DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

October 3, 2014

FSC Laboratories, Inc.
C/O Mr. Paul Dryden
Promedic, Inc., President
Regulatory Consultant for FSC Laboratories
6000 Fairview Rd., Suite 600
Charlotte, NC 28210

Re: K140062
Trade/Device Name: FSC Anti-Static Valved Collapsible Holding Chamber
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: NVP
Dated: September 4, 2014
Received: September 4, 2014

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

*Tejashri Purohit-Sheth, M.D.*

**Tejashri Purohit-Sheth, M.D.**
**Clinical Deputy Director**
**DAGRID/ODE/CDRH FOR**

Erin I. Keith, M.S
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# 4 Indications for Use Statement

We have prepared the Indications for Use statement utilizing Form 3881 which follows.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*

Device Name
FSC Anti-Static Valved Collapsible Holding Chamber

Indications for Use *(Describe)*

The FSC Anti-Static Valved Collapsible Holding Chamber is intended to be used by patients who are under the care or treatment of a licensed health care professional. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers. (pMDIs).

Environment of use - Home, hospitals and clinics.

This product is intended for patients who can follow verbal instructions.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

**Date Prepared:** 03-Sep-2014

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**Official Contact:** Karla Worley Ham
Quality and Regulatory Affairs Officer

**Proprietary or Trade Name:** FSC Anti-Static Valved Collapsible Holding Chamber

**Common/Usual Name:** Spacer / Holding Chamber

**Classification Name:** Holding Chambers, Direct Patient Interface
Product Classification – NVP
21 CFR 868.5630
Class II

**Predicate Devices:** K052332 – Trudell - AeroChamber Plus Z-stat
K933090 – FSC Laboratories - E-Z Spacer

**Device Description:**
The FSC Anti-Static Valved Collapsible Holding Chamber is intended for use in the inhalation of medications delivered via an MDI and for which the medication is to be delivered to the upper and lower respiratory system. The device consists of a collapsible housing and mouth piece and a one-way valve to prevent exhaling into the chamber.

The FSC Anti-Static Valved Holding Chamber is intended to be used to inhale aerosolized drugs of approved MDIs from the following groups of active substances:

- Corticosteroids (anti-inflammatory medications)
- Anti-cholinergics and β2-sympathomimetics (bronchodilator medications)
- Non-steroidal chromones (DNCG)

It is a single patient, multi-use, non-sterile device.

**Indications for Use:**
The FSC Anti-Static Valved Collapsible Holding Chamber is intended to be used by patients who are under the care or treatment of a licensed health care professional. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers, (pMDIs).

Environment of use - Home, hospitals and clinics.

This product is intended for patients who can follow verbal instructions.

**Comparison to Predicates**

We have chosen two (2) predicates for our substantial equivalence claim. The following is a rationale for this selection.

AeroChamber Plus Z-stat (K052332) and E-Z Spacer (K933090)

**Table 1** is a table which highlights the reason for selecting each predicate.

| SE Element | AeroChamber Plus Z-stat (K052332) | E-Z Spacer (K933090) |
|---|---|---|
| Indications for Use | X | X |
| Environment of Use | X | X |
| Patient Population | X | X |
| Technology of collapsible chamber | | X |
| Feature inhalation progress | X<br>Has a whistle | X<br>Bag collapses as visual indicator |
| Anti-static feature | X | |
| Design and usability | | X |

**Table 2 – Comparison to Predicate – AeroChamber Plus Z-Stat (K052332)**

| Attribute | AeroChamber Plus Z-stat K052332 | Proposed FSC Chamber |
|---|---|---|
| **Intended Use** | For use with MDIs | For use with MDIs |
| **Indications for Use** | 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 from most pressurized Metered Dose Inhalers, prescribed by a physician or health care professional. | The FSC Anti-Static Valved Collapsible Holding Chamber is intended to be used by patients who are under the care or treatment of a licensed health care professional. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers, (pMDIs).<br><br>Environment of use - Home, hospitals and clinics.<br><br>This product is intended for patients who can follow verbal instructions. |
| **Environments of use** | Home, hospitals and clinics. | Home, hospitals and clinics |
| **Prescriptive** | Yes | Yes |
| **Patient population** | All – not specified | Intended for patients who can follow verbal instructions |

| Attribute | AeroChamber Plus Z-stat<br>K052332 | Proposed<br>FSC Chamber |
|---|---|---|
| **Single patient, multi-use** | Yes | Yes |
| **Patient interface** | Mouthpiece<br>Face Mask | Integral Mouthpiece |
| **Basic components** | Housing<br>One-way valve to prevent exhalation into chamber<br>End caps – removable | Housing<br>One-way valve to prevent exhalation into chamber<br>End caps – removable |
| **Anti-static properties** | Yes | Yes |
| **Housing** | Rigid | Collapsible |
| **Indicator of inhalation** | Whistle to alert user | Visual collapse of the bag |
| **Single patient, multi-use** | Yes | Yes |
| **Materials Patient Contact** | Materials in the gas pathway<br>External Communicating<br>Tissue<br>Prolonged<br><br>Materials in direct patient contact<br>Surface Contact<br>Mucosal<br>Prolonged | Materials in the gas pathway<br>External Communicating<br>Tissue<br>Prolonged Duration of Use<br><br>Materials in direct patient contact<br>Surface Contact<br>Mucosal<br>Prolonged Duration of Use |
| **Performance testing** | Particle characterization<br>Comparison results found to be equivalent | Particle characterization<br>Mechanical<br>Environmental<br>Simulated lifetime cycle (cleaning)<br>Differential Pressure<br>ISO 10993 testing |

