August 16, 2019

Trudell Medical International
c/o Paul Dryden
Consultant
725 Third Street
London, N5V 5G4 CA

Re: K183108
Trade/Device Name: Combined VersaPAP device and Aerobika OPEP
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: Class II
Product Code: BWF
Dated: July 18, 2019
Received: July 19, 2019

Dear Paul 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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Lee, Ph.D.
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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)*

K183108

Device Name

Combined VersaPAP™ device and Aerobika® OPEP

Indications for Use *(Describe)*

The Combined VersaPAP™ and Aerobika® OPEP device is intended for use as a Positive Airway Pressure (PAP) device and a Positive Expiratory Pressure (PEP) device. The combined device has the ability to provide supplemental oxygen when used with compressed oxygen. The combined device is for patients (ages 5 years and above) who are capable of following directions for Positive Airway Pressure Therapy and capable of generating exhalation flow of 10 lpm for 3 – 4 seconds. The combined device is a single patient, multiple use device intended to be used in a hospital environment under the supervision of a healthcare professional.

Type of Use *(Select one or both, as applicable)*

XX 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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510(k) Summary

Date Prepared 16-Aug-19

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Official Contact: Marianne Tanton – Director, Quality and Regulatory Affairs

Proprietary or Trade Name: Combined VersaPAP™ device and Aerobika® OPEP

Common/Usual Name: Incentive Spirometer

Classification Code/Name: BWF – Incentive Spirometer
21 CFR 868.5690
Class II

Predicate Devices: K150173 – Trudell – Aerobika® OPEP
K173918 – Trudell – VersaPAP™ device

Reference Device: K151689 – Hill-Rom – MetaNeb®

Device Description:
The Aerobika® OPEP device and VersaPAP™ device can be used independently or combined. When combined for ease of use. The combined device creates oscillations during the exhalation phase (OPEP) to aid in secretion clearance and during the inhalation phase (PAP) helps to maintain positive airway pressure for the treatment and prevention of atelectasis.

Indications for Use:
The Combined VersaPAP™ and Aerobika® OPEP device is intended for use as a Positive Airway Pressure (PAP) device and a Positive Expiratory Pressure (PEP) device. The combined device has the ability to provide supplemental oxygen when used with compressed oxygen. The combined device is for patients (ages 5 years and above) who are capable of following directions for Positive Airway Pressure Therapy and capable of generating exhalation flow of 10 lpm for 3 – 4 seconds. The combined device is a single patient, multiple use device intended to be used in a hospital environment under the supervision of a healthcare professional.

Table 1 – Comparison to Predicates

	Proposed Combined Aerobika® OPEP and VersaPAP™ device	Predicate Aerobika® OPEP K150173	Predicate VersaPAP™ device K173918
CFR Classification	868.5690 BWF		
Classification name	Incentive Spirometer		
Intended Use	Intended for use as a Positive Expiratory Pressure (PEP) device (exercise patient's lungs and to improve secretion clearance) Intended for use as a Positive Airway Pressure (PAP) device (Treatment and prevention of atelectasis)	Intended for use as a Positive Expiratory Pressure (PEP) device.	Treatment and prevention of atelectasis
Indications for Use	The Combined VersaPAP™ and Aerobika® OPEP device is intended for use as a Positive Airway Pressure (PAP) device and a Positive Expiratory Pressure (PEP) device. The combined device has the ability to provide supplemental oxygen when used with compressed oxygen. The combined device is for patients (ages 5 years and above) who are capable of following directions for Positive Airway Pressure Therapy and capable of generating exhalation flow of 10 lpm for 3 – 4 seconds. The combined device is a single patient, multiple use device intended to be used in a hospital environment under the supervision of a healthcare professional	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 exhalation flow of 10 lpm for 3–4 seconds.	The VersaPAP™ device is indicated for the treatment and prevention of atelectasis. The VersaPAP™ device also has the ability to provide supplemental oxygen when used with compressed oxygen. The VersaPAP™ device is for patients (ages 5 years and above) who are capable of following directions for Positive Airway Pressure Therapy in a hospital environment. The VersaPAP™ device is a single patient, multiple use device intended to be used under the supervision of a healthcare professional.
Patient Population	Patients capable of generating exhalation flow of 10 lpm for 3–4 seconds. Patients (ages 5 years and above) who are capable of following directions.	Patients capable of generating exhalation flow of 10 lpm for 3–4 seconds.	Patients (ages 5 years and above) who are capable of following directions.

	Proposed Combined Aerobika® OPEP and VersaPAP™ device	Predicate Aerobika® OPEP K150173	Predicate VersaPAP™ device K173918
Environments	Hospital settings	Hospital and clinical Home settings	Hospital settings
Operating principles **OPEP**	Oscillations generated by patient's exhaled breath. Adjustable exhalation resistance Visual feedback via manometer	Oscillations generated by patient's exhaled breath. Adjustable exhalation resistance Visual feedback only when used with the manometer	
PAP	Venturi principle created by compressed gas source Supplemental oxygen Measures airway pressure with manometer		Venturi principle created by compressed gas source Supplemental oxygen Measures airway pressure with manometer
Single patient, multi-use	Components may be cleaned and reused by the same patient		

Table 2 - Comparison of the Subject vs. the Reference Hill-Rom MetaNeb (K151689)

