K041082

SEP - 7 2004

SECTION 11. 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. Name, Address, Phone and Fax Number of the Applicant

Newport Medical Instruments, Inc.
760 West 16th Street, Building N
Costa Mesa, California 92627
Telephone: (949) 642-3910
Fax: (949) 645-5026

B. Contact Person

Richard Waters
Vice President, Regulatory Affairs / Quality Assurance
760 West 16th Street, Building N
Costa Mesa, California 92627
Telephone: (949) 642-3910
Fax: (949) 645-5026

C. Date Prepared

April 23, 2004

D. Device Name

Newport NebSonic N550 Ultrasonic Nebulizer

E. Device Description

The NebSonic N550 Nebulizer is an ultrasonic nebulizer designed to deliver nebulized medication to patients being mechanically ventilated without affecting ventilator performance or patient data. It is powered by external AC (100-240 volts), allowing its use with patients on mechanical ventilation or for patient use independent of a ventilator. The NebSonic N550 Nebulizer contains piezoelectric crystal that generates ultrasonic vibrations that travel through distilled water in a vial to liquid medication in a medication cup. The vibrations convert the medication into an aerosol

mist. The nebulized medication is carried to the patient by the gas traveling through the ventilator breathing circuit.

F. Device Intended Use

The NebSonic N550 Nebulizer delivers nebulized medication for patients on mechanical ventilation or for patient use independent of a ventilator. The NebSonic is indicated for adult, pediatric, and neonatal patients.

G. Substantial Equivalence Summary

The NebSonic N550 Nebulizer is substantially equivalent to the Siemens Servo Ultra Nebulizer, Models 145 and 345, cleared under K960854, and the Puritan-Bennett EasyNeb Nebulizer, cleared as an accessory to the Puritan-Bennett 700 Series Ventilator under K990897.

H. Device Testing

The NebSonic N550 Nebulizer has been thoroughly evaluated at the unit and system level. Comprehensive testing has been conducted on the NebSonic N550 Nebulizer in accordance with various industry recognized standards, including: IEC 60601-1-2:1993, CSA 22.2 No 601-1-M90, UL 2601-1, EN 55011:1998 &A1:1999. Testing was conducted to characterize particle size and drug mass generated by the NebSonic N550 Nebulizer in comparison to a predicate device. The combined testing and analysis of results provides assurance that the device meets its specifications and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2004

Mr. Richard Waters
Vice President, Regulatory Affairs/Quality Assurance
Newport Medical Instruments, Incorporated
760 West 16th Street, Building N
Costa Mesa, California 92627

Re: K041082
Trade/Device Name: NebSonic N550 Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: August 31, 2004
Received: August 31, 2004

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.

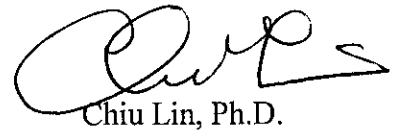
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K041082

Device Name: NebSonic N550 Nebulizer

Indications for Use:

The NebSonic N550 Nebulizer delivers nebulized medication for patients on mechanical ventilation or for patient use independent of a ventilator. The NebSonic is indicated for adult, pediatric, and neonatal patients

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K041082

(Posted November 13, 2003)