DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 15, 2015

Trudell Medical International
Darryl Fischer
Associate Director, Global Regulatory Affairs
725 Third Street
London, Ontario
NSV 5G4 CANADA

Re: K150173
Trade/Device Name: Aerobika* OPEP Device with Manometer
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: Class II
Product Code: BWF
Dated: September 14, 2015
Received: September 15, 2015

Dear Mr. Fischer:

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" (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 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.

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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150173

Device Name
Aerobika* OPEP with Manometer

Indications for Use *(Describe)*
The Aerobika* Oscillating Positive Expiratory Pressure device is intended for use as a Positive Expiratory Pressure (PEP) device. The Aerobika* Oscillating PEP device may also be used simultaneously with nebulized aerosol drug delivery. The device is intended to be used by patients capable of generating an exhalation flow of 10 lpm for 3 - 4 seconds.

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.

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*Aerobika** OPEP with Manometer Accessory 510(k) Summary

510(k) Number (if known): K150173

1. Device Identification

Trade/Proprietary Name: ***Aerobika**** OPEP with Manometer
Common/Usual Name: Spirometer, Therapeutic (Incentive)
Classification / Name: 21 CFR 868.5690 / Incentive Spirometer
Product Code: BWF
Device Class: Class II
Classification Panel: Anesthesiology

2. Submitter and Contact

Trudell Medical International
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Phone: 1 519 455 7060 ext. 2140
Fax: 1 519 455 6329
Contact: Darryl Fischer, Associate Director - Global Regulatory Affairs
Email: dfischer@trudellmed.com

3. Date Prepared

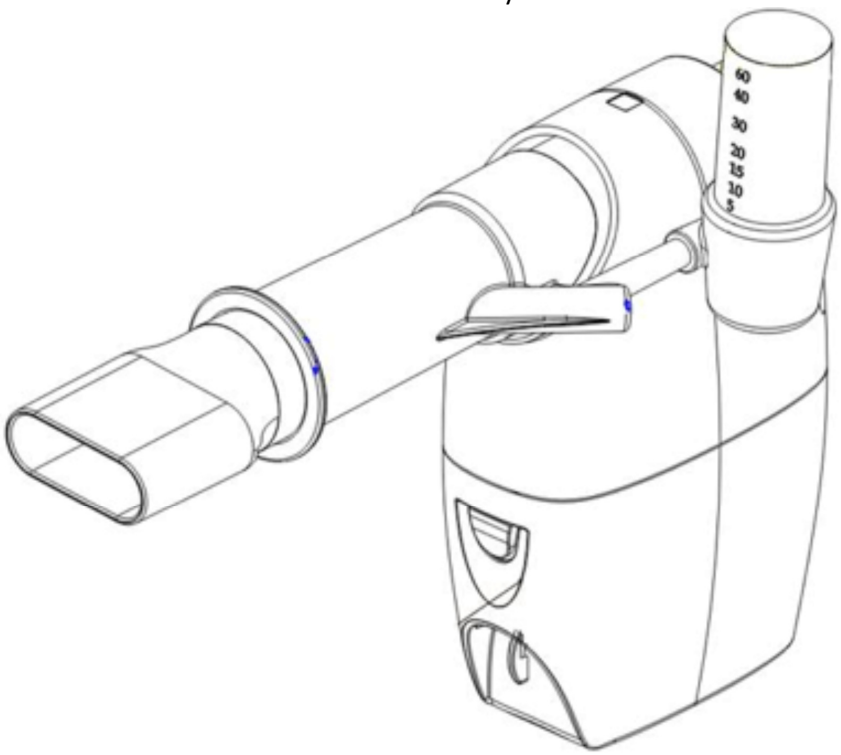
14 Oct 2015

4. Predicate Device

The ***Aerobika**** OPEP with Manometer device is substantially equivalent to Trudell Medical International's ***Aerobika**** OPEP device, which was classified under product code BWF, regulation 868.5690, Incentive Spirometer, and cleared on May 16, 2013 under 510(k) number K123400. The predicate ***Aerobika**** OPEP device was found to be substantially equivalent to DHD Healthcare Corp's Acapella Spirometer, 510(k) K002768.

5. Device Description

The ***Aerobika**** OPEP with Manometer device combines Positive Expiratory Pressure (PEP) with oscillations upon exhalation with visual feedback relative to the patient's expiratory pressure. A view of the ***Aerobika**** OPEP with Manometer assembly is below:



The ***Aerobika**** OPEP with Manometer device is mechanically driven using only the energy from the patient's exhaled breath. Upon exhalation, a portion of the patient's exhaled breath is routed through the manometer device and exits through it. While the manometer is pressurized by the patient's exhaled breath, an indicator contained within the manometer housing indicates the patient's exhaled pressure.

