January 15, 2025

Trudell Medical International
Marianne Tanton
Vice President, Quality and Regulatory Affairs
725 Baransway Drive
London, ON N5V 5G4
Canada

Re: K242667
Trade/Device Name: AeroChamber2go Anti-Static Valved Holding Chamber
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: NVP
Dated: August 30, 2024
Received: September 5, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242667

Device Name
AeroChamber2go Anti-Static Valved Holding Chamber

Indications for Use *(Describe)*
This product is intended to be used by patients (5+ years) who are under the care or treatment of a physician or licensed healthcare professional. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers. It is a single patient, multiple use device intended for home 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary

Prepared: 14 January 2025

1. Contact Details - 21 CFR 807.92(a)(1)

Applicant Name: Trudell Medical International
Applicant Address: 725 Baransway Drive, London, ON N5V 5G4, Canada
Applicant's Contact Telephone: +1 519-515-2557
Applicant Contact: Ms. Marianne Tanton
Applicant Contact Email: mtanton@trudellmed.com

2. Device Name - 21 CFR 807.92(a)(2)

Device Trade Name: ***AeroChamber2go**** Anti-Static Valved Holding Chamber
Common Name: Nebulizer
Classification Name: Holding Chambers, Direct Patient Interface
Medical Specialty: Anesthesiology
Regulation Number: 868.5630
Product Code(s): NVP

3. Legally Marketed Predicate Devices - 21 CFR 807.92(a)(3)

Predicate Number: K181649
Predicate Trade Name: ***AeroChamber Plus**** ***Flow-Vu**** Anti-Static Valved Holding Chamber
Common Name: Nebulizer
Classification Name: Holding Chambers, Direct Patient Interface
Medical Specialty: Anesthesiology
Regulation Number: 868.5630
Product Code(s): NVP
Predicate Owner: Trudell Medical International

4. Device Description Summary - 21 CFR 807.92(a)(4)

The ***AeroChamber2go**** Anti-Static Valved Holding Chamber (VHC) is a portable holding chamber intended to be used by patients (5+ years) who are under the care or treatment of a physician or licensed healthcare professional. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers. It is a single patient, multiple use device intended for home use. This device is not used with a specific drug nor is it distributed with such drugs.

5. Intended Use/Indications for Use - 21 CFR 807.92(a)(5)

This product is intended to be used by patients (5+ years) who are under the care or treatment of a physician or licensed healthcare professional. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers. It is a single patient, multiple use device intended for home use.

6. Intended Use/Indications for Use and Technological Comparison - 21 CFR 807.92(a)(5) and 21 CFR 807.92(a)(6)

The proposed ***AeroChamber2go**** Anti-Static Valved Holding Chamber and ***AeroChamber Plus* Flow-Vu**** Anti-Static Valved Holding Chamber (predicate) are similar in purpose, function, scientific technology and method of operation. Only minor differences exist between the subject ***AeroChamber2go**** Anti-Static Valved Holding Chamber and the predicate, which do not affect the safety or effectiveness of the subject device.

Table 1 provides a comparison of the subject and predicate device on all applicable parameters. The following parameters which do not apply to the device are not: “Disposable”, “Conformance”, “Shelf Life”, “Contraindications”, “Regulation Conformance”, and “Average Treatment Time”.

Table 1: Comparison to Predicate Device

Element of Comparison	***AeroChamber2go**** Anti-Static VHC (Subject Device)	***AeroChamber Plus* Flow-Vu**** Anti-Static VHC (Predicate Device - K181649)	**Comparison**
Device Classification Name	Holding Chamber, direct patient interface		Similar
Medical Specialty	Anesthesiology		Similar
Classification	Class II		Similar
Regulation Number	21 CFR 868.5630		Similar
Product Code	NVP		Similar
Intended Use/Indications for Use	This product is intended to be used by patients (5+ years) who are under the care or treatment of a physician or licensed healthcare professional. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers. It is a single patient, multiple use device intended for home use.	This product is intended to be used by adult and pediatric patients who are under the care or treatment of a physician or licensed healthcare professional. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers and Soft Mist Inhalers. The intended environments for use include the home, hospitals and clinics. It is a single patient, multiple use device.	Similar

