January 11, 2019

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

Re: K181649
Trade/Device Name: AeroChamber Plus* Flow-Vu* Anti-Static Valved Holding Chamber
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: NVP
Dated: December 12, 2018
Received: December 13, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

James J. Lee -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

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)*
K181649

Device Name
AeroChamber Plus* Flow-Vu* Anti-Static Valved Holding Chamber

Indications for Use *(Describe)*
The AeroChamber Plus* Flow-Vu* Anti-Static Valved Holding Chamber 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5 – 510(k) Summary

Prepared: 08 Jan 2019

1. Submitter

Trudell Medical International
725 Third Street
London, Ontario N5V 5G4, Canada

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

2. Device

Trade Name: ***AeroChamber Plus* Flow-Vu*** Anti-Static Valved Holding Chamber
Common Name: Holding Chamber
Classification: Holding Chambers, Direct Patient Interface, 21 CFR 868.5630
Regulatory Class: II
Product Code: NVP

3. Predicate Device

Trade Name: ***AeroChamber Plus* Flow-Vu*** Anti-Static Valved Holding Chamber
510(k) Number: K112010
510(k) Owner: Trudell Medical International

The predicate device has not been subject to a recall.

4. Device Description

The ***AeroChamber Plus* Flow-Vu*** Anti-Static Valved Holding Chamber (VHC) is a holding chamber used for the administration of aerosolized medications. The ***AeroChamber Plus* Flow-Vu*** Anti-Static VHC line of products is designed to be used with a broad range of FDA approved pressurized metered dose inhaler (pMDI) or soft mist inhaler (SMI) pharmaceutical formulations prescribed by a healthcare provider. It is a single patient, multi-use device intended to be used by patients who are under the care or treatment of a licensed health care professional. This device is not used with a specific drug nor is it distributed with such drugs.

5. Principle of Operation

The VHC has two primary modes of operation, one is to contain an aerosol plume from a metered dose inhaler or soft mist inhaler and the second is to deliver the aerosol to the patient. The device is designed to allow for the potential delay between actuation of the metered dose inhaler and the inhalation breaths of the patient. The containment is accomplished by a valve acting as a movable barrier between the chamber and the mouthpiece or mask. The valve acts to direct the patient's exhalation away from the chamber to minimize any aerosol loss to the atmosphere between inhalation breaths. The chamber is sized to ensure the proper amount of aerosol is available for delivery through the valve.

Section 5 – 510(k) Summary

6. Intended Use

The ***AeroChamber Plus* Flow-Vu*** Anti-Static Valved Holding Chamber 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.

7. Comparison to predicate device

The proposed ***AeroChamber Plus* Flow-Vu*** Anti-Static VHC line of products and the current ***AeroChamber Plus* Flow-Vu*** Anti-Static VHC line of products are similar in purpose, function, scientific technology and method of operation. Only minor differences exist between the subject ***AeroChamber Plus* Flow-Vu*** Anti-Static VHC line of products 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.

Table 1: Comparison to Predicate Device

Element of Comparison	***AeroChamber Plus* Flow-Vu*** Anti-Static VHC Adult Small Mask (Subject Device)	***AeroChamber Plus* Flow-Vu*** Anti-Static VHC Adult Large Mask (Predicate Device - K112010)	Comparison
Classification Name	Holding Chambers, Direct Patient Interface,		Similar
Product Code	NVP		Similar
Regulation Number	21 CFR 868.5630		Similar
Classification Type	Class II		Similar
Intended Use	The ***AeroChamber Plus* Flow-Vu*** Anti-Static Valved Holding Chamber 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 ***AeroChamber Plus* Flow-Vu*** Anti-Static VHC is intended to be used by 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. The intended environments for use include the home, hospitals and clinics.	Similar

Section 5 – 510(k) Summary

	the home, hospitals and clinics. It is a single patient, multiple use device.		
Patient Interface	VHC with Small Mask VHC with Medium Mask VHC with Adult Small Mask VHC with Adult Large Mask VHC with Mouthpiece Device configurations differentiated by color	VHC with Small Mask VHC with Medium Mask VHC with Adult Large Mask VHC with Mouthpiece Device configurations differentiated by color	Similar Addition of VHC with Adult Small Mask
Principle of Operation	Valved Holding Chamber		Similar
Environment of Use	Hospital, Clinic or Home		Similar
Patient Population	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		Similar
Chamber Size	5.86” length x 1.75’ Diameter		Similar
Chamber Volume	149 cc		Similar

