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K-jump Health Co., Ltd
Pre-market Notification for Ultrasonic Nebulizer (Mesh Type)

510(k) Summary of Safety and Effectiveness

May 18, 2012

1. Submitter

K-jump Health Co., Ltd
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2. Name of Device

Common/Usual Name: Ultrasonic Nebulizer (Mesh Type)
Classification Name: Nebulizer (Direct Patient Interface)
Regulatory Number: 21CFR 868.5630
Regulatory Class: II
Product Code: CAF

3. Predicate Device

Device Name	510(k) Number	Decision Date
Omron Micro Air Vibrating mesh nebulizer NE-U22	K062263	02/23/2007

4. Device Description

The Ultrasonic Nebulizer is a small, compact, and battery powered potable nebulizer which transforms liquid medicines into aerosol form and delivers directly to patient for inhalation. It makes patient's respiratory treatment easier and more convenient.

5. Indications for Use

The Ultrasonic Nebulizer is intended to transform liquid medications into aerosol form for patient inhalation. The device can be used by adult or pediatric patients for respiratory treatment in the home, hospital or healthcare environment.

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6. Technological Characteristics

The Mesh Type Ultrasonic Nebulizer utilizes ceramic resonator and mesh plate to transform liquid medications into aerosol form and deliver fine particles to the patients. The device is powered by two AA type batteries which make it ultra-light and quiet compared with traditional compressor and ultrasonic nebulizer.

7. Comparison to Predicate Device

The Ultrasonic Nebulizer is substantially equivalent to the predicate devices, K062263, Omron Micro Air Vibrating mesh nebulizer. The comparison of their technological characteristics is summarized in the table below.

Characteristics	K-jump Ultrasonic Nebulizer (Mesh Type)	Omron Micro Air Vibrating Mesh Nebulizer
510(K) Number	TBD	**K062263**
Intended Use	Similar	Similar
Technology	Mesh Type	Vibrating Mesh
Characteristics		
Vibrating Frequency	190 kHz	180 kHz
Button	ON/OFF Switch	Same
Ampoule Capacity	7.0 ml	Same
Nebulization Rate	0.3 ml/min(Typical)	0.25-0.9 ml/min
Environment		
Operation condition	5℃ ~40℃, 15%-93% RH non-condensing	0℃ ~45℃ 30%-85% RH
Storage condition	-25℃ ~70℃, Up to 93% RH non-condensing	-25℃ ~70℃ 10%-90% RH
Power		
Power source	Two AA batteries	Two AA batteries AC adapter AC 120V (60Hz/DC 3V)
Power consumption	1.0W	1.5W
Power indicator	LED	LED

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Characteristics	K-jump Ultrasonic Nebulizer (Mesh Type)	Omron Micro Air Vibrating Mesh Nebulizer
Physical		
Dimensions	35mm(W) x 60 mm(D) x 104 mm (H)	38mm(W) x 51 mm(D) x 104 mm (H)
Weight	90g (without batteries)	97g (without batteries)

8. Performance Summary

The performance of the Ultrasonic Nebulizer is verified and validated according to FDA Guidance Document "Reviewer Guidance for Nebulizer, Metered Dose Inhalers, Spacers and Actuators", dated October 1, 1993, and following recognized standards.

1. ANSI/AAMI ES60601-1:2005 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance

   The Ultrasonic Nebulizer complies with to applicable ANSI/AAMI ES60601-1 requirements including general requirements, protection against electrical hazards, protection against mechanical hazards, protection against excessive temperatures, hazardous situations and fault conditions, and constructions.

2. ANSI/AAMI/IEC 60601-1-2:2007 Medical Electrical Equipment – Part 1-2: General Requirements for Safety; Electromagnetic Compatibility

   The Ultrasonic Nebulizer complies with applicable ANSI/AAMI/IEC 60601-1-2 requirements including radiated emission test, electrostatic discharge immunity test, radiated RF electromagnetic field immunity test, and power frequency magnetic field immunity test

9. Conclusions

The Ultrasonic Nebulizer has similar intended use, similar fundamental scientific technology, and similar technological characteristics with the predicate device. Moreover, both devices comply with equivalent safety standards and have similar performance. All information described above can demonstrate the Ultrasonic Nebulizer is substantial 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

March 15, 2013

Mr. JM Lin
Regulatory Affairs Representative
K-Jump Health Company, Limited
No. 56, Wu Kung 5th Road
New Taipei Industrial Park
New Taipei City Taiwan 24890

Re: K121520
Trade/Device Name: Ultrasonic Nebulizer (Mesh Type)
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: February 20, 2013
Received: February 28, 2013

Dear Mr. Lin:

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,

Kwame O. Ulmer for

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

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Ultrasonic Nebulizer (Mesh Type)

Indications For Use:

The Ultrasonic Nebulizer is intended to transform liquid medications into aerosol form for patient inhalation. The device can be used by adult or pediatric patients for respiratory treatment in the home, hospital or healthcare environment.

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

Albert E. Moyal -S

for LS

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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