K130598

510(k) Summary
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JUN 0 5 2013

Date Prepared: 04-Jun-2013

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Proprietary or Trade Name: InspiraChamber® Anti-Static Valved Holding Chamber

Common/Usual Name: Spacer / Holding Chamber

Classification Name: Holding Chambers, Direct Patient Interface
NVP - CFR 868.5630
Class II

Predicate Devices: K872037 – Trudell AeroChamber

Device Description:
The InspiraChamber® 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 translucent housing and mouth piece or face mask and a one-way valve to prevent exhaling into the chamber.

The InspiraChamber® 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 (bronchodilater medications)
- Non-steroidal chromones (DNCG)

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

Indications for Use:
The InspiraChamber® Anti-Static Valved 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 – The proposed device may be used in home, hospitals and clinical settings where patients may require the use of a holding chamber with pMDIs.

The intended patient population is 3 years and older who have been prescribed pMDI medications.

Comparison to Predicates

Attribute	K872073 Trudell Medical AeroChamber	Proposed InspiraChamber®
Intended Use	For use with pMDIs	For use with pMDIs
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 intended environments for use include the home, hospitals and clinics.	The InspiraChamber® Anti-Static Valved 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).
Environments of use	Home, hospitals, clinics	Home, hospitals and clinics where patients may require the use of a holding chamber with pMDIs.
Prescriptive	Yes	Yes
Patient population	All	The intended patient population is 3 years and older who have been prescribed pMDI medications.
Single patient, multi-use	Yes	Yes
Patient interface	Mouthpiece Face Mask	Mouthpiece Face Mask
Basic components	Housing One-way valve to prevent exhalation into chamber End caps – removable	Housing One-way valve to prevent exhalation into chamber End caps – removable Audible Signal Alert
Performance testing	Particle characterization Comparison results found to be equivalent	Particle characterization Mechanical Environmental Simulated life cycle (cleaning) ISO 10993 testing •BPA levels

Substantial Equivalence Discussion

The above table compares the key features of the proposed InspiraChamber® with the identified predicate 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 nearly identical for the proposed device when compared to the predicate – K872037 – Trudell AeroChamber.

Discussion – Each device is indicated for use with pMDIs of the same category of medications.

Technology and construction –
The design, fabrication, shape, size, etc. are equivalent to the predicate – K872037 – Trudell AeroChamber.
Discussion – This design incorporates a housing, end caps, one way valve for inhalation, and patient interface of a mouthpiece which is the same for the predicate

Environment of Use –
The environments of use are home, hospital and clinics.
Discussion – The environments of use are identical to the predicate K872037 – Trudell AeroChamber.

Patient Population –
The patient population of pediatrics > 3 years old is equivalent to the predicate - K872037 – Trudell AeroChamber.
Discussion – The patient populations are equivalent to the predicate K872037 – Trudell AeroChamber.

Technology and construction –

Non-clinical Testing Summary –

Materials:
We have performed ISO 10993 testing on the component materials of the InspiraChamber® which is considered as Indirect contact (aerosol mediated) and direct (skin) contact with the patient which means the following tests are required if a material certification cannot be provided.

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- BPA extractables – non-BPA
- Device not manufacturer with natural rubber latex

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

- Particle Characterization testing via Cascade Impactor
  - Adult – 28 lpm
  - Pediatric – 12 lpm
  - Intra- and Inter-sample variance
- Simulated life 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
- Performance of Auditory alert

A series of aerosol performance tests were performed using an 8 stage cascade impactor at a 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.
ProAir HFA
Atrovent HFA
QVAR 40

Table 1 – 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			
	ProAir HFA	**Atrovent HFA**	**QVAR 40**
MDI only	37.5 – 46.8	7.5 – 8.1	12.1 – 14.8
MDI - Spacer	40.9 – 59.3	5.3 – 7.0	9.4 – 11.7

Table 2 – Total Dose Delivered @ 28 lpm flow rate
MDI vs. MDI-Spacer – 95% Confidence Intervals

Total Dose Delivered - ug/burst			
	ProAir HFA	**Atrovent HFA**	**QVAR 40**
MDI only	102.7 – 104.8	19.0 – 21.0	33.6 – 38.4
MDI - Spacer	55.0 – 69.4	11.2 – 13.3	21.4 – 25.3

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

	ProAir HFA	Atrovent HFA	Qvar 40
Particle Size (MMAD) (um)	1.52-1.68	1.54-1.77	0.44-0.52
Geometric Standard Deviation (GSD)	1.92-2.21	3.0-3.91	2.55-3.04
Total Delivered Dose by Device - ug / burst	55.0-69.4	11.2-13.3	21.4-25.3
Total Respirable Dose (0.5 – 5 um) - ug/burst	40.9-59.3	5.3-7.0	9.4-11.7
Coarse Particle Dose >4.7 microns - ug/burst	6.7-9.7	4.2-5.2	0.9-1.6
Fine Particle Dose <4.7 microns - ug/burst	45.6-62.4	6.8-8.3	20.2-23.9
Ultra-Fine Particle Dose <1.0 microns - ug/burst	14.0-22.0	2.8-3.6	16.4-19.2

Table 4 – MDI – Spacer with 3 Drugs @ 12 lpm

	ProAir HFA	Atrovent HFA	Qvar 40
Particle Size (MMAD) (um)	1.74-2	1.8-2.06	0.57-0.7
Geometric Standard Deviation (GSD)	2.16-2.26	2.72-3.1	2.48-2.67
Total Delivered Dose by Device - ug / burst	49.4-55.5	11.8-13.4	16.4-20.7
Total Respirable Dose (0.5 – 5 um) - ug/burst	37.2-43.4	6.2-8.2	8.7-11.4
Coarse Particle Dose >4.7 microns - ug/burst	9.6-11.8	4.3-5	1.9-2.4
Fine Particle Dose <4.7 microns - ug/burst	38.9-44.6	6.8-9.1	14.5-18.4
Ultra-Fine Particle Dose <1.0 microns - ug/burst	9.1-10.2	2.2-2.9	9.8-12.9

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 substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 5, 2013

InspiRx, Incorporated
C/O Paul Dryden
President
ProMedic, Inc.
24301 Woodsage Drive
BONITA SPRINGS, FL 34134

Re: K130598
Trade/Device Name: InspiraChamber® Anti-Static Valved Holding Chamber
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: NVP
Dated: March 5, 2013
Received: March 7, 2013

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.

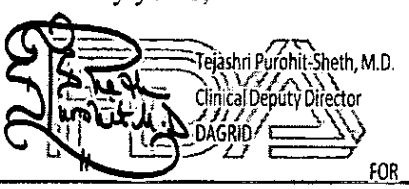
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,



FOR

Kwame-Ulmer,-M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: **K130598**

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Environment of use – Home, hospitals and clinics where patients may require the use of a holding chamber with pMDIs.

The intended patient population is 3 years and older who have been prescribed pMDI medications.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anya C. Harry

Digitally signed by Anya C. Harry
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry, 0.9.2342.19200300.100.1.1=0011315590
Date: 2013.06.05 08:52:51 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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