K132247

JAN - 8 2014

510(k) SUMMARY

Date of Summary Prepared: 11/05/2013

1. Submitter's Name: Foshan Gaunying Electronics Co., Ltd.

Address: 4F, #4 Industry Country, Cheng Nan Park of Foshan Hi-tech Industrial Development Foshan Guangdong, China 528000

Contact person: Ladi Lee, General Manager

Tel: +86-757 -8310 7610

Fax: +86-757 -8310 7621

E-mail xhli@fseagle.com.cn

2. Proposed New/Modified Device:

Trade Name: Ultrasonic Mesh Nebulizer NE105

Classification Name: Nebulizer (Direct Patient Interface)

Regulation Number: 868.5630

Product Code: CAF

Device Class: II

3. Predicate (cleared) Device:

Predicate Device: Micro Air Vibrating Mesh Nebulizer NE-U22

510(k) Number: K062263

Manufacturer: Omron Healthcare Inc.

4. Description of Proposed Device:

The Ultrasonic Mesh Nebulizer NE105 is similar to the predicate device, the FDA-cleared Model NE-U22 Micro Air Vibrating Mesh Nebulizer, cleared under 510(k) K062263.

Similarities are that both, the NE105 and the predicate NE-U22, are identical in purpose, function, core technology and method of operation. They are single-patient use, reusable electronic nebulizers, using micro-perforated vibrating mesh technology to aerosolize liquid medications. They have the same 'Indication for Use' stating that they are for inhalation therapy by adults and pediatric patients in a home, hospital & sub-acute care setting. Both devices are hand-held and portable. Power input for both devices is provided by either AA batteries or an AC/DC adapter.

The model NE105 incorporates several design differences in comparison with the predicate NE-U22, mainly body shape, dimension/weight, a larger capacity reservoir, power source and software controlled electronics. Although body shape, dimensions/weight, reservoir size are somewhat different they have been evaluated and passed the testing according to IEC60601-1 and therefore pose no new questions of safety and effectiveness. As for the software, the predicate device has none, the Model NE105 has microprocessor controlled functions that include automatic turn-off when medication is used up, batteries are below voltage, or after a preset idle time. These features serve as additional safety features and extend the life of the batteries and the product and pose no new questions of safety and effectiveness.

The NE105 is substantially equivalent to the technological features as the predicate devices.

5. Statement of Indications for Use:

The Ultrasonic Mesh Nebulizer, Model NE105 is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize medications for inhalation by the patient. The device may be used by adult and pediatric patients at the discretion of their physician at home, hospital & sub-acute care setting.

6. Technological Characteristics Compared to the Predicate Device

Both the nebulizer NE105 and the Predicate device NE-U22 have the same intended use and fundamental technology. As with its predicate the NE105 uses micro-perforated membrane technology to aerosolize liquid medications. This technology uses a waver-thin plastic membrane, perforated with numerous laser-drilled holes. This micro-perforated membrane vibrates at high frequencies against a body of fluid. The vibration source is a piezo-electric actuator that is activated by an electronic drive circuit. The actuator and the membrane form the atomizing head that is in contact with the liquid medication to be aerosolized. Liquid micro-jets are created as a response to the vibration of the membrane. Surface tension and hydrodynamic effects then cause these jets to disperse to produce a stream of precisely-controlled droplets.
In comparison of the two devices the NE105 versus the predicate NE-U22, they both work with the same technology, the principle of jet nebulization.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:

The NE105 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:

a. EMC and electrical safety

IEC 60601-1 "Medical Electrical Equipment-Part 1: General requirements for basic safety and essential performance ".
IEC 60601-1-2 "Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance-collateral standard: Electromagnetic compatibility-requirements and tests"
All tests were verified by the testing laboratories and were certified with a Declaration of Conformity.

b. **Biocompatibility**

Biocompatibility Testing on the Body contacting components such as Masks, Mouthpieces, Liquid Container and Transducer that contact the gas path of the patients were performed according to ISO 10993-1 as required. These tests included testing for: Cytotoxitity, Sensitization, Irritation, Subchronic Toxitity, Genotoxitity and Implantation. These tests did confirm the biocompatibility of the materials used.

c. **Software**

Based upon the test results it was concluded that the software performs within specifications and is safe to the stated intended use. Since a permanent hazard analysis is implemented in the software development process, and due to the clear software architecture, it is believed that the test protocol sufficiently verifies the software's main functional operation.

d. **Cleaning**

The cleaning instructions as described the Instruction Manual have been tested to be sufficient. Testing involved validation of the manual cleaning method as per the instructions. All testing concluded that that the nebulizer can be cleaned by the use of the methods described in the Instruction Manual.

e. **Simulated Lifetime Testing**

A "Simulated Lifetime Study" was conducted by a renowned Laboratory and an in-house 1000-cycle life test was performed, only to conclude that when cleaned after use as per the cleaning instructions in the Instruction Manual, there was no change in the performance, effectiveness and safety of the device.

f. **Aerosol Characterization**

An aerosol characterization (particle size distribution) was performed by Piper Medical Lab in comparison with the predicate device. All tests confirmed that the results were in line with the results of the predicate device.

Each device was tested with albuterol sulfate, ipratropium bromide and cromolyn sodium for particle size distribution and total medication dose delivered as percent of fill. Furthermore, Inter-Sample and Intra-Sample Variability Tests were performed to demonstrate that there is no indication of any measurable inter-sample variance. All test showed that the Model NE 105 performed equally

well compared with the predicate device.

g. **EMC and Electrical Safety**

Performance testing has established that, with respect to EMC and electrical safety in its intended operational environment, the device conforms to all applicable requirements of IEC 60601-1 and IEC 60601-1-2 as certified by Declarations of Conformity by the Testing Laboratories.

8. Conclusions:

The Ultrasonic Mesh Nebulizer, Model NE105 has the same intended use and technological characteristics as the predicate device. Moreover, bench testing and safety report documentation demonstrate that the submitted Model NE105. In the other words, the differences do not affect the intended use and do not raise any new questions of safety or effectiveness or alter the fundamental scientific technology of the device. Thus, the NE105 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 Center – WO66-G609
Silver Spring, MD 20993-0002

January 08, 2014

Foshan Gaunying Electronics Co., Ltd.
C/O Mr. Guenter Ginsberg
President
Media Trade Corporation
11820 Red Hibiscus Drive
Bonita Springs, FL 34135

Re: K132247
Trade/Device Name: Ultrasonic Mesh Nebulizer NE105
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer (Direct Patient Interface)
Regulatory Class: Class II
Product Code: CAF
Dated: December 2, 2013
Received: December 5, 2013

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.

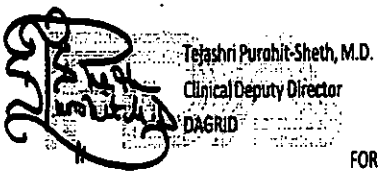
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

QUATEK
佛山廣鷹電子有限公司
FOSHAN GAUNYING ELECTRONICS CO.,LTD

Indications for Use

510(k) Number (K132247):

Device Name:

Ultrasonic Mesh Nebulizer NE105

Indications for Use:

The ultrasonic mesh nebulizer model NE105 is an ultrasonic (vibrating mesh) nebulizer system designed to aerosolize medications for inhalation by the patient. The device may be used by adult and pediatric patients at the discretion of their physician 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)

FDA

Anya C. Harry -S
2014.01.07 15:44:19
-05'00'