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 8, 2015

Suzhou Weikang Medical Apparatus Co., Ltd.
c/o Mr. Mike Gu
Regulatory Affairs Manager
OSMUNDA Medical Device Consulting Co., Ltd.
7th Floor, Jingui Business Building
N0. 982 Congyun Rd., Baiyun District
Guangzhou, Guangdong
CHINA 510420

Re: K140237
Trade/Device Name: Disposable Nebulizer Set
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer (Direct Patient Interface)
Regulatory Class: Class II
Product Code: CAF
Dated: December 4, 2014
Received: December 8, 2014

Dear Mr. Gu:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k140237

Device Name
Disposal nebulizer set

Indications for Use *(Describe)*
The disposable nebulizer set is used to administer various aerosol treatments to adult patients in hospital environments. It is not intended for transport use. The Disposable Nebulizer Set is for single use for less than 24 hours cumulative use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	Jan 21,2014
Submitter:	Suzhou Weikang Medical Apparatus Co., Ltd Add: No. 89, Wangmi Street, Jianlin Road, Suzhou New District, Suzhou, 215129 CHINA
Primary Contact Person:	Mike Gu Regulatory Manager Guangzhou Osmunda Medical Device Consulting Co., Ltd Tel: +86-20-62321333 Fax: +86-20-86330253
Secondary Contact Person:	Wu Wenhe Quality Director Suzhou Weikang Medical Apparatus Co., Ltd Tel: + 86-512-66627328 Fax: +86-512-66650996
Device Trade Name:	Disposable Nebulizer Set
Common/Usual Name:	Nebulizer
Classification Name:	Nebulizer 21CFR 868.5630
Product Code:	CAF
Predicate Device(s):	Headstar Medical Small Volume Jet Nebulizer K121770; Miller (VixOne) K926055
Device Description:	The disposal nebulizer set is designed and manufactured by SUZHOU WEIKANG MEDICAL APPARATUS CO., LTD. The disposal nebulizer sets are made of PVC; they are supplied as sterile. It is for single use for less than 24 hours cumulative use. The nebulizer set consists of a hollow tube connected to a nebulizer jar/bottle, which holds the liquid medication; a compressed gas source respiratory size aerosolized liquids into gasses that are delivered directly to the patient for breathing.
Intended Use:	The disposal nebulizer set is used to administer various aerosol treatments to adult patients in hospital environments. It is not intended for transport use. It is intended for adult patients consistent with the indications for the aerosol medication. The Disposable Nebulizer Set is for single use for less than 24 hours cumulative use

Technology: The Weikang Disposable Nebulizer Set is a light weight portable aerosol Nebulizer which uses a compressor that causes compressed air to flow at high velocity through a liquid medicine to turn it into an aerosol which is inhaled by the patient.

Determination of Substantial Equivalence:

Summary of Non-Clinical studies:

Attributes	Predicate Device	Predicate Device	Proposed Device
Manufacturer	HEADSTAR MEDICAL PRODUCTS CO., LTD	WARREN C. MILLER	SUZHOU WEIKANG MEDICAL APPARATUS CO., LTD
Product	Headstar Medical Small Volume Jet Nebulizer	Miller (VixOne)	Disposable Nebulizer Set
510(k) Number	K121770	K926055	/
Intended use	The Headstar medical Small Volume Jet nebulizer creates respiratory mist out of the drug and is used to administer various aerosol treatments to adult and pediatric patients in homecare and hospital environments. It is not intended for transport use.	A handheld, pneumatic nebulizer designed to aerosolize prescription drugs for inhalation by a patient. Its use is indicated whenever a healthcare professional administers or prescribes medical aerosol products to a patient using a small volume nebulizer	The disposal nebulizer set is used to administer various aerosol treatments to adult patients in hospital environments. It is not intended for transport use.
Mechanism	Air compressor	Pneumatic (gas powered) jet nebulizer	Air compressor
Raw materials	Nebulizer Bottle: PS Mouth Piece: PP Oxygen Tubing: PVC Corrugated Tubing: EVA CPA: PP	Unknown	Nebulizer Bottle: PP Mouth Piece: PP Oxygen Tubing: PVC Corrugated Tubing: PVC CPA: PP
Sterilization	EO	EO	EO
Population	Asthma Patient, adult and pediatric patients	Adult and pediatric patients	Asthma Patient, adult patients

Anatomic site	Mouth	Mouth	Mouth
Environment of Use	Home or hospital	Home or hospital	hospital
Flow rate	4-8 l/min	6-8 l/min	4-8 l/min
Air pressure (Kpa)	700	Unknown	700
Total dose delivered by device (µg)	Unknown	Albuterol sulfate: 1557±113;	Albuterol sulfate: 1483±46;
		Ipratropium bromide: 276±5;	Ipratropium bromide: 284±8;
		Cromolyn sodium: 6227±945	Cromolyn sodium: 6387±361
Particle size (MMAD) (µm)	Unknown	Albuterol sulfate: 2.1;	Albuterol sulfate: 2±0.1;
		Ipratropium bromide: 1.53±0.06;	Ipratropium bromide: 1.5±0.13;
		Cromolyn sodium: 1.97±0.06	Cromolyn sodium: 2.2±0.33
Geometric standard deviation	Unknown	Albuterol sulfate: 3.33±0.48;	Albuterol sulfate: 3.28±0.28;
		Ipratropium bromide: 3.45±1.23;	Ipratropium bromide: 3.13±0.3;
		Cromolyn sodium: 2.88±0.33	Cromolyn sodium: 2.59±0.58
Total respirable dose (0.5-5 µm) (µg)	Unknown	Albuterol sulfate: 786±63;	Albuterol sulfate: 737±22;
		Ipratropium bromide: 146±9;	Ipratropium bromide: 141±13;
		Cromolyn sodium: 4001±506	Cromolyn sodium: 4075±320
Biocompatibility	ISO 10993-5 and ISO 10993-10	Unknown	ISO 10993-5 and ISO 10993-10

Applicable standard	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 11135-1 ISO 10993-7		ISO 10993-1 Fourth Edition: 2009 ISO 10993-5 Third Edition: 2009 ISO 10993-10 Third Edition: 2010 ISO 11135-1 Second Edition: 2007 Part 1 ISO 10993-7 Second Edition 2008-10-15
Guidance	REVIEWER GUIDANCE FOR NEBULIZER, METERED DOSE INHALERS, SPACERS AND ACTUATORS	REVIEWER GUIDANCE FOR NEBULIZER, METERED DOSE INHALERS, SPACERS AND ACTUATORS	REVIEWER GUIDANCE FOR NEBULIZER, METERED DOSE INHALERS, SPACERS AND ACTUATORS

The nebulizer complies with voluntary standards as following:

1. ISO 10993-1 Fourth Edition: 2009 Biological evaluation of medical devices Part 1: Evaluation and testing within the risk management process
2. ISO 10993-5 Third Edition: 2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
3. ISO 10993-10 Third Edition: 2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
4. ISO 11135-1 Second Edition: 2007 Sterilization of health care products —Ethylene oxide —Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
5. ISO 10993-7 Second Edition 2008-10-15, Biological Evaluation Of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

Summary of Clinical Tests:

The subject of this premarket submission, disposal nebulizer set, did not require clinical studies to support substantial equivalence.

The proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device.

Therefore, the subject device is determined as safe and effectiveness.

Refer to the section 12 for further information.

Conclusion: Suzhou Weikang Medical Apparatus Co., Ltd Considers the Disposable Nebulizer Set to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).