K030780

JAN 2 3 2004

SECTION 4. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter's Name and Address

Newport Medical Instruments, Inc.

760 West 16th Street – Building N

Costa Mesa, California 92627

Mailing Address:

P.O. Box 2600

Newport Beach, California 92658

B. Submitter's Phone and FAX Number

(949) 642-3910 Telephone

(949) 645-5026 FAX

C. Name of Contact Person

Richard Waters

Vice President, Quality Assurance & Regulatory Affairs

D. Date the Summary was Prepared

March 8, 2003

E. Name of the Device

1. Trade or Proprietary Name

Newport e500 Wave Ventilator

2. Common or Usual Name

e500 Ventilator

3. Classification Name

868.5895 Continuous Ventilator 73CBK

4. Device Class

Class II

F. Summary of Substantial Equivalence

The Newport e500 Wave Ventilator, the E200 Ventilator and the Siemens Servo Ventilators are intended to provide continuous or intermittent ventilatory support for the care of the individuals who require mechanical ventilation. The performance and clinical features of each ventilator supports infant/pediatric (= 20 mL) through adult applications.

The materials and design of this device are similar to those of the predicate devices. The technical characteristics of the e500 Ventilator do not introduce new questions regarding safety and effectiveness of critical care ventilators. Additionally, the labeling of the e500 provides similar information as the predicate devices.

The information provided in the 510(k) submission supports the determination of substantial equivalence. Biocompatibility analysis demonstrates that the product is safe for its intended environment.

Software design and development, including verification and validation testing, have been conducted using the FDA's Reviewer Guidance of Medical Device Software

Submissions, December 15, 1995 draft as a guidance, and per company internal requirements.

G. Description of the Device

The Newport e500 Wave Ventilator is a self-contained, electrically powered microprocessor controlled ventilator. Performance characteristics and clinical features support infant/pediatric (=20mL) through adult patients.

Front panel controls allow trained operators to select between a number of operational modes, pressure support and volume or pressure control. A comprehensive alarm system is built-in to alert the user to violations of preset safety limits. When fully charged, the internal battery provides an average of 1.5 hours of power.

The alarms associated with the e500 meet or exceed standards of critical care ventilators and have been developed in compliance with ISO9703-1, ISO9703-2 and EN475. The alarms of the e500 span both technical (ventilator related) alarms and non technical alarms (patient related alarms).

H. Device Intended Use

The e500 Ventilator is intended to provide continuous (ET tube) or non-continuous (mask) ventilatory support and monitoring for infant, pediatric and adult patients with a tidal volume of = 20 mL. The device is prescription use only.

The intended environments include hospital, hospital-type and intra-hospital transport environments. Hospital use typically includes general care floors, operating rooms, special procedure areas, and intensive and critical care areas within the hospital. Hospital-type use includes facilities such as or similar to surgicenters, sub-acute centers, and special nursing ficilities outside of the hospital. Intra-hospital transport includes patient transport within the hospital or hospital-type facility.

I. Summary of Comparison of Technological Characteristics

The e500 is substantially equivalent with the E200 Ventilator and the Siemens Servo Ventilators across the spectrum of the patient population (infant/pediatric to adult) for which each was designed. All of the devices share common modalities (volume control,

pressure control, pressure support) and significantly overlap in the clinical range of function for their target population. Although some differences in design application are noted, the essential clinical function of each device is significantly similar and mimics each other in the typical frame of use by the health care provider. Each provide significant safety features in terms of alarms, back up ventilation, and fail safe mechanisms. Each provides internal battery, ease of use, simple circuit design and matching clinical function.

J. Summary of Non-clinical Tests

The Newport e500 Wave Ventilator meets all applicable device specification requirements for performance testing as identified in the FDA Reviewer Guidance for Ventilators as well as the

Additionally, the e500 has been tested to and conforms to the following domestic and international standards.
IEC601-1
CISPR 11
EN60601-1-2
EN 794-1
ISO9703-1&2
ASTM F 1100-90
MIL-STD461D
MIL-STD810E

K. Conclusion

The Newport e500 Wave Ventilator as a self-contained, electrically powered, microprocessor controlled ventilator, has functionally proven to be safe. The device meets its stated performance specifications and the *Reviewer Guidance for Pre-market Computer Controlled Medical Devices Undergoing 510(k) Review.* NMI concludes that the device will operate safely for its intended environments and will be effective in fulfilling its intended use. Given the intended use and patient criticality level, the e500 Wave Ventilator features are as safe and effective as the respective features provided on the predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 2004

Mr. Richard Waters
Vice President, Regulatory Affairs/QA
Newport Medical Instruments
760 West 16th Street, Bldg. N
Costa Mesa, CA 92627

Re: K030780
Trade/Device Name: Newport e500 Wave Ventilator
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: October 24, 2003
Received: October 28, 2003

Dear Mr. Waters:

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.

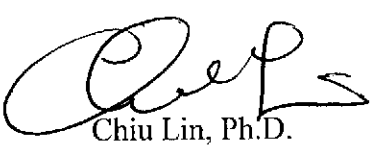
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K030780

Device Name: Newport e500 Wave Ventilator

Indications for Use:

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

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

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

510(k) Number: K030780