K073179
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## 510(K) SUMMARY

**As required by section 807.92(c)**

JUN - 9 2008


**Subscribers Name & Address**
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Röntgenvägen 2
SE-171 95 Solna, Sweden
Tel: (011) 46 8 730 73 00
Fax: (011) 46 8 730 78 38

Contact Persons for this submission:

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USA Contact :

Mr. Jamie Yieh
Director, Regulatory Affairs
Maquet, Inc.
1140 Route 22 East, Suite 202
Bridgewater, NJ 08807
Phone: 908-947-2311
Fax: 908-947-2301
Email: jamie.yieh@maquet-inc.com


**Trade Names**
SERVO-i Ventilator System with Heliox option

Preparation date 2007-11-09

**Device Classification**

| *Common Name* | *Classification Number* | *Class* | *Regulation Number* |
|---|---|---|---|
| Ventilator, continuous (Respirator) | 73 CBK | II | 21 CFR 868.5895 |

**Predicate Device Identification**

| *Legally marketed devices to which equivalence is being claimed* | *510(k) #* |
|---|---|
| Maquet, SERVO-i Ventilator System | K063404 |
| Viasys, Avea with Heliox option | K022674 |
| GE Datex-Ohmeda, Aptaér Heliox Delivery System | K041524 |

**Device Description**
Summary of technological characteristics of modified Device and Predicate Device:
The predicate device SERVO-i Ventilator System is a ventilator, which gives, ventilation (Invasive and Non Invasive) to critical care patients in the weight range 0.5 to 250 Kg's. The modified device adds an option, called "Heliox option", which is a mechanical adaptor along with software for SERVO-i Ventilator System integration.

**Intended Use of the Device:**
The SERVO-i Ventilator System with Heliox option 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. The SERVO-i Ventilator System with Heliox option is also MR conditional.

The SERVO-i Ventilator System with Heliox option is indicated for use with the delivery of Air, Oxygen, or Heliox (a mixture of Helium and Oxygen).

**Comparison to predicate devices.**
The subject device is comparable to the predicate devices in that the intended use is for delivery of Heliox, for the patient ranges of neonatal to adult, and in invasive and non-invasive applications. All devices utilize gas connectors or adapters and software enhancements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2008

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

Re: K073179
Trade/Device Name: SERVO-i Ventilator System with Heliox Option
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: May 12, 2008
Received: May 13, 2008

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.

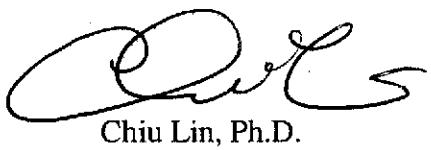
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 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 STATEMENT

510(k) Number (if known): K073179

Device Name: SERVO-i Ventilator System with Heliox option

Indications for Use:
The SERVO-i Ventilator System with Heliox option 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. The SERVO-i Ventilator System with Heliox option is also MR conditional.

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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)

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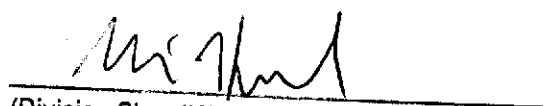
Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number: K073179