K123400

MAY 16 2013

Section 5 – 510(k) Summary

Prepared: 10 May 2013

510(k) Owner

Trudell Medical International
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Device Name

Proprietary: ***Aerobika**** Oscillating Positive Expiratory Pressure (PEP) Device

Common/Classification: Spirometer, Therapeutic (Incentive)

Product Code: BWF

Classification Regulation: 868.5690

Predicate Device

510(k) Number	*Trade/Model Name*	*Manufacturer*
K002768	**Acapella**	**DHD Healthcare Corp.**

Device Description

The ***Aerobika**** Oscillating Positive Expiratory Pressure (PEP) device is indicated as a single patient use, hand held secretion clearance and lung expansion device that creates vibrating positive expiratory pressure when a patient exhales through the device. The **Aerobika*** device may be used simultaneously with aerosol drug delivery from a nebulizer.

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Intended Use

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.

Technological Characteristic Comparison to Predicate Device(s)

Common Device Characteristics	
Aerobika* PEP Device	**Acapella** (predicate device - K002768) PEP Device
• 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
• can be adjusted to increase or decrease the exhalation resistance	• can be adjusted to increase or decrease the exhalation resistance
• 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
Relevant Differences in Device Characteristics	
• The ***Aerobika**** Oscillating PEP can be disassembled for cleaning	• Only the mouthpiece of the Acapella device can be disassembled for cleaning
• The ***Aerobika**** Oscillating PEP may be used for patients with an exhalation flow of 10 lpm and above	Two devices are available. • The green or high flow device suitable for most patients. The expiratory flow of the patient must be 15 lpm or greater • The blue or low flow device is for those patients who have low expired lung volumes / less than 15 lpm

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Non-Clinical Test Summary

Mechanical testing was conducted to characterize the operating parameters (amplitude and frequency) of the ***Aerobika**** device to the predicate device.

The test parameters evaluated are a) oscillation frequency and b) oscillation amplitude. It was observed that the ranges of data for each parameter are similar for both devices, showing clear overlap. The mean Frequency and Amplitude values for the Aerobika* device are also within 15% of the respective mean values of the predicate device.

The slightly lower minimum frequency value observed for the ***Aerobika**** device is considered clinically insignificant in terms of therapeutic effect. In addition to the fact that the predicate device has exhibited lower frequencies of 8.0 Hz in previous evaluations (*Volsko et al, 2003*), it is also known that other medical devices utilizing wave oscillation to aid mucocillary clearance are effective down to 3Hz (Vest device, *Douglas and Bond-Kendall*) and 6Hz (Quake device, *Okeson and McGowen, 2007*).

The patient contacting components of the ***Aerobika**** oscillating positive expiratory pressure device meets the requirements of ISO 10993-1:2009, Biological evaluation of medical devices, and are classified according to the within ISO 10993-1 as follows;

- Category: Surface device
- Contact: Mucosal membranes
- Contact Duration: A - Limited Exposure (≤ 24hrs)
- Evaluation Testing for Biological Effect
    - Cytotoxicity – according to ISO 10993-5
    - Sensitization – according to ISO 10993-10
    - Irritation or Intracutaneous Reactivity - according to ISO 10993-10

Section 15 of this submission contains the information regarding the biocompatibility profile of the device under review.

Cascade impactor testing was also conducted comparing the ***Aerobika**** oscillating positive expiratory pressure device to the Acapella using a nebulizer and three (3) different drugs. The results demonstrate that the ***Aerobika**** device performs comparably to the Acapella device, and does not raise any new safety or efficacy related issues.

Clinical Performance Summary

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

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Conclusions from Testing

The ***Aerobika**** oscillating positive expiratory pressure device has been evaluated against the currently marketed (predicate) Acapella PEP device for the determination of substantial equivalency. The ***Aerobika**** oscillating positive expiratory pressure 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 ***Aerobica**** PEP device raises no new issues regarding safety or efficacy.

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

May 16, 2013

Mr. Darryl Fischer
Associate Director, Global Regulatory Affairs
Trudell Medical International
725 Third Street
LONDON Ontario N5V 5G4

Re: K123400
Trade/Device Name: *Aerobika** Oscillating Positive Expiratory Pressure (PEP) Device
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: II
Product Code: BWF
Dated: January 29, 2013
Received: April 17, 2013

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 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,

Kwame O. Ulmer for
-S FDA

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Dental Devices
Office of Device Evaluation
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Enclosure

Indications for Use

510(k) Number: K123400

Device Name: ***Aerobika**** Oscillating Positive Expiratory Pressure (PEP) Device

Indications for Use:

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.

Prescription Use: ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Paul H. Shin -S
2013.05.15 10:10:35 -04'00'

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

510(k) Number: K123400