**Table 3 – Comparison to Predicate – E-Z Spacer (K933090)**

| Attribute | E-Z Spacer K933090 | Proposed FSC Chamber |
|---|---|---|
| **Intended Use** | For use with MDIs | For use with MDIs |
| **Indications for Use** | 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 from most pressurized Metered Dose Inhalers, prescribed by a physician or health care professional. (Not specified in FDA database) | The FSC Anti-Static Valved Collapsible Holding Chamber is intended to be used by patients who are under the care or treatment of a licensed health care professional. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers, (pMDIs).<br><br>Environment of use - Home, hospitals and clinics.<br><br>This product is intended for patients who can follow verbal instructions. |
| **Environments of use** | Home, hospitals and clinics. | Home, hospitals and clinics |
| **Prescriptive** | Yes | Yes |
| **Patient population** | All – not specified | This product is intended for patients who can follow verbal instructions |
| **Single patient, multi-use** | Yes | Yes |
| **Patient interface** | Integral Mouthpiece | Integral Mouthpiece |
| **Basic components** | Housing<br><br>End caps – removable | Housing<br>One-way valve to prevent exhalation into chamber<br>End caps – removable |
| **Anti-static properties** | No | Yes |
| **Housing** | Collapsible | Collapsible |
| **Indicator of inhalation** | Visual collapse of the bag | Visual collapse of the bag |
| **Single patient, multi-use** | Yes | Yes |
| **Materials Patient Contact** | Materials in the gas pathway<br>External Communicating<br>Tissue<br>Prolonged<br><br>Materials in direct patient contact<br>Surface Contact<br>Mucosal<br>Prolonged | Materials in the gas pathway<br>External Communicating<br>Tissue<br>Prolonged<br><br>Materials in direct patient contact<br>Surface Contact<br>Mucosal<br>Prolonged |

**Substantial Equivalence Discussion**

**Tables 2 to 3** above compare the key features of the proposed FSC Anti-static Valved Collapsible Holding Chamber with the identified predicates 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:

**Indications for Use –**
The indications for use are identical for the proposed device when compared to the predicate – K052332 – AeroChamber Plus Z-Stat. The predicate K933090 – E-Z spacer does not have published indications but is known to be similar.
**Discussion** – Each device is indicated for use with MDIs of the same category of medications.

**Technology and construction –**
The design, fabrication, shape, size, etc. are equivalent to the predicate – K933090 – E-Z Spacer which is a collapsible chamber with integral mouthpiece.
**Discussion** – This design incorporates a collapsible housing, end caps, one way valve for inhalation, and patient interface of a mouthpiece which are the same as the predicate.

We are offering Anti-static properties for the whole device, which is identical to the predicate K052332 – AeroChamber Plus Z-Stat.
**Discussion** – We have performed testing to support the anti-static claim.

**Environment of Use –**
The environments of use are identical to both predicates - K052332 – AeroChamber Plus Z-Stat and K933090 – E-Z spacer.
**Discussion** – The environments of use are identical to both predicates - K052332 – AeroChamber Plus Z-Stat and K933090 – E-Z spacer.

**Patient Population –**
The patient population are those who are able to follow verbal instructions. This is similar to the predicates which do not specify the patient population, however they offer face mask for pediatric patients.
**Discussion** – The patient populations are equivalent to both predicates - K052332 – AeroChamber Plus Z-Stat and K933090 – E-Z spacer.

**Non-clinical Testing Summary –**

**Particle Characterization –**
We performed comparative particle characterization testing via Cascade Impactor and the results demonstrated equivalent performance concluding that the proposed device is equivalent to the predicate K052332 – AeroChamber Plus Z-Stat.

In addition, we performed testing related to simulated life testing, cleaning validation, environmental and mechanical, differential pressure, and anti-static property testing. The results demonstrated that the proposed device either passed or met its performance specifications after each test and where appropriate was equivalent or better than the predicate, K052332 – AeroChamber Plus Z-Stat.

**Materials –**
We have performed ISO 10993-1 testing on the component materials of the FSC Anti-Static Valved Collapsible Holding Chamber which is considered as having two(2) patient contact classifications, External Communicating and Surface Contact. Per ISO 10993-1 and G95-1 the required tests for the duration of use are the same. The following are details.

