May 2, 2018

Trudell Medical International
Marianne Tanton
Director, Quality and Regulatory Affairs
725 Third Street
London, Ontario N5V 5G4
Canada

Re: K173825
Trade/Device Name: MC 300*R Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: March 29, 2018
Received: April 2, 2018

Dear Marianne Tanton:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173825

Device Name
MC 300*R Nebulizer

Indications for Use *(Describe)*
The nebulizer is intended to be used with pediatric (ages 2 years and above) and adult patients, who are under the care of a licensed healthcare provider or physician. The device is designed to aerosolize prescribed medication for inhalation by a patient in the hospital, clinic or home care environment. The nebulizer is a single patient use device.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5 – 510(k) Summary

Prepared: 01-May-2018

1. **Submitter**

Trudell Medical International
725 Third Street
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Contact: Marianne Tanton
Director, Quality and Regulatory Affairs
Phone: 1-519-455-7060
Email: mtanton@trudellmed.com

2. **Device Name**

Trade Name:	MC 300*R Nebulizer
Common Name:	Small Volume Nebulizer
Classification Name:	Nebulizer 21 CFR 868.5630
Regulatory Class:	II
Product Code:	CAF

3. **Predicate Device**

AeroEclipse* Durable (XL) Nebulizer - K080926
Trudell Medical International

The predicate device has not been subject to a recall.

4. **Reference Device**

MC 300* Nebulizer – K173367
Trudell Medical International

The predicate device has not been subject to a recall.

5. **Device Description**

The MC 300*R Nebulizer is a small volume jet nebulizer designed to deliver aerosolized medications for inhalation to the respiratory system. The device is intended to be used by pediatric (ages 2 years and above) and adult patients in hospital, clinic or home settings. The MC 300*R Nebulizer is a single patient use device and may be used for multiple treatments. This device is not used with a specific drug nor is it distributed with such drugs. The MC 300*R Nebulizer consists of four components: mouthpiece, nebulizer top, nozzle cover, and nebulizer bottom. It is marketed with oxygen tubing. The MC 300*R Nebulizer is not packaged with a mask, however the Disposable Aerosol Mask Assembly can be ordered per the reorder information on the IFU.

Section 5 – 510(k) Summary

6. Principle of Operation

This device operates on the Venturi principle. Compressed air is driven through a converging nozzle, where it accelerates and emerges at a high velocity, creating a vacuum (Venturi effect). The vacuum draws a liquid residing in a reservoir up through a cylindrical channel and into the emerging airstream formed by the nozzle, to mix with air and impact upon a rigid surface. This process uses energy from the airstream to convert liquid into small droplets called aerosol. Upon reaching the user aerosol is suitably refined to enter the lungs effectively.

7. Indications for Use

The nebulizer is intended to be used with pediatric (ages 2 years and above) and adult patients, who are under the care of a licensed healthcare provider or physician. The device is designed to aerosolize prescribed medication for inhalation by a patient in the hospital, clinic or home care environment. The nebulizer is a single patient use device.

8. Comparison to predicate device

The MC 300*R Nebulizer and ***AeroEclipse**** Durable (XL) Nebulizer (K080926), are identical in purpose, function, core technology and method of operation. Only minor differences exist between the MC 300*R Nebulizer and predicate, which do not affect the safety or effectiveness of the subject device. Table 1 provides a comparison of the subject and predicate devices.

Section 5 – 510(k) Summary

Table 1: Comparison to Predicate Device

Element of Comparison	**MC 300*R Nebulizer** (Subject Device)	***AeroEclipse** Durable (XL) Nebulizer** (Predicate Device - K080926)
Indications for Use	The MC 300*R Nebulizer is intended to be used with pediatric (ages 2 years and above) and adult patients, who are under the care of a licensed healthcare provider or physician. The device is designed to aerosolize prescribed medication for inhalation by a patient in the hospital, clinic or home care environment. The nebulizer is a single patient use device.	The AeroEclipse* Durable (XL) nebulizer is a single patient, reusable device, intended to be used by patients who are under the care or treatment of a licensed health care provider or physician. The device is intended to be used by these patients to administer aerosolized medication prescribed by a physician or health care professional. The intended environments for use include the home, hospitals and clinics.
Principle of Operation	Pneumatic Jet Nebulizer	
Environment of use	Hospital, Clinic or Home	
Patient population	Adult and pediatric patients (ages 2 years and above)	All
Single Patient Use	Yes	
Aerosolization	Continuous during inhalation and exhalation	Built-in mode selector for breath actuated or continuous mode
Type of device	Reusable Device for single patient use, prescription only, non-sterile	
Manufacturing process	Plastic molding	
Type of gas source	Compressed air or oxygen	
Flow rate	4-8 LPM	2.75 – 8 LPM
Maximum Fill Volume	6 mL	

9. Performance Data

9.1 Aerosol Characterization

Aerosol characterization testing for the subject (Mouthpiece and Mask) and predicate device was conducted in accordance with the relevant sections of the CDRH Guidance Document “Reviewer Guidance for Nebulizer, Metered Dose Inhalers, Spacers and Actuators” (FDA/CDRH – 1993). Testing was performed at both low and high supplied air flow rates. The table below reflects data at 8 l/min supplied air flow rate to the nebulizer and 15 l/min flow rate through the cascade impactor. The table below also includes data from testing conducted with the medium mask, however, the nebulizer was also tested with small and large masks, which demonstrated similar performance to the medium mask.

