ATTACHMENT 5

510(k) SUMMARY K121154

AUG 20 2012

1. Sponsor:

Date of Submission Preparaton: 02/20/2012

510(k) S ubmitter's Na me: Foshan Gaunying Electronics Co.,Ltd.

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3.Proposed Device:

Trade Name: Nebulizer NE403
Classification Name: Nebulizer (Direct Patient Interface)
Regulation Number: 868.5630
Product Code: CAF
Device Class: II

4. Predicate Device:

Predicate Device: Micro Air Vibrating Mesh Nebulizer
510(k) Number: K062263
Manufacturer: Omron Healthcare Inc.

5. Description of Proposed Device:

Nebulizer NE403 is a mesh screen ultrasonic nebulizer which was used ultrasonic Vibrating Mesh Technology (VMT). The device creates aerosols of liquid medication by ejection of droplets from a mesh vibrated at ultrasonic frequencies. As with other mesh screen ultrasonic nebulizers, the mesh is caused to vibrate by fluidic contact with a ultrasonic piezoelectric member that is energized by application of a high frequency alternating

voltage. The VMT nebulizer is portable and quiet. This nebulizer is powered by four AA alkaline batteries or a cable connecting to an AC adapter.
Nebulizer NE403 consists of several function units: liquid medication containment, liquid nebulization and ejection, nebulized medicine (brume) channel (breathing parts), power supply, operating and display unit.
liquid medication is poured into medicinde container, transformed into something like brume, which is inhaled by patient via breathing parts, thus, the intended use of device is achieved.

6. Statement of indications for Use:

The ultrasonic mesh nebulizer model NE403 is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize medications for inhalation by the patient.

The device may be used by adult patients at home, hospital & sub-acute care settings.

7. Biocompatibility Certification:

Biocompatibility Testing conducted on the Masks, Mouthpiece and the components which contact the gas path of the patients according to ISO10993-1, ISO10993-3, ISO10993-5, ISO10993-6, ISO10993-10.

8. Comparison to predicate device

Both the nebulizer and the Predicate device have the same intended use and fundamental technology. They have the same energy type, nebulizing method, particle size, etc. although differences between them in the respect of the target population, nebulizing rate, those items of nebulizer NE403 fall into the range of predicate device. A side-by-side comparison of the NE403 and the cited predicate devices is included in the 510(k) submission (Section 09). The NE403 is substantially equivalent to the technological features as the predicate devices.

9. Discussion of Non -Clinical Tests Perf ormed for Determi nation of Substantial Equivalence are as follows:

The NE403 did not conduct, nor rely upon, clinical tests to determine substantial equivalence. Non-clinical testing was performed in order to validate the design according to the company's specified design requirements, and to assure conformance with the following voluntary design standards:

IEC 60601-1 "Medical electrical equipment - Part 1: General requirements for safety".
IEC 60601-1-2 "Medical electrical equipment - Part 1-2: General requirements for safety – Collateral Standard"
EN 13544-1:2007 "Respiratory therapy equipment - Part 1: Nebulizing systems and their components".

In addition, according to FDA guidance (reviewer guidance for nebulizers,metered dose inhalers, spacers andactuators), the Aerosol Performance Comparison Testing of the proposed device(NE403) and predicate device(NE-U22) , as well as the Intra-Sample and Inter-Sample Dose and Particle Size Variability Testing of NE403 were conducted.

10. Conclusions:

The NE403 has the same intended use and technological characteristics as the predicate device. Moreover, bench testing and safety report documentation supplied in this submission demonstrates that the difference in the submitted models could maintain the same safety and effectiveness as that of predicate device. In the other words, those engineering difference do not affect the intended use or alter the fundamental scientific technology of the device. Thus, the NE403 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Foshan Gaunying Electronics Company, Limited
C/O Mr. Guenter Ginsberg
Media Trade Corporation
11820 Red Hibiscus Drive
Bonita Springs, Florida 34135

AUG 2 0 2012

Re: K121154
Trade/Device Name: Nebulizer NE403
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: July 7, 2012
Received: July 10, 2012

Dear Mr. Ginsberg:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 4

Indications for Use

510(k) Number ( ):

Device Name:

Nebulizer NE403

Indications for Use:

The ultrasonic mesh nebulizer model NE403 is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize medications for inhalation by the patient.

The device may be used by adult patients at home, hospital & sub-acute care setting.

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

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