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K041223

MAQUET	Document Type ~~Special 510(k)~~	Section-Page 135 (140)
Object/Subject NIV option for Servo-i		Doc-ID EVU-116506 Issue no. - 00

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

Subscribers Name & Address

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Trade Names

Servo-i **Ventilator System** article no.; 64 87 800 E407E
NIV option article no.; 66 67 187 E407E

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	K040221
Evita 4, NIV option	K010093

Device Description

The ventilator is a platform with several selectable ventilation modes which monitor patients whom need respiratory assistance.

Summary of technological characteristics of modified Device and Predicate Device: NIV option for Non –Invasive ventilation

The Non-Invasive Ventilation Option is a software controlled feature available on the Servo-i ventilator. The microprocessor control of this feature allows a larger range of flow capabilities designed to meet patient needs safely in a non-invasive application.

To detect disconnect or excessive leakage there are two independent alarm functions:

- an alarm will be given if the leakage is excessive.
- if the minimum PEEP will be unable to maintain (as in predicate device Servo-i)

If leakage decreases the ventilation will resume automatically (or by manual start as in predicate Servo-i).

Intended Use of the Device:

The intended use(s) and indications of the Servo-i application, as described in its labelling, are the same as the intended uses and indications for the *unmodified* Servo-i, except for the intended population for Infant using the NIV option where the lower range is changed from 0,5 Kg to 3 Kg.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2004

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

Re: K041223
Trade/Device Name: Modification to Servo-I Ventilator System, Model 64 87 800
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: May 10, 2004
Received: May 10, 2004

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.

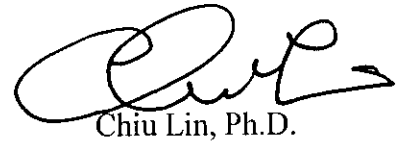
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4646. 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/dsma/dsmamain.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

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.

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

510(k) Number: K041223