflow centrifugal pump RF-32 (K080470). The optionally available arterial filter of the QUADROX-iR is equivalent to the optional arterial filter of the QUADROX-i (K082117 and K093522). Similar to the QUADROX-i the QUADROX-iR is available in the sizes "Adult" and "Small Adult".

Non-clinical Testing and Performance:

Performance testing has resulted in data that demonstrates that the CARDIOHELP System performs within its specifications and within the acceptable limits of the applied performance standards. The following performance characteristics of the CARDIOHELP System were extensively compared with the predicate devices to determine substantial equivalence: technical data, measurement ranges and measurement accuracy, construction, features, interfaces, handling, critical situations and interventions.

To evaluate the safety and effectiveness of the CARDIOHELP-i with accessories and disposable components the following areas have been tested:

- Electrical and mechanical Safety
- Electromagnetic Compatibility
- Software Validation
- Usability
- Verification of Alarms
- Tests for Inter-hospital transportation
- Packaging
- Verification of Operating Data and Accuracy of Measurements

To evaluate the safety and effectiveness of the HLS/HIT Set Advanced and QUADROX-iR the following areas have been tested:

- Integrity
- Performance
- Tightness
- Biocompatibility
- Shelf life

Determination of Substantial Equivalence

Testing and evaluation in regards to safety and effectiveness was conducted to demonstrate that the CARDIOHELP System described in this submission is substantially equivalent to the above mentioned predicate devices.

The following areas have been evaluated in accordance with various standards when applicable:

- Performance
- Electrical and mechanical safety on the CARDIOHELP-i including accessories
- Software Validation on CARDIOHELP-i
- Biocompatibility on suitable disposables
- Sterility on suitable disposables
- Integrity on suitable disposables

Conclusion

The data provided demonstrate that the CARDIOHELP System is substantially equivalent to the named predicate devices.

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

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APR - 4 2011

Re: K102726
Trade/Device Name: Maquet CARDIOHELP System
Regulation Number: 21 CFR 870.4220
Regulation Name: Cardiopulmonary bypass heart-lung machine console
Regulatory Class: Class II
Product Code: DTQ
Dated: February 16, 2011
Received: February 17, 2011

Dear Mr. Jehle:

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 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): **K102726**

**CARDIOHELP System**

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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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Page _1_ of _1__

Division of Cardiovascular Devices

*(Posted November 13, 2003)* 510(k) Number K102726