February 19, 2020

D R Burton Healthcare, LLC
Paul Dryden
Consultant
3936 S Fields St
Farmville, North Carolina 27828

Re: K192000
Trade/Device Name: D R Burton OxyPAP
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: Class II
Product Code: BWF
Dated: February 8, 2020
Received: February 11, 2020

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,

for Michael Ryan
Division 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: June 30, 2020
See PRA Statement on last page.

510(k) Number *(if known)*

K192000

Device Name

D R Burton® OxyPAP™

Indications for Use *(Describe)*

The D R Burton® OxyPAP™ device is indicated for the treatment and prevention of atelectasis. It also has the ability to provide supplemental oxygen when used with compressed oxygen. It includes the option of a pressure manometer. The device is for patients (ages 5 years and above) who are capable of following directions for positive airway pressure (PAP) therapy.

Normal use of the D R Burton OxyPAP™ should not be more than 24 hours total combined time.

The environment of use is for hospital and clinical setting.

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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510(k) Summary

Date Prepared 19-Feb-20

D R Burton Healthcare, LLC
3936 S Fields St
Farmville, NC 27828
Tel – 252-228-7038

Official Contact: Dennis Cook – President

Proprietary or Trade Name: D R Burton OxyPAP

Common/Usual Name: Incentive Spirometer

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

Predicate Device: K991300 – DHD Healthcare Corp. – Boeing, Positive Airway Pressure (PAP) Therapy Device

Reference Devices: K173819 – Trudell VersaPAP™ Device
K040991 – Ambu Disposable Pressure Manometer

Device Description:
The OxyPAP device is a handheld respiratory therapy device that creates a positive airway pressure. The OxyPAP 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 OxyPAP device is a single patient use device.

Indications for Use:
The D R Burton® OxyPAP™ device is indicated for the treatment and prevention of atelectasis. It also has the ability to provide supplemental oxygen when used with compressed oxygen. It includes the option of a pressure manometer. The device is for patients (ages 5 years and above) who are capable of following directions for positive airway pressure (PAP) therapy.

Normal use of the D R Burton OxyPAP™ should not be more than 24 hours total combined time.

The environment of use is for hospital and clinical setting.

Table 1 – Comparison to Predicate and Reference Devices

	Proposed OxyPAP	Predicate DHD EzPAP	Reference Trudell VersaPAP	Reference Ambu Pressure Manometer
510(k)		**K991300**	**K173918**	**K040991**
CFR Classification	868.5690 BWF			868.2600 CAP
Classification name	Incentive Spirometer			Monitor, airway pressure (includes gauge and/or alarm
Indications for Use	D R Burton OxyPAP is indicated for the treatment and prevention of atelectasis. It also has the ability to provide supplemental oxygen when used with compressed oxygen. The device is for patients (ages 5 years and above) who are capable of following directions for positive airway pressure (PAP) therapy. Normal use of the D R Burton OxyPAP™ should not