K063404

510 (k) Summary
as required by section 807.92(c)

Subscribers Name & Address

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FEB 15 2007

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USA Contact :

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Trade Names

SERVO-i **Ventilator System** article no.; 64 87 800
MR Environment option:
MR Environment kit (on-site) 66 71 712 and (factory installed) 66 72 289

Device Classification

Common Name	*Classification Number*	*Class*	*Regulation Number*
Ventilator, Continuous (Respirator)	73 CBK	II	868.5895

Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	*510(k) #*
SERVO-i Ventilatory System	K041223
Aestiva/5 MR1 GE, Datex-Ohmeda Inc.	K050055
IC-2A Bio-med Devices Inc.	K896380
MVP-10 Bio-med Devices Inc.	K896391
iVent 201 VersaMed Medical Systems Inc.	K061627

Device Description

The ventilator is a platform with several selectable ventilation modes, which monitor patients whom need respiratory assistance. The MR environment option makes it possible to qualify the Servo-i ventilator to be used in MR environment

Indications for use:

The SERVO-i Ventilator System is intended for treatment and monitoring of patients in the range of neonates, infants and adults with respiratory failure or respiratory insufficiency. SERVO-i is a ventilator system to be used only by healthcare providers in hospitals or healthcare facilities and for in-hospital transport.

The SERVO-i Ventilator with MR environment option is classified as MR Conditional for 1.T, 1.5T and 3T MR scanners. This means that it is safe to use in the MR environment if the conditions in the MR Environment Declaration for SERVO-i are met.

Summary of technological characteristics of modified Device and Predicate Device: MR Environment option

The SERVO-i ventilator with MR option have been tested with 1.0, 1.5, 3.0 T scanners without impairing its performance or the image quality of the scanner.

Vital parts of the ventilator have been tested for performance in excessive magnetic fields to evaluate the safety margins.
The emission from the SERVO-i has been further decreased with the MR option to reduce the probability for artifacts on the scanner images.
Each scanner and its environment forms an individual device. The MR Environment Declaration describes how a SERVO-i with MR option can be qualified to be used with an MR scanner forming a safe Medical System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Maquet Critical Care AB
C/O Mr. Jamie Yieh
Director, Regulatory Affairs/Quality Assurance
Maquet, Incorporated
1140 Route 22 East, Suite 202
Bridgewater, New Jersey 08807

FEB 15 2007

Re: K063404
Trade/Device Name: SERVO-i Ventilator System
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: January 24, 2007
Received: January 26, 2007

Dear Mr. Yieh:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: SERVO-i Ventilator System

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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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