The manometer adapter consists of plastic components constructed of polypropylene material, and the manometer is a purchased component to TMI, and is previously cleared under K040991.

6. Intended Use

The ***Aerobika**** Oscillating Positive Expiratory Pressure device intended for use as a Positive Expiratory Pressure (PEP) device. The ***Aerobika**** Oscillating PEP device may also be used simultaneously with nebulized aerosol drug delivery. The device is intended to be used by patients capable of generating an exhalation flow of 10 lpm for 3 – 4 seconds.

7. Summary of Substantial Equivalence

The ***Aerobika**** OPEP with Manometer and the ***Aerobika**** OPEP device share the same:

Intended use;
Indications for use;
Fundamental technology and operating principle;
Materials of construction

Substantial Equivalence Comparison Table

Common Device Characteristics	
Aerobika* OPEP with Manometer	***Aerobika**** OPEP Device (K123400)
• combines PEP therapy with oscillations upon exhalation	• combines PEP therapy with oscillations upon exhalation
• may be used with a nebulizer to deliver aerosol drug	• may be used with a nebulizer to deliver aerosol drug
• mechanically driven using only the patient's exhaled breath	• mechanically driven using only the patient's exhaled breath
• not orientation dependent	• not orientation dependent
• the device has a removable mouthpiece	• the device has a removable mouthpiece
• the device can remain in the mouth through the treatment	• the device can remain in the mouth through the treatment
• can be adjusted to increase or decrease the exhalation resistance	• can be adjusted to increase or decrease the exhalation resistance
Relevant Differences in Device Characteristics	
• provides visual feedback to patient with regard to exhalation resistance	• does not provide visual feedback regarding resistance
• The Aerobika* OPEP with manometer can be disassembled for the cleaning process. The manometer indicator is not intended to be cleaned	• The ***Aerobika**** Oscillating PEP can be disassembled for cleaning

8. Summary of Conformance Assessment and Conclusion

Risk analysis and design verification and validation activities were conducted by Trudell Medical International to confirm that the ***Aerobika**** OPEP with Manometer meets the same requirements as the current, legally marketed ***Aerobika**** OPEP device.

The test results have demonstrated that the design outputs continue to meet the design inputs, and that the ***Aerobika**** OPEP with Manometer is substantially equivalent to the current, legally marketed ***Aerobika**** OPEP device.
The use of the ***Aerobika**** OPEP with Manometer device does not affect the intended use or indications for use of the original ***Aerobika**** OPEP device.

Furthermore, Trudell Medical International has demonstrated that the addition of this accessory does not modify the fundamental scientific technology of the original device, which is using only the energy derived from the patient's exhaled breath to operate the device.

Non-Clinical Testing Summary

Materials:
The patient contacting components of the ***Aerobika**** *OPEP with Manometer* device meet the requirements of *ISO 10993-1:2009 - Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process*, for Cytotoxicity, Sensitization and Intracutaneous Reactivity.

Mechanical:
Mechanical testing was conducted to characterize the operating parameters of the ***Aerobika**** OPEP with Manometer device.

- Manometer pressure accuracy
- Plug retention
- Inhalation resistance
- Lifecycle
- Cleaning and disinfection cycle testing
- Drop tests
- Aerosol drug delivery

The results show that the ***Aerobika**** OPEP with Manometer device meets specifications and performs comparably to the predicate ***Aerobika**** OPEP device (K123400).

Environmental:
The ***Aerobika**** OPEP with Manometer was exposed to various environmental conditions of high and low temperatures over time. The results of the device performance was evaluated and compared before and after these tests to confirm that the proposed device meets its performance specifications.

Clinical Performance:
A clinical performance summary is not applicable. The determination of substantial equivalence of the subject device is not based on clinical performance data.

Substantial Equivalence Conclusion
The ***Aerobika**** OPEP with Manometer device and the predicate device share common indications for use, operating characteristics and usage environments. The devices are both single patient use, non-sterile and are available by prescription.
The subject ***Aerobika**** OPEP device with Manometer raises no new issues of safety and/or effectiveness.

Based on the above analysis, Trudell Medical International considers that the performance of the ***Aerobika**** OPEP with Manometer device to be substantially equivalent to the ***Aerobika**** OPEP device, and that the addition of this accessory does not change the fundamental scientific technology, nor the intended use of the device.