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K 112041

DEC 22 2011

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**Official Contact:** Chris Koo - President

**Proprietary or Trade Name:** Koo Small Volume Nebulizer (SVN)

**Common/Usual Name:** Small Volume Nebulizer

**Classification Name:** Nebulizers (direct patient interface)
Procode – CAF – CFR 868.5630

**Predicate Devices:** K926055 – Miller (Vixone) Westmed

**Device Description:**
The Koo SVN is a simple handheld small volume nebulizer powered by compressed air to nebulize the liquid drug placed in the reservoir. It can be used with a mouthpiece or standard aerosol / oxygen face mask. The SVN can be packaged with optional accessories, i.e., oxygen tubing, mouthpiece and hose, and face mask. The nebulizer and its accessories are single patient, multi-use devices.

**Indications for Use:**
The Koo SVN is 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 Koo SVN is intended for use with pediatric (defined by the prescribed medication) and adult patients consistent with the indications for the aerosol medication. This includes hospital/institutional settings, home care use, schools and long term care facilities.

**Patient Population:** Pediatric (defined by the prescribed medication) and adult patients consistent with the indications for the aerosol medication

**Environment of Use:** Hospital/institutional settings, home care use, schools and long term care facilities

**Contraindications:** None

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**Comparison to Predicates**

| Features | Proposed SVN | Predicate Miller (VixOne) K926055 |
|---|---|---|
| **Indications for use** | The Koo SVN nebulizer is 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. | 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 |
| **Environment of Use** | Hospital/institutional settings, home care use, schools and long term care facilities. | Hospital/institutional settings, home care use, schools and long term care facilities. |
| **Patient Population** | Pediatric (defined by the prescribed medication) and adult patients consistent with the indications for the aerosol medication | Pediatric and Adult<br>Pediatric population not defined |
| **Contraindications** | None | None |
| **Principle of Operation** | Pneumatic (gas powered) jet nebulizer | Pneumatic (gas powered) jet nebulizer |
| **Aerosolization** | Continuous during inhalation and exhalation | Continuous during inhalation and exhalation |
| **Compressed gas source** | Nebulizer compressor<br>Wall air / oxygen with flow rate control | Nebulizer compressor<br>Wall air / oxygen with flow rate control |
| **Typical flow rate** | 6-8 lpm | 6-8 lpm |
| **Components available in kit with nebulizer** | Mouthpiece / Hose<br>Face Mask<br>Oxygen / Delivery tubing<br>Aerosol tee | Mouthpiece / Hose<br>Face Mask<br>Oxygen / Delivery tubing<br>Aerosol tee |
| **Component / Accessories intended use** | All are single patient, multi-use | All are single patient, multi-use |
| **Software driven** | No | No |
| **Performance** | | |
| **Materials tested per ISO 10993 or identical to another device** | Cytotoxicity<br>Sensitization<br>Irritation | Identical tests to K091272<br>For the tests required |
| **DEHP** | PVC based components certified DEHP Free | Not labeled |