Element of Comparison	***AeroChamber2go**** Anti-Static VHC (Subject Device)	***AeroChamber Plus* Flow-Vu**** Anti-Static VHC (Predicate Device - K181649)	Comparison
Patient Interface	VHC with Mouthpiece	VHC with Small Mask VHC with Medium Mask VHC with Adult Small Mask VHC with Adult Large Mask VHC with Mouthpiece Device configurations are differentiated by color	Similar
Principle of Operation	Valved Holding Chamber		Similar
Environment of Use	Home	Hospital, Clinic or Home	Similar
Patient Population	Patients 5+ years	Adult and pediatric patients	Similar
Type of Device	Prescription only, single patient use, non-sterile		Similar
Useful Life	Recommended replacement after 12 months of use		Similar
Material of Construction	Thermoplastic Polymer, Thermoplastic Elastomer and Silicone components		Similar
Manufacturing process	Plastic molding and mechanical assembly		Similar
Chamber Size	Width - 3.6 cm, Length - 6.2 cm, Height - 12.7 cm	5.86” Length x 1.75’ Diameter	Similar
Chamber Volume	140 cc	149 cc	Similar

7. Non-Clinical and/or Clinical Tests Summary & Conclusions - 21 CFR 807.92(b)

Aerosol Characterization Testing:

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). Testing involved comparison of ***AeroChamber2go**** Anti-Static Valved Holding Chamber (test) with Take ***Apart AeroChamber Plus**** aVHCs with ***Flow-Vu**** IFI (predicate) and pMDI alone for three formulations.

By comparing the range of aerosol metrics reported in the summary of performance data, it can be concluded that the performance of the ***AeroChamber2go**** Anti-Static Valved Holding Chamber (test) was substantially equivalent to the predicate VHC tested. The aerodynamic particle size distributions and fine particle fractions were very closely matched, and although the fine particle dose metric for the test VHC was a little lower than the predicate in some cases, it remained similar or higher to the metered dose inhaler when used alone, therefore would not be clinically significant.

Mechanical Testing:

Evaluation of ***AeroChamber2go**** Anti-Static Valved Holding Chamber was performed to characterise the device's mechanical performance. The following mechanical tests were performed on the subject device:

- Temperature Storage and Washing Test
- Drop Test
- Transportation Test
- High Pressure Exhalation
- Dishwasher Test

Results demonstrate that the ***AeroChamber2go**** Anti-Static Valved Holding Chamber meets the requirements outlined in the Product Design Specification. No new issues of safety and efficacy were identified based on the testing performed.

Biocompatibility Testing:

Biological endpoints applicable to an externally communicating device with tissue contact, long term duration (permanent) is listed below. All *in vitro* and *in vivo* studies were performed by an independent source and included the following battery of tests: Cytotoxicity, Sensitization, Irritation, Systemic Toxicity (Pyrogen Study), and Chemical Characterization. The ***AeroChamber2go**** Anti-Static Valved Holding Chamber meets the requirements of ISO 10993-1:2018 and can be considered safe for use, as intended.

Summary of Biocompatibility/Chemical Characterization Testing Conducted

ISO Standard	Test/Assessment
10993-5	Tests for *in vitro* cytotoxicity
10993-10	Tests for skin sensitization
10993-23	Tests for irritation (Intracutaneous)
10993-11	Tests for systemic toxicity (Pyrogen Study)
10993-18	Chemical characterization of medical device materials within a risk management process

Dry Gas Pathway Testing:
To support the safe use of the device in dry gas conditions, a worst-case assessment of volatile organic compounds (VOCs) and fine particles (particulate matter) was conducted. Test results and risk assessment demonstrated that exposure during use of the device is unlikely to result in toxicological effects.

ISO Standard	Test/Assessment
18562-1	Risk Assessment
18562-2	Tests for emissions of particulate matter
18562-3	Tests for emissions of VOCs and aldehydes

Clinical Testing:

Not applicable.
The determination of substantial equivalence is not based on clinical performance data.

Conclusion:

The non-clinical test data demonstrate that the ***AeroChamber2go**** Anti-Static Valved Holding Chamber is substantially equivalent to the predicate (***AeroChamber Plus**** ***Flow-Vu**** Anti-Static Valved Holding Chamber). Use of the subject device does not raise any new questions of safety and/or effectiveness.