- External Communication (Indirect contact) for all materials not in direct contact
- Tissue communicating
- Permanent duration (>30 days)

For those materials in direct contact, the mouthpiece, it is considered

- Surface Contact
- Mucosal membrane
- Permanent duration (> 30 days)

We performed: cytotoxicity, sensitization, genotoxicity, and exhaustive leachable and extractable testing and included a risk assessment.

**Discussion** – We have tested the materials which are common to chambers.

**Performance Testing including Comparative Testing:**
We performed comparative particle characterization testing via Cascade Impactor and the results demonstrated equivalent performance between the proposed device and the predicate. This testing included:

- Particle Characterization testing via Cascade Impactor
  - Adult – 28 lpm
  - Pediatric – 12 lpm
  - Intra- and Inter-sample variance
- Simulated lifetime testing
  - Pre and post- exposure
  - Cleaning
- Environmental and mechanical testing (part of Simulated Life Cycle testing)
  - High and Low temperature
  - Drop test
- Anti-static surface resistivity
- Differential Pressure – comparative

A series of aerosol performance tests were performed using an 8 stage cascade impactor at sampling flow rates of 28 lpm and 12 lpm, equipped with a USP <601> induction port throat. Aerosol was sampled directly from the outlet. A summary of the results is listed below with 95% confidence intervals.

@ 28 lpm – 3 samples of the device were tested with 3 drugs, 3 times for a total of 9 sample points.

@ 12 lpm – 3 samples of the device were tested with 3 drugs, 3 times for a total of 9 sample points.

MDI only – 3 samples were tested with 3 drugs.

Ventolin HFA
Atrovent HFA
QVAR 40

**Table 4 – Total Respirable Dose Delivered @ 28 lpm flow rate**
**MDI vs. MDI-Spacer – 95% Confidence Intervals**

| Total Respirable Dose Delivered (0.5-5.0 microns) ug/burst | | | |
|---|---|---|---|
| | **Ventolin HFA** | **Atrovent HFA** | **QVAR 40** |
| **MDI only** | 37.5 – 46.8 | 7.5 – 8.1 | 12.1 – 14.8 |
| **MDI - Spacer** | 50.6 – 55.0 | 6.3 – 8.3 | 10.7 – 15.4 |

**Table 5 – Total Dose Delivered @ 28 lpm flow rate**
**MDI vs. MDI-Spacer – 95% Confidence Intervals**

| Total Dose Delivered - ug/burst | | | |
|---|---|---|---|
| | **Ventolin HFA** | **Atrovent HFA** | **QVAR 40** |
| **MDI only** | 102.7 – 104.8 | 19.0 – 21.0 | 33.6 – 38.4 |
| **MDI – Spacer** | 61.3 – 66.1 | 13.2 – 15.4 | 26.4 – 34.1 |

**Table 6 – MDI – Spacer with 3 Drugs @ 28 lpm**

| | **Ventolin HFA** | **Atrovent HFA** | **Qvar 40** |
|---|---|---|---|
| **Particle Size (MMAD) (um)** | 1.68-1.8 | 0.76-0.92 | 0.4-0.49 |
| **Geometric Standard Deviation (GSD)** | 1.87-2.15 | 3.03-3.51 | 2.84-3.33 |
| **Total Delivered Dose by Device - ug / burst** | 61.3-66.1 | 13.2-15.4 | 26.4-34.1 |
| **Total Respirable Dose (0.5 – 5 um) - ug/burst** | 50.6-55.0 | 6.3-8.3 | 10.7-15.4 |
| **Coarse Particle Dose >4.7 microns - ug/burst** | 9.0-10.1 | 3.1-4 | 1.8-2.3 |
| **Fine Particle Dose <4.7 microns - ug/burst** | 51.6-56.7 | 9.5-12.0 | 24.4-32.0 |
| **Ultra-Fine Particle Dose <1.0 microns - ug/burst** | 10.3-14.7 | 5.4-6.8 | 19.2-25.1 |

**Table 5.7 – MDI – Spacer with 3 Drugs @ 12 lpm**

| | Ventolin HFA | Atrovent HFA | Qvar 40 |
|---|---|---|---|
| **Particle Size (MMAD) (um)** | 1.97-2.1 | 0.99-1.21 | 0.6-0.73 |
| **Geometric Standard Deviation (GSD)** | 1.85-2.02 | 2.71-3.0 | 2.14-3.0 |
| **Total Delivered Dose by Device - ug / burst** | 56.0-68.9 | 12.7-13.8 | 21.7-28.5 |
| **Total Respirable Dose (0.5 – 5 um) - ug/burst** | 49.0-57.2 | 6.5-7.4 | 13.1-17.2 |
| **Coarse Particle Dose >4.7 microns - ug/burst** | 8.2-13.2 | 3.3-3.5 | 0.8-1.9 |
| **Fine Particle Dose <4.7 microns - ug/burst** | 47.8-55.7 | 9.4-10.3 | 20.9-26.5 |
| **Ultra-Fine Particle Dose <1.0 microns - ug/burst** | 6.3-8.3 | 4.7-5.6 | 13.9-17.8 |

**Substantial Equivalence Conclusion -**

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to be substantially equivalent.