8. Performance Data - Change in Intended Use for *AeroChamber Plus* Flow-Vu** Anti-Static VHC product line

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 aerosol characterization of SMI formulations in combination with the ***AeroChamber Plus* Flow-Vu**** Anti-Static VHC (facemask & mouthpiece configurations) and results were compared to aerosol characterization data obtained for SMI without the VHC. Tables 2 to 4 include a summary of testing performed for three Soft Mist Inhaler formulations alone and in combination with the ***AeroChamber Plus* Flow-Vu**** Anti-Static VHC at adult flow rate (30 L/min). Table 5 includes a summary of testing performed for one Soft Mist Inhaler formulation alone and in combination with the pediatric ***AeroChamber Plus* Flow-Vu**** Anti-Static VHC at pediatric flow rate (15 L/min).

Section 5 – 510(k) Summary

Table 2: Summary of Performance Data – SMI Formulation 1 (2 APIs) at 30 L/min

Aerosol Characteristics	**Particle Characterization**				
	SMI alone (Group A)	SMI with the AeroChamber Plus* Flow-Vu* aVHC Mouthpiece (Group B)	SMI with the AeroChamber Plus* Flow-Vu* aVHC Small Mask (Group C)	SMI with the AeroChamber Plus* Flow-Vu* aVHC Adult Large Mask (Group D)	SMI with the AeroChamber Plus* Flow-Vu* aVHC Adult Small Mask (Group E)
Total Mass Recovered (µg)	18.4 ± 0.9 Ipratropium bromide 94.2 ± 4.2 Salbutamol	20.3 ± 1.0 Ipratropium bromide 98.8 ± 4.6 Salbutamol	19.0 ± 1.0 Ipratropium bromide 95.7 ± 3.9 Salbutamol	18.9 ± 0.1 Ipratropium bromide 93.1 ± 2.0 Salbutamol	19.6 ± 0.8 Ipratropium bromide 103.9 ± 4.4 Salbutamol
Total Emitted Mass ex VHC (µg)	NA	15.0 ± 0.6 Ipratropium bromide 71.0 ± 3.2 Salbutamol	15.9 ± 1.1 Ipratropium bromide 79.3 ± 3.2 Salbutamol	14.3 ± 0.1 Ipratropium bromide 69.2 ± 1.1 Salbutamol	16.9 ± 0.5 Ipratropium bromide 86.8 ± 2.1 Salbutamol
Fine Particle Dose (µg)	12.3 ± 0.8 Ipratropium bromide 61.7 ± 2.5 Salbutamol	11.4 ± 0.9 Ipratropium bromide 54.8 ± 5.0 Salbutamol	11.7 ± 0.8 Ipratropium bromide 54.6 ± 1.5 Salbutamol	10.0 ± 0.5 Ipratropium bromide 47.4 ± 2.5 Salbutamol	12.3 ± 0.4 Ipratropium bromide 61.3 ± 1.7 Salbutamol
Fine Particle† Fraction (%)	66.6 ± 3.3 Ipratropium bromide 65.5 ± 2.7 Salbutamol	76.0 ± 3.2 Ipratropium bromide 77.0 ± 4.1 Salbutamol	73.2 ± 0.6 Ipratropium bromide 68.9 ± 2.3 Salbutamol	70.3 ± 3.2 Ipratropium bromide 68.5 ± 3.3 Salbutamol	72.5 ± 2.6 Ipratropium bromide 70.6 ± 2.5 Salbutamol
MMAD (µm)	2.8 Ipratropium bromide 2.9 Salbutamol	2.1 Ipratropium bromide 2.2 Salbutamol	2.5 Ipratropium bromide 2.6 Salbutamol	2.4 Ipratropium bromide 2.4 Salbutamol	2.2 Ipratropium bromide 2.4 Salbutamol
GSD	2.6 Ipratropium bromide 2.5 Salbutamol	2.2 Ipratropium bromide 2.2 Salbutamol	2.4 Ipratropium bromide 2.5 Salbutamol	3.3 Ipratropium bromide 3.3 Salbutamol	2.5 Ipratropium bromide 2.5 Salbutamol