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| Features | Proposed SVN | | Predicate Miller (VixOne) K926055 | |
|---|---|---|---|---|
| **Particle Characterization per Cascade Impactor** | | | | |
| **Total Output (ug)** | Albuterol –<br>Ipratropium –<br>Cromolyn – | 1005 ± 21<br>184 ± 10<br>4156 + 113 | Albuterol –<br>Ipratropium –<br>Cromolyn – | 1160 ± 96<br>196 ± 7<br>4344 ± 353 |
| **Particle size (MMAD) (Microns)** | Albuterol –<br>Ipratropium –<br>Cromolyn – | 1.80 ± 0.2<br>1.90 ± 0.1<br>1.53 ± 0.06 | Albuterol –<br>Ipratropium –<br>Cromolyn – | 2.10 ± 0.17<br>1.93 ± 0.06<br>1.57 ± 0.21 |
| **Geometric Std. Dev. (GSD)** | Albuterol –<br>Ipratropium –<br>Cromolyn – | 2.84± 0.14<br>2.71± 0.1<br>2.63± 0.2 | Albuterol –<br>Ipratropium –<br>Cromolyn – | 3.00 ± 0.25<br>3.11± 0.48<br>2.83± 0.05 |
| **Respirable Fraction (% Mass 0.5-5 microns)** | Albuterol –<br>Ipratropium –<br>Cromolyn – | 69.0%± 2.0%<br>70.3%± 0.6%<br>71.0%± 3.6% | Albuterol –<br>Ipratropium –<br>Cromolyn – | 67.3%± 3.2%<br>66.7%± 5.8%<br>68.0%± 2.0% |
| **Respirable Mass (ug 0.5 -5.0 microns)** | Albuterol –<br>Ipratropium –<br>Cromolyn – | 693 ± 17<br>129 ± 6<br>2953 ± 232 | Albuterol –<br>Ipratropium –<br>Cromolyn – | 781 ± 71<br>131 ± 13<br>2949 ± 155 |
| **Treatment time (min)** | Albuterol –<br>Ipratropium –<br>Cromolyn – | 4.00 ± 0<br>2.67 ± 0.29<br>1.50 ± 0 | Albuterol –<br>Ipratropium –<br>Cromolyn – | 4.33 ±0.38<br>2.92 ± 0.38<br>1.58 ± 0.38 |
| **Confidence level of testing** | The test and number of samples tested provided a 95% confidence level | | The test and number of samples tested provided a 95% confidence level | |
| **Simulated Life / Mechanical and Environmental testing** | | | | |
| **Nebulizer** | Cleaned and tested after 30 cycles | | Single patient, multi-use | |
| **Environmental testing all components** | Hot / Cold cycles | | | |
| **Mechanical testing** | Dimensional changes<br>Drop test | | | |

## Substantial Equivalence Discussion

The above table compares the key features of the proposed Koo SVN nebulizer with the identified predicate and demonstrates that the device can be found to be substantially equivalent.

In summary one can conclude that substantial equivalence is met based upon the following:

The SVN small volume, handheld nebulizer is viewed as substantially equivalent to the predicate device because:

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**Indications –**
The proposed indications for use are to aerosolize commonly prescribed medications is identical to predicate – K926055 – Miller – Vixone, now owned by Westmed.

**Technology –**
The design as a jet (gas powered) nebulizer powered by an external compressed gas source is the identical principle of operation as the predicate – K926055 – Miller – Vixone.

**Materials –**
The materials in the gas and fluid pathway have been tested per ISO 10993 and found to be non-reactive.

In addition evidence to support DEHP free for accessories made of PVC is provided.

**Environment of Use –**
The proposed environments of use are common and usual for handheld nebulizers and identical to predicate – K926055 – Miller – Vixone.

**Patient Population –**
The patient population of adult and pediatric (defined by the prescribed medication) patients consistent with the indications for the aerosol medication. With the typical gas flow of 6-8 lpm, this is sufficient to satisfy the expected tidal volume of pediatric population as well as an adult. This is identical to predicate – K926055 – Miller – Vixone.

**Comparative Performance –**
We performed comparative particle characterization testing via Cascade Impactor and the results demonstrated equivalent performance to the predicate K926055.

In addition, we performed testing related to intra- and inter-sample dose and particle variability, simulation life / cleaning validation, environmental and mechanical testing. The results demonstrated that the proposed device either passed or met its performance specifications after each test

All testing demonstrated that the proposed device is substantially equivalent to the predicate devices.

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

KOO (Shanghai) Industries Company, Limited
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

DEC 2 2 2011

Re: K112041
Trade/Device Name: Koo Small Volume Nebulizer (SVN)
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: December 14, 2011
Received: December 15, 2011

Dear Mr. Dryden:

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,

for

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

## Indications for Use Statement



**510(k) Number:** _____ (To be assigned)

**Device Name:** **Koo Small Volume Nebulizer (SVN)**

**Indications for Use:**

The Koo SVN is 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 Koo SVN is intended for use with pediatric (defined by the prescribed medication) and adult patients consistent with the indications for the aerosol medication. This includes hospital/institutional settings, home care use, schools and long term care facilities.

**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)

L Schultheiss

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 112041