August 17, 2018

Trudell Medical International
Marianne Tanton
Director, Quality and Regulatory Affairs
725 Third Street
London, n5V 5G4 Ca

Re: K173918
Trade/Device Name: VersaPAP Positive Airway Pressure (PAP) Device
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: Class II
Product Code: BWF
Dated: July 18, 2018
Received: July 19, 2018

Dear Ms. Tanton:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Amy K. Levelle -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K173918

Device Name
VersaPAP* Positive Airway Pressure (PAP) Device

Indications for Use *(Describe)*
VersaPAP* is indicated for the treatment and prevention of atelectasis. VersaPAP* 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.

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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Section 5 – 510(k) Summary

Prepared: 17-Aug-2018

1. **Submitter**

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2. **Device**

Trade Name:	VersaPAP* Positive Airway Pressure (PAP) Device
Common Name:	Positive Airway Pressure (PAP) Device
Classification Name:	Incentive Spirometer 21 CFR 868.5690
Regulatory Class	II
Product Code:	BWF

3. **Predicate Device**

Boeing, Positive Airway Pressure (PAP) Therapy Device, K991300
DHD Healthcare Corp

DHD Healthcare Corp was purchased by Smith Medical. Smith Medical has changed the device name to EzPAP. The predicate device is referred to as EzPAP throughout the submission.

The predicate device has not been subject to a recall.

4. **Reference Device**

MC 300* R Nebulizer – K173825
Trudell Medical International

Aerobika* OPEP with Manometer Accessory - K150173
Trudell Medical International

The reference devices have not been subject to a recall.

5. **Device Description**

The VersaPAP* device is a hand held respiratory therapy device that creates a positive airway pressure. The VersaPAP* device is intended to be used by pediatric (ages 5 years and above) and adult patients in the hospital environment, under the supervision of a healthcare professional. The VersaPAP* device is a single patient use device and may be used for two treatments per day

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for 7 days. A manometer gauge is included to monitor airway pressure while operating the VersaPAP* device.

The VersaPAP* device consists of seven components: a mouthpiece, the VersaPAP* backpiece (includes 3 components: the baffle, body and end cap), a manometer adapter, a manometer gauge, and oxygen tubing.

6. Principle of Operation

The VersaPAP* device creates positive airway pressure using the Venturi-vacuum principle. Compressed air or compressed oxygen is driven through an orifice where it accelerates and emerges at a high velocity creating a vacuum (Venturi effect). The vacuum draws additional air from the atmosphere through a cylindrical channel where it combines with the orifice airstream and flows out the mouthpiece. This flow creates a net positive airway pressure during the breathing cycle.

7. Indications for Use

VersaPAP™ is indicated for the treatment and prevention of atelectasis. ***VersaPAP™*** 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.

8. Comparison to predicate device

The VersaPAP* device and predicate EzPAP (K991300), are identical in purpose, function, core technology and method of operation. Only minor differences exist between the VersaPAP* device and predicate, which do not affect the safety or effectiveness of the subject device. Table 1 provides a comparison of the subject and predicate devices.

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Table 1: Comparison to Predicate Device

Element of Comparison	**VersaPAP* device** (Subject Device)	**EzPAP device** (Predicate - K991300)
Indications for Use	***VersaPAP***™ is indicated for the treatment and prevention of atelectasis. ***VersaPAP***™ 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.	EzPAP is indicated for the treatment and prevention of atelectasis. EzPAP facilitates opening of airways in patients requiring prevention or treatment of atelectasis. EzPAP also has the ability to provide supplemental oxygen when used with compressed oxygen.
Technology	Pneumatic	
Environment of Use	Hospital	
Patient population	Pediatric (ages 5 years and above) and adult patients	Patient population not specified
Single Patient Use	Yes	
Therapy Type	Lung expansion therapy for patients with spontaneous breathing	
Type of Device	Single patient use, prescription only, non-sterile	
Manufacturing Process	Plastic Molding	
Patient Interface	Mouthpiece	Mouthpiece, Face Mask
Flow rate (L/min)	5-15	
Type of gas source	Compressed air or compressed oxygen	
Manometer Gauge	Included with device to monitor airway pressure	
Principle of Operation	Venturi-vacuum principle	

9. Performance Data

9.1 Summary of Performance Testing

Performance testing included comparative testing against the predicate device using representative patient generated breathing patterns. Testing confirmed that the VersaPAP* device is substantially equivalent to the predicate.

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9.2 Biocompatibility Testing Summary

To evaluate the biological safety of the VersaPAP* device, consideration was given to the following: type of patient contact, potential hazards of the materials of construction, the history of clinical use and testing of the materials of construction, biocompatibility and chemical characterization testing on a similar device, and other information available in the literature.

When used as intended, the VersaPAP* device has direct contact with the mucosal membrane and indirect contact with tissue in the patient respiratory pathway. It is considered externally communicating by way of gas pathway. In accordance with ISO 10993-1, the VersaPAP* device is considered to be an externally communicating, with limited (≤ 24 hours) indirect contact with tissue.

The materials of the VersaPAP* device components are identical to materials used in the following reference devices: MC300*R Nebulizer (K173825) and Aerobika* OPEP device (K150173)

Comparison to Reference Devices:

VersaPAP* Component	Reference Device (K Number)
Mouthpiece	***Aerobika**** OPEP Device with Manometer
Manometer Adapter and Plug	***Aerobika**** OPEP Device with Manometer
Manometer Gauge	***Aerobika**** OPEP Device with Manometer
Oxygen Tubing	***MC300**R Nebulizer
Backpiece – End cap	***MC300**R Nebulizer
Backpiece - Baffle	***MC300**R Nebulizer
Backpiece - Body	***MC300**R Nebulizer

9.3 Dry Gas Pathway Testing

Testing pertaining to the dry gas pathway and associated risk assessments/conclusions were conducted by an independent source. Testing included the following assessments:

- Emissions of volatile organic compounds (VOCs)
- Fine particles (particulate matter PM2.5)

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10. Clinical Performance Summary

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

11. Conclusion

The non-clinical data demonstrate that the VersaPAP* device is as safe and effective as the predicate and therefore substantially equivalent to the cleared predicate device (K991300) and does not raise any new issues of safety and efficacy.