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JAN 13 2012

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

K 112114

Date
July 22, 2011

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Trade name:	**Model:**	**Model number:**
FLOW-i Anaesthesia System	MAQUET FLOW-i C20	6677200
	MAQUET FLOW-i C30	6677300
	MAQUET FLOW-i C40	6677400

Device Classification

Common Name	*Classification Number*	*Class*	*Regulation Number*
Gas-Machine, Anaesthesia	73 BSZ	II	21 CFR 868.5160

Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	*510(k) #*
Maquet FLOW-i Anesthestia System	K102182
GE Datex-Ohmeda, Aisys Anaesthesia System	K090233

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Device Description
FLOW-i (K102182 SE5/9/2011) is a high-performance Anaesthesia system designed to meet the many ventilatory challenges within Anaesthesia, as well as to provide inhalation Anaesthesia. It is intended to serve a wide range of patients from neonatal to adult.

FLOW-i is a software-controlled semi-closed system for inhalation Anaesthesia (Sevoflurane, Desflurane, Isoflurane and/or nitrous oxide).
The most important performance features of the FLOW-i Anaesthesia system are:

- a ventilator whose functionality is based on ICU-ventilator technology,
- the volume reflector technology,
- the electronically controlled injector vaporizers and
- the ergonomic design.

The proposed modification (K112114) includes two additional ventilation modes and a backup function:

- PRVC, Pressure Regulated Volume Control
- SIMV (VC and PC), Synchronized Intermittent Mandatory Ventilation
- Pressure Support with Backup

In addition to the new ventilation modes the proposed modification includes a number of minor changes.

PRVC is a controlled mode of ventilation which combines the advantages of volume controlled and pressure controlled ventilation. FLOW-i assures that the preset tidal volume is delivered at the lowest possible pressure in order to protect the lungs. The flow during inspiration is decelerating and patient can trigger extra breaths.
SIMV is designed to improve synchronization of breaths which can decrease patient's tendency to fight against the Anaesthesia ventilator.
Backup functionality has been added to Pressure Support to add safety for the patient and improve the work flow for the users by minimizing apnea alarms.

Indications for Use
The indication for FLOW-i Anaesthesia System is administering inhalation Anaesthesia while controlling the entire ventilation of patients with no ability to breathe, as well as in supporting patients with a limited ability to breathe. The system is intended for use on neonatal to adult patient populations. The system is intended for use in hospital environments, except MRI environment, by healthcare professionals trained in inhalation Anaesthesia administration.

Non-clinical Testing and Performance
Performance testing has demonstrated that the FLOW-i Anaesthesia System performs within its specifications and within the limits of the applied performance standards. The following performance characteristics of FLOW-i Anaesthesia System were thoroughly tested: technical data, measurement ranges and measurement accuracy, delivery accuracy, construction, features, interfaces, handling, critical situations and interventions.

To evaluate the safety and effectiveness of the FLOW-i Anaesthesia System the following areas have been covered:

- Electrical and mechanical Safety
- Electromagnetic Compatibility
- Software Validation
- Usability
- Tightness
- Verification of Alarms
- Packaging
- Verification of Operating Data and Accuracy of Measurements
- Performance
- Biocompatibility
- Vaporizer filling system

Comparison of Technological Characteristics to Predicate Devices
The indications for use and fundamental technology for the modified FLOW-i Anaesthesia System is identical to the cleared FLOW-i Anaesthesia System K102182.

Comparison of Intended Use
The Intended Use for the modified FLOW-i Anaesthesia System (K112114) and the predicate devices FLOW-i Anaesthesia System and Aisys (K090233) are in all essentials the same.

Comparison of Technology Used
The modified device has the same technological characteristics as the cleared FLOW-i Anaesthesia System (K102182). The functionality of the new ventilation modes is equivalent to the predicate anaesthesia machine Aisys (K090233).

Conclusion
MAQUET believes that the modified FLOW-i Anaesthesia System (K112114) is substantially equivalent to the cleared FLOW-i Anaesthesia System (K102182) and Aisys (K090233) regarding intended use of the devices, the indications for use and the fundamental technology of the devices. Based on the risk analysis, MAQUET has conducted the necessary design verification and validation activities to demonstrate that the design outputs of the subject device meet the design input requirements. MAQUET has concluded that FLOW-i is substantially equivalent to the 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

Maquet Critical Care AB
C/O Ms. Whitney Torning
Director, Regulatory Affairs
Maquet Incorporated
45 Barbour Pond Drive
Wayne, New Jersey 07470

JAN 13 2012

Re: K112114
Trade/Device Name: FLOW-I Anesthesia System
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: January 3, 2012
Received: January 4, 2012

Dear Ms. Torning:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number: K112114

Device Name: FLOW-i Anesthesia System

Indications for Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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