July 17, 2020

Trudell Medical International
Marianne Tanton
Director, Quality and Regulatory Affairs
725 Baransway Drive
London, N5V 5G4 Ca

Re: K200063
Trade/Device Name: AeroEclipse* ONE BAN
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: June 16, 2020
Received: June 18, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

James J. Lee Ph.D.
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K200063

Device Name
AeroEclipse* ONE BAN

Indications for Use *(Describe)*
The AeroEclipse* ONE BAN is intended to be used with adults and pediatric patients over 5 years old, 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.

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: 17 July 2020

1. **Submitter**

Trudell Medical International
725 Baransway Drive
London, Ontario N5V 5G4, Canada

Contact: Marianne Tanton
Director, Quality and Regulatory Affairs
Phone: 1-519-455-7060
Email: mtanton@trudellmed.com

2. **Device Name**

Trade Name:	AeroEclipse* ONE BAN
Common Name:	Nebulizer
Classification Name:	Nebulizer 21 CFR 868.5630
Regulatory Class:	II
Product Code:	CAF

3. **Predicate Device**

AeroEclipse* II BAN - K053605
Manufacturer: Trudell Medical International (TMI)

The predicate device has not been subject to a recall.

4. **Device Description**

The subject device, AeroEclipse* ONE BAN (Breath Actuated Nebulizer) is a jet nebulizer intended to administer medication (prescribed by a physician or health care provider) in the form of an aerosol for patient inhalation. It operates in conjunction with a compressed air source and a liquid medication. The subject device is designed to produce and deliver aerosolized medication only during the patient inspiratory cycle, thus significantly reducing fugitive emissions to the environment. It can be used in hospitals, clinics and in the home.

Liquid medication is placed in the medication cup of the nebulizer bottom, into which the nebulizer top sub-assembly is attached. The air supply tubing provides the interface for the pressurized air. Aerosol is inhaled by the patient via the oral interface of the mouthpiece. As the patient inhales, ambient air travels down through the nebulizer, creating a pressure drop which causes the actuator, connected to the diaphragm to move down into the nebulizing position. As inhalation continues, aerosol is created and inhaled through the mouthpiece. When inhalation ceases, the actuator returns to the up position thereby eliminating the pressure drop which leads to the device discontinuing the creation of an aerosol. As the patient inhales through the mouthpiece, the actuator drops, and the creation of aerosol begins again.

The overall device is comprised of a nebulizer bottom with nozzle feature, a nebulizer top sub-assembly, a mouthpiece and air supply tubing.

Section 5 – 510(k) Summary

5. Principle of Operation

The subject device, AeroEclipse* ONE BAN, is considered a jet nebulizer, with the driving gas and liquid traveling through separate orifices. The gas orifice is located in the center of the nebulizer. The driving gas (air or oxygen), passes through the small orifice and is deflected by a baffle on the actuator. The high velocity jet of gas produces a negative pressure behind it, which draws liquid up to the nozzle area. The deflected gas flow shears off the liquid being drawn up which generates the aerosol.

6. Indications for Use

The AeroEclipse* ONE BAN is intended to be used with adults and pediatric patients over 5 years old, 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.

7. Comparison to Predicate Device

The subject device, AeroEclipse* ONE BAN, is equivalent in terms of indications for use and technological characteristics to that of the predicate device, AeroEclipse* II BAN (K053605).

The difference between the subject and predicate devices involves the aerosolization mode which does not affect the safety or effectiveness of the subject device. The subject device operates in breath actuated mode only while the predicate device operates in both breath actuated and continuous mode. Table 1 provides a comparison of the subject and predicate devices.

Table 1: Comparison to Predicate Device

Element of Comparison	**AeroEclipse* ONE BAN** (Subject Device)	**AeroEclipse* II BAN** (Predicate Device - K053605)
Indications for Use	The AeroEclipse* ONE Breath Actuated Nebulizer is intended to be used with adults and pediatric patients over 5 years old, who are under the care or treatment of a licensed healthcare 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.	The AeroEclipse* II Breath Actuated Nebulizer is intended to be used by patients who are under the care or treatment of a licensed healthcare 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.

Section 5 – 510(k) Summary

Principle of Operation	Pneumatic Jet Nebulizer	
Environment of use	Hospital, Clinic or Home	
Single Patient Use	Yes	
Aerosolization Mode	Breath Actuated Mode only	Built-in mode selector for breath actuated or continuous mode
Type of Device	Single patient use, multiple use, prescription only, non-sterile	
Manufacturing process	Plastic molding	
Type of gas source	Compressed air or oxygen	
Flow Rate	2.75 – 8 lpm (liters per minute)	
Maximum Fill Volume	6ml	

8. Performance Data

8.1. Aerosol Characterization

Aerosol characterization testing was performed in accordance with relevant sections of the CDRH Guidance Document “Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators” (FDA/CDRH – 1993). The results of the aerosol characterization testing demonstrated substantially equivalent in-vitro performance subject device, AeroEclipse* ONE BAN, and the predicate device, AeroEclipse* II BAN.

8.2 . Design Verification Testing

The following design verification tests were performed on the subject device, AeroEclipse* ONE BAN:

- Flow Performance
- Drop Testing
- Environmental Testing
- Life Cycle Testing

Results demonstrate the subject device, AeroEclipse* ONE BAN meets the requirements outlined in the design verification plan. No new issues of safety and efficacy were identified as a result of the testing performed.

Section 5 – 510(k) Summary

9. Biocompatibility and Dry Gas Pathway

9.1. Biocompatibility Testing

No additional biocompatibility testing was performed to demonstrate compliance with ISO 10993-1 since the materials of construction of the subject device, AeroEclipse* ONE BAN, in its final finished form are identical to the materials of construction of the cleared commercial device, AeroEclipse* II BAN K053605, in formulation, processing and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

9.2. Dry Gas Pathway Testing

To support the safe use of the subject device, AeroEclipse* ONE BAN, testing pertaining to the dry gas pathway and associated risk assessments/conclusions per ISO 18562 were conducted. Testing included the following assessments:

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

Testing results and risk assessment demonstrated that exposure during use is unlikely to result in toxicological effects.

10. Clinical Performance Summary

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

11. Conclusion

The AeroEclipse* ONE BAN is substantially equivalent to the predicate device, AeroEclipse* II BAN, cleared under K053605.