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Table 2: Performance Data

Aerosol Characteristics	Particle Characterization	
	Continuous Nebulizer, with Mouthpiece (Subject Device) (Job # 1668)	**Continuous Nebulizer, with Mask* (Subject Device) (Job # 1655)**
Total Mass (µg)	1494.4 ± 38.4 Albuterol† 602.5 ± 34.5 Ipratropium Bromide†† 338.9 ± 29.9 Budesonide†††	1604.3 ± 28.1 Albuterol† 689.5 ± 16.3 Ipratropium Bromide†† 357 ± 19.3 Budesonide†††
Total Output Rate (µg/s)	7.1 ± 0.1 Albuterol† 1.9 ± 0.2 Ipratropium Bromide†† 0.9 ± 0.1 Budesonide†††	3.7 ± 0.2 Albuterol† 1.1 ± 0.1 Ipratropium Bromide†† 0.5 ± 0.0 Budesonide†††
Fine Particle Fraction (0.98-5.39 µm aerodynamic diameter) (%)	72.4 ± 0.4 Albuterol† 72.0 ± 0.4 Ipratropium Bromide†† 64.6 ± 1.4 Budesonide†††	71.1 ± 0.9 Albuterol† 69.3 ± 2.8 Ipratropium Bromide†† 65.9 ± 2.2 Budesonide†††
Fine Particle Mass (µg)	1081.2 ± 30.2 Albuterol† 433.9 ± 23.3 Ipratropium Bromide†† 218.8 ± 17.0 Budesonide†††	1150.1 ± 19.7 Albuterol† 478.1 ± 22.3 Ipratropium Bromide†† 235.0 ± 6.6 Budesonide†††
Fine Particle Output Rate (µg/s)	5.1 ± 0.1 Albuterol† 1.4 ± 0.1 Ipratropium Bromide†† 0.6 ± 0.1 Budesonide†††	2.7 ± 0.1 Albuterol† 0.8 ± 0.1 Ipratropium Bromide†† 0.3 ± 0.0 Budesonide†††
Particle Size (MMAD)	2.6 µg Albuterol† 2.7 µg Ipratropium Bromide†† 4.2 µg Budesonide†††	2.4 µg Albuterol† 2.5 µg Ipratropium Bromide†† 4.1 µg Budesonide†††
GSD	2.1 Albuterol† 2.1 Ipratropium Bromide†† 1.9 Budesonide†††	2.2 Albuterol† 2.3 Ipratropium Bromide†† 1.9 Budesonide†††

† Albuterol Sulfate Inhalation Solution, 833µg/ml
†† Ipratropium Bromide Inhalation Solution 250µg/ml
††† Budesonide Suspension for Inhalation 0.25mg/ml
* Disposable Aerosol Mask Assembly – Medium Mask

Section 5 – 510(k) Summary

9.2 Biocompatibility Testing

Biological endpoints applicable to an externally communicating device, tissue contact by way of gas pathway with permanent duration (> 30 days) are listed below. All *in vitro* and *in vivo* studies were performed by an independent source and included the following battery of tests: Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Genotoxicity and Extractables/Leachables with a Biological Risk Assessment.

Summary of Biocompatibility Testing Conducted

ISO Standard	Biological Endpoint
10993-5	Tests for In Vitro Cytotoxicity
10993-10	Tests for Irritation and Skin Sensitization
10993-11	Tests for systemic toxicity (Acute Toxicity)
10993-3	Tests for genotoxicity (Bacterial Reverse Mutation Study and Mouse Lymphoma Assay)
10993-12	Sample preparation and reference materials
10993-17	Establishment of allowable limits for leachable substances
10993-18	Chemical characterization of materials

9.3 Dry Gas Pathway Testing

Testing pertaining to the dry gas pathway and associated risk assessments/conclusions were conducted by an independent source. Testing included the following assessments:

- Emissions of volatile organic compounds (VOCs)
- Fine particles (particulate matter PM2.5)
- Inorganic gases (ozone, CO2, and CO)

10. Clinical Performance Summary

Not applicable, the determination of substantial equivalence is not based on Clinical Performance data.

11. Conclusion

The non-clinical data demonstrates that the MC 300*R Nebulizer is as safe and as effective as the predicate and therefore substantially equivalent to the predicate device.