	Proposed **Combined** **OPEP + PAP**	**Reference** **Hill-Rom - MetaNeb®** **K151689**
Classification	BWF 868.5690 Incentive Spirometer	NHJ 868.5905 Device, positive pressure breathing, intermittent (IPPB)
Intended use	Intended for use as a Positive Expiratory Pressure (PEP) device (exercise patient's lungs and to improve secretion clearance) Intended for use as a Positive Airway Pressure (PAP) device (Treatment and prevention of atelectasis)	Intended for use as a Positive Expiratory Pressure (PEP) device. Treatment and prevention of atelectasis
Indications for Use	The Combined VersaPAP™ and Aerobika® OPEP device is intended for use as a Positive Airway Pressure (PAP) device and a Positive Expiratory Pressure (PEP) device. The combined device has the ability to provide supplemental oxygen when used with compressed oxygen. The combined device is for patients (ages 5 years and above) who are capable of following directions for Positive Airway Pressure Therapy and capable of generating exhalation flow of 10 lpm for 3 – 4 seconds. The combined device is a single patient, multiple use device intended to be used in a hospital environment under the supervision of a healthcare professional	The MetaNeb® System is indicated for mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis, and also has the ability to provide supplemental oxygen when used with compressed oxygen.
Patient Population	Patients capable of generating exhalation flow of 10 lpm for 3–4 seconds. Patients (ages 5 years and above) who are capable of following directions.	Patient 5 years and older
Environments of Use	Hospital	Hospital sub-acute facilities Nursing care Homecare

	Proposed Combined OPEP + PAP	Reference Hill-Rom - MetaNeb® K151689
Mode of Operation	OPEP Oscillations generated by patient's exhaled breath. Adjustable exhalation resistance Visual feedback via manometer PAP Venturi vacuum created by compressed gas source Supplemental oxygen Measures airway pressure with manometer	Can deliver continuous expiratory pressure (CPEP) combined with medicated aerosol. Oscillations generated by device Venturi from compressed gas source continuous Supplemental oxygen Measures airway pressure with manometer
Therapy	OPEP PAP	CPEP CHFO Aerosol
Patient Interface	Mouthpiece	Disposable circuit includes connection for in-line nebulizer with mouthpiece
Gas source	Compressed air or oxygen	Pneumatic and air or oxygen
Control settings	OPEP resistance adjustable PAP flow rate: 5-15 L/min.	Mode selection Frequency selection for CHFO mode Pressure adjustment for CPEP mode

Predicate, Reference and Proposed Device Comparison and Substantial Equivalence Discussion:

The proposed and predicates are similar in the following categories:

- Indications for Use
- Patient Population
- Technological Characteristics
- Materials in patient contact
- Shelf-life
- Cleaning methods

The Combined Aerobika® OPEP and VersaPAP™ device is substantially equivalent to the predicate and reference devices because:

Indications –
The proposed indications for use for secretions clearance and the treatment and prevention of pulmonary atelectasis, and also has the ability to provide supplemental oxygen when used with compressed oxygen are identical to the predicate and reference devices.
Discussion – There are no differences between the subject and predicate devices.

Patient Population –
The patient population is identical to the predicates.
Discussion – There are no differences between the subject and predicate devices.

Environment of Use –
The environments of use are similar to the predicates. Noting that the OPEP also includes the home setting when used individually, but the home setting is not intended for the subject device.
Discussion – There are no differences between the subject and predicate devices except the combined device will not be used in the home setting.

Technology –
The technology for generating OPEP and PAP is identical to the predicates. The technology of having a device which offers the combination of OPEP and PEP is similar to the reference device.
Discussion – There are no differences between the subject and predicate devices.

Performance –
The pressure was compared to the reference device. While the pressure of the subject device is less than that of the reference device, it is higher than that of the predicates when they are tested as standalone devices.
Discussion – The difference in performance is within the range of the separate predicate devices and the reference device and does not raise new safety or effectiveness concerns.

The frequency of the combined device is higher than that of the reference MetaNeb device, however, the measured frequency is comparable to the Aerobika® OPEP predicate device and is within acceptable clinical frequency efficacy range.
Discussion - The frequency of the subject device is comparable to the Aerobika® OPEP predicate device. As such, the frequency generated by the subject device does not add risk to the patient compared to other FDA cleared devices.

Non-clinical Comparative Performance

Biocompatibility –
The materials that are patient contacting and gas pathway are same as K150173 – Trudell – Aerobika® OPEP and K173918 – Trudell – VersaPAP™ device

Discussion – Additionally testing was performed, ISO 18562, which supported patient exposure in new configurations.

Bench Testing -
We performed comparative testing at adult and child breathing setting to the predicates and reference. The results demonstrate that the subject device is substantially equivalent to the predicate and reference devices.

Discussion of Differences

The only differences are:

- Environment is only hospital setting
    - Where the Aerobika® OPEP device when used individually can also be used in the home setting
- Certain performance categories differ when the devices are combined vs. when they are used separately.
    - These differences relate to pressure and frequency (oscillations) when they are combined. When compared to the predicates and reference device, these differences in pressure and frequency are within the performance specifications of the cleared predicates and reference device.

Any differences do not raise new or different concerns of safety and effectiveness.

Substantial Equivalence Conclusion

Based upon the comparative performance testing we have demonstrated that the proposed device compared to the predicate and reference devices can be found to substantially equivalent.