† Percentage of particles between 0.54 & 6.40 µm aerodynamic diameter

Table 3: Summary of Performance Data – SMI Formulation 2 (2 APIs) at 30 L/min

Aerosol Characteristics	**Particle Characterization**				
	SMI alone (Group A)	SMI with the AeroChamber Plus* Flow-Vu* aVHC Mouthpiece (Group B)	SMI with the AeroChamber Plus* Flow-Vu* aVHC Small Mask (Group C)	SMI with the AeroChamber Plus* Flow-Vu* aVHC Adult Large Mask (Group D)	SMI with the AeroChamber Plus* Flow-Vu* aVHC Adult Small Mask (Group E)
Total Mass Recovered (µg)	3.3 ± 0.2 Tiotropium bromide 2.9 ± 0.1 Olodaterol HCl	3.3 ± 0.2 Tiotropium bromide 2.6 ± 0.1 Olodaterol HCl	3.3 ± 0.2 Tiotropium bromide 2.6 ± 0.2 Olodaterol HCl	3.1 ± 0.2 Tiotropium bromide 2.7 ± 0.1 Olodaterol HCl	3.2 ± 0.2 Tiotropium bromide 2.5 ± 0.2 Olodaterol HCl
Total Emitted Mass ex VHC (µg)	NA	2.2 ± 0.3 Tiotropium bromide 1.8 ± 0.2 Olodaterol HCl	2.6 ± 0.2 Tiotropium bromide 2.6 ± 0.2 Olodaterol HCl	2.1 ± 0.1 Tiotropium bromide 2.1 ± 0.1 Olodaterol HCl	2.6 ± 0.2 Tiotropium bromide 2.1 ± 0.2 Olodaterol HCl
Fine Particle Dose (µg)	2.0 ± 0.1 Tiotropium bromide 2.0 ± 0.1 Olodaterol HCl	1.7 ± 0.3 Tiotropium bromide 1.4 ± 0.2 Olodaterol HCl	1.8 ± 0.2 Tiotropium bromide 1.5 ± 0.2 Olodaterol HCl	1.6 ± 0.1 Tiotropium bromide 1.4 ± 0.1 Olodaterol HCl	1.9 ± 0.2 Tiotropium bromide 1.5 ± 0.2 Olodaterol HCl
Fine Particle† Fraction (%)	60.5 ± 1.4 Tiotropium bromide 60.5 ± 1.4 Olodaterol HCl	79.0 ± 3.4 Tiotropium bromide 81.4 ± 3.8 Olodaterol HCl	67.7 ± 1.8 Tiotropium bromide 69.4 ± 1.5 Olodaterol HCl	68.8 ± 4.8 Tiotropium bromide 65.4 ± 2.4 Olodaterol HCl	71.5 ± 1.9 Tiotropium bromide 72.4 ± 1.5 Olodaterol HCl
MMAD (µm)	3.2 Tiotropium bromide 3.3 Olodaterol HCl	2.1 Tiotropium bromide 2.2 Olodaterol HCl	2.7 Tiotropium bromide 2.8 Olodaterol HCl	2.4 Tiotropium bromide 2.8 Olodaterol HCl	2.4 Tiotropium bromide 2.4 Olodaterol HCl
GSD	NM*	2.4 Tiotropium bromide 2.2 Olodaterol HCl	3.3 Tiotropium bromide 2.4 Olodaterol HCl	NM*	2.6 Tiotropium bromide 2.7 Olodaterol HCl

† Percentage of particles between 0.54 & 6.40 µm aerodynamic diameter
* Not Measured as the 84th percentile was larger than the upper size limit (11.72 µm aerodynamic diameter) of the impactor

