K062263

Non-Confidential Summary of Safety and Effectiveness FEB 23 2007

15-Feb-07

Omron Healthcare, Inc.
1200 Lakeside Dr.
Bannockburn, IL 60015

Tel – 847-247-5609
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Official Contact: Randy Kellogg – VP Marketing and Product Development

Proprietary or Trade Name: Omron Micro Air Vibrating mesh nebulizer

Common/Usual Name: Nebulizer

Classification Name: Nebulizer (Direct Patient Interface)

Device: Model NE-U22

Predicate Devices: Omron – NE-U04 – K923024

Device Description:

Micro Air Vibrating Mesh Nebulizer (NE-U22) uses low frequency vibration to create aerosol and provide fine particles to the patient's lungs. The mesh plate has more than 6,000 holes to create low velocity aerosol. The VMT nebulizer is portable and quiet. This nebulizer is battery powered, 2 "AA" and it is lightweight. The batteries last approximately 40 treatments. This nebulizer provides precise drug delivery in a very short time. The metal alloy mesh cap is durable and resistant to corrosion.

Indications for Use:

Indicated Use -- The Omron NE-U22 is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize liquid medications for inhalation by the patient.

It is not intended for use with Pentamidine.

Patient Population -- Pediatric and adult

Environment of Use -- Home, hospital, and sub-acute care settings.

Contraindications -- None

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Device Attributes:

Features	NE-U22	NE-U04
Indications for use	The Omron NE-U22 is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize liquid medications for inhalation by the patient. It is not intended for use with Pentamidine.	Same
Environment of Use	Home, Hospital, Sub-acute Institutions	Same
Patient Population	Pediatric and adult	Same
Contraindications	None	Same
Power source	Battery – 2 "AA" AC Adapter AC 120V (60Hz/ DC 3 V	Same
Nebulizing method	Vibrating mesh	Same
Software driven	No	No
Materials in patient contact	Polypropylene	Identical
Standard met	IEC 60601-1, IEC 60601-1-2, UL 60601-1, FCC Part 15 Subpart B Class B, ISO 14971	Same
Drug delivery rate	0.25 ml/min to 0.9 ml/min	<0/3 ml/min
Reservoir size	7 ml	7 ml
Nebulizer components cleanable	Yes	Yes
Operating conditions	0°C to 45°C 30% to 85% RH	Same
Storage conditions	-25°C to 70°C 10% to 90% RH	Same
Dimensions (mm)	38(W) x 51(D) x 104(H)	68(W) x 60(D) x 172(H)
Weight (kg) without battery	97 grams without battery	148 gm without battery

Differences Between Other Legally Marketed Predicate Devices

The Model Micro Air Vibrating Mesh Nebulizer (NE-U22) is viewed as substantially equivalent to the following predicate device – Omron NE-U04 – K923024.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 2007

Mr. Randdy Kellogg
VP Marketing and Product Development
Omron Healthcare, Incorporated
1200 Lakeside Drive
Bannockburn, Illinois 60015-1243

Re: K062263
Trade/Device Name: Micro Air Vibrating Mesh Nebulizer Model – NE-U22
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: February 4, 2007
Received: February 6, 2007

Dear Mr. Kellogg:

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.

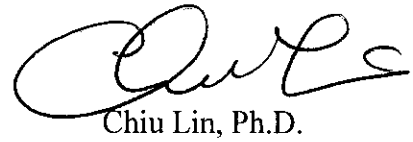
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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: K062263

Device Name: Micro Air Vibrating Mesh nebulizer Model - NE-U22

Indications for Use: The Omron NE-U22 is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize liquid medications for inhalation by the patient.

The device may be used with pediatric and adult patients in the home, hospital, and sub-acute care settings.

It is not intended for use with Pentamidine.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (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)

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