K090147

MAQUET

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

APR 22 2009

Submitter: Maquet Cardiopulmonary AG
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Date Prepared: January 14, 2009

Device Trade Name: Blood Monitoring Unit BMU 40

Common/Usual name: Blood Parameter Monitor,
Sensor / Cell

Classification names: Cardiopulmonary bypass online gas monitor
Cardiopulmonary bypass in-line blood gas sensor

Predicate Devices: CDI Blood Parameter Monitoring System 500, K972962
M3 Monitor, K072131

Device Description:

The Blood Monitoring Unit BMU 40 monitors blood parameters during cardiopulmonary bypass or similar procedures with extracorporeal circulation, which require continuous monitoring of the arterial and/or venous blood parameters

The Blood Monitoring Unit BMU 40 is blood monitoring system consisting of the following componens:

- the control unit (monitor, called BMU 40) which comprises a display showing the actual measured sensor values and time course.
- Sterile single use connectors (BMU Sensor/ BMU Cell) to be clamped on the probes, one in the venous line and one in the arterial line. The

connectors are available in different sizes. BMU Sensor is connected to arterial probe and BMU Cell is connected to venous probe.

Indications for Use:

The intended purpose of the MAQUET Blood Monitoring Unit BMU 40 is to monitor blood parameters during cardiopulmonary bypass (CPB) or similar procedures with extracorporeal circulation, which require continuous monitoring of the arterial and/or venous blood parameters: partial pressure of oxygen (pO2), temperature (Ta and Tv), oxygen saturation (SO2), hemoglobin (Hb) and hematocrit (Hct). Oxygen consumption (VO2) can also be calculated. Blood flow (QBlood) can be entered manually or values can be received from a connected heart-lung machine.

The duration of application of the disposable products (arterial BMU Sensor and venous BMU Cell) is limited to six hours.

The BMU 40 is designed for continuous operation.

Statement of Technical Comparison:

The Blood Monitoring Unit BMU 40 is comparable to the CDI Blood Parameter Monitoring System 500 as well as to the M3 Monitor regarding the intended use, design and performance.

Non-clinical Testing and Performance:

The Blood Monitoring Unit BMU 40 performs as intended according to its performance specifications.

The performance characteristics of the Blood Monitoring Unit BMU 40 were exhaustively tested and compared with the predicate device (CDI 500).

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Determination of Substantial Equivalence

Testing and evaluation on safety and effectiveness was executed to demonstrate that the Blood Monitoring Unit BMU 40 described in this submission is substantially equivalent to the CDI Blood Parameter Monitoring System 500 and to the M3 Monitor.

The following areas have been tested:

- Performance
- Electrical and mechanical safety on the monitor- BMU 40
- Software Validation on the monitor- BMU 40
- Biocompatibility on the BMU Sensor and BMU Cell
- Sterility on the BMU Sensor and BMU Cell
- Integrity on the BMU Sensor and BMU Cell

Conclusion

The data given demonstrate that the Blood Monitoring Unit BMU 40 is substantially equivalent to the named predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2009

Maquet Cardiopulmonary AG
c/o Ms. Anastasia Mueller
Hechinger Strasse 38
72145 Hiirrlingen
Germany

Re: K090147
Blood Monitoring Unit BMU40
Regulation Number: 21 CFR 870.4410
Regulation Name: Cardiopulmonary bypass online gas monitor
Regulatory Class: Class II
Product Code: DRY
Dated: January 14, 2009
Received: January 21, 2009

Dear Ms. Mueller:

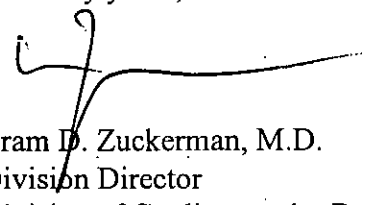
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K090147

Blood Monitoring Unit BMU 40 _____

Indications for Use:

The intended purpose of the MAQUET Blood Monitoring Unit BMU 40 is to monitor blood parameters during cardiopulmonary bypass (CPB) or similar procedures with extracorporeal circulation, which require continuous monitoring of the arterial and/or venous blood parameters: partial pressure of oxygen (pO2), temperature (Ta and Tv), oxygen saturation (SO2), hemoglobin (Hb) and hematocrit (Hct). Oxygen consumption (VO2) can also be calculated. Blood flow (QBlood) can be entered manually or values can be received from a connected heart-lung machine.

The duration of application of the disposable products (arterial BMU Sensor and venous BMU Cell) is limited to six hours.

The BMU 40 is designed for continuous operation.

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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K090147

(Posted November 13, 2003)