Section 5 – 510(k) Summary

Table 4: Summary of Performance Data – SMI Formulation 3 (1 API) at 30 L/min

Aerosol Characteristics	**Particle Characterization**				
	SMI alone (Group A)	SMI with the AeroChamber Plus* Flow-Vu* aVHC Mouthpiece (Group B)	SMI with the AeroChamber Plus* Flow-Vu* aVHC Small Mask (Group C)	SMI with the AeroChamber Plus* Flow-Vu* aVHC Adult Large Mask (Group D)	SMI with the AeroChamber Plus* Flow-Vu* aVHC Adult Small Mask (Group E)
Total Mass Recovered (µg)	2.9 ± 0.2 Tiotropium bromide	2.8 ± 0.1 Tiotropium bromide	3.2 ± 0.2 Tiotropium bromide	3.0 ± 0.3 Tiotropium bromide	3.1 ± 0.4 Tiotropium bromide
Total Emitted Mass ex VHC (µg)	NA	1.9 ± 0.1 Tiotropium bromide	2.5 ± 0.1 Tiotropium bromide	2.1 ± 0.2 Tiotropium bromide	2.5 ± 0.2 Tiotropium bromide
Fine Particle Dose (µg)	1.8 ± 0.1 Tiotropium bromide	1.4 ± 0.1 Tiotropium bromide	1.7 ± 0.1 Tiotropium bromide	1.4 ± 0.2 Tiotropium bromide	1.7 ± 0.1 Tiotropium bromide
Fine Particle† Fraction (%)	62.4 ± 1.8 Tiotropium bromide	71.7 ± 3.5 Tiotropium bromide	68.1 ± 4.5 Tiotropium bromide	64.5 ± 4.9 Tiotropium bromide	66.7 ± 3.7 Tiotropium bromide
MMAD (µm)	3.1	2.4	2.6	2.7	2.6
GSD	NM*	2.8	NM*	NM*	3.0

† Percentage of particles between 0.54 & 6.40 µm aerodynamic diameter
* Not Measured as the 84th percentile was larger than the upper size limit (11.72 µm aerodynamic diameter) of the impactor

Table 5: Summary of Performance Data - SMI Formulation 1 at 15 L/min

Aerosol Characteristics	**Particle Characterization**		
	SMI alone	SMI with the AeroChamber Plus* Flow-Vu*Anti-Static VHC Small Mask	SMI with the AeroChamber Plus* Flow-Vu*Anti-Static VHC Medium Mask
Total Mass Recovered (µg)	17.0 ± 0.8 Ipratropium bromide 91.7 ± 8.1 Salbutamol	15.2 ± 1.0 Ipratropium bromide 85.4 ± 7.9 Salbutamol	15.7 ± 1.1 Ipratropium bromide 94.3 ± 10.9 Salbutamol
Total Emitted Mass ex VHC (µg)	NA	11.0 ± 0.7 Ipratropium bromide 56.0 ± 8.1 Salbutamol	10.6 ± 1.8 Ipratropium bromide 60.4 ± 8.6 Salbutamol
Fine Particle Dose (µg)	9.0 ± 0.5 Ipratropium bromide 47.7 ± 5.7 Salbutamol	7.7 ± 0.8 Ipratropium bromide 40.2 ± 4.0 Salbutamol	8.2 ± 0.8 Ipratropium bromide 46.7 ± 5.7 Salbutamol
Fine Particle† Fraction (%)	53.0 ± 0.8 Ipratropium bromide 51.9 ± 2.8 Salbutamol	70.6 ± 6.5 Ipratropium bromide 72.8 ± 10.7 Salbutamol	78.4 ± 9.3 Ipratropium bromide 77.9 ± 8.1 Salbutamol
MMAD (µm)	4.9 Ipratropium bromide 5.0 Salbutamol	1.8 Ipratropium bromide 1.7 Salbutamol	1.5 Ipratropium bromide 1.5 Salbutamol

† Percentage of particles between between 0.98 & 5.39 µm aerodynamic diameter

Section 5 – 510(k) Summary

9. Performance Data – Addition of *AeroChamber Plus* Flow-Vu** Anti-Static VHC Adult Small Mask configuration

9.1 Aerosol Characterization (***AeroChamber Plus* Flow-Vu**** Anti-Static VHC, Adult Small Mask)

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) using three different commercially available pressurized Metered Dose Inhaler (pMDI) formulations. Table 6 includes a summary of testing performed for three pressurized Metered Dose Inhaler formulations in combination with the subject (***AeroChamber Plus* Flow-Vu**** Anti-Static VHC, Adult Small Mask) device and the predicate (***AeroChamber Plus* Flow-Vu**** Anti-Static VHC, Adult Large Mask) device.

Table 6: Summary of Performance Data

Aerosol Characteristics	***AeroChamber Plus* Flow-Vu**** Anti-Static VHC (Adult Small Mask) (Subject Device)	***AeroChamber Plus* Flow-Vu**** Anti-Static VHC (Adult Large Mask) (Predicate Device - K112010)
Total Mass Recovered (µg)	20.0 ± 0.4 Ipratropium bromide 122.6 ± 3.7 Fluticasone Propionate 107.9 ± 3.8 Albuterol Sulfate	19.9 ± 0.4 Ipratropium bromide 124.6 ± 5.7 Fluticasone Propionate 100.6 ± 2.9 Albuterol Sulfate
Total Emitted Mass ex VHC (µg)	11.3 ± 0.5 Ipratropium bromide 53.5 ± 5.2 Fluticasone Propionate 52.9 ± 7.9 Albuterol Sulfate	10.4 ± 0.7 Ipratropium bromide 58.1 ± 2.5 Fluticasone Propionate 56.3 ± 2.6 Albuterol Sulfate
Fine Particle Dose (µg)	10.5 ± 0.4 Ipratropium bromide 43.6 ± 5.6 Fluticasone Propionate 43.7 ± 8.4 Albuterol Sulfate	9.4 ± 0.7 Ipratropium bromide 47.4 ± 2.5 Fluticasone Propionate 48.1 ± 3.1 Albuterol Sulfate
Fine Particle Fraction† (%)	93.0 ± 0.8 Ipratropium bromide 81.4 ± 2. Fluticasone Propionate 82.3 ± 3.7 Albuterol Sulfate	90.5 ± 0.8 Ipratropium bromide 81.5 ± 1.8 Fluticasone Propionate 85.4 ± 1.9 Albuterol Sulfate
Particle Size (MMAD) (µm)	1.0 Ipratropium bromide 3.0 Fluticasone Propionate 3.0 Albuterol Sulfate	1.1 Ipratropium bromide 2.9 Fluticasone Propionate 2.8 Albuterol Sulfate
GSD	NA* Ipratropium bromide 1.7 Fluticasone Propionate 1.8 Albuterol Sulfate	NA* Ipratropium bromide 1.7 Fluticasone Propionate 1.7 Albuterol Sulfate

† Percentage of particles between 0.54 & 3.99 µm aerodynamic diameter.
* Not Measured as the 16th percentile was smaller than the lower size limit (0.4µm aerodynamic diameter) of the impactor

9.2 Biocompatibility Testing (***AeroChamber Plus* Flow-Vu**** Anti-Static VHC, Adult Small Mask)

Biological endpoints applicable to an externally communicating device with prolonged contact duration (>24 h to 30 d) 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.

Section 5 – 510(k) Summary

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 Mechanical Testing (***AeroChamber Plus* Flow-Vu*** Anti-Static VHC, Adult Small Mask)

The following mechanical tests were performed on the subject device:

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

10. Clinical Performance Summary

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

11. Conclusion

Change in Intended Use for ***AeroChamber Plus* Flow-Vu*** Anti-Static VHC product line:

The non-clinical data demonstrate that the ***AeroChamber Plus* Flow-Vu*** Anti-Static VHC (facemask and mouthpiece configurations) used in combination with Soft Mist Inhaler formulations is comparable to use of a SMI formulation alone. Use of the VHC device with an SMI does not raise any new questions of safety and/or effectiveness.

Addition of *AeroChamber Plus* Flow-Vu* Anti-Static VHC Adult Small Mask configuration:

The non-clinical data demonstrate that the ***AeroChamber Plus* Flow-Vu**** Anti-Static VHC, Adult Small Mask is substantially equivalent to the predicate (***AeroChamber Plus* Flow-Vu**** Anti-Static VHC, Adult Large Mask). Use of the subject device does not raise any new questions of safety and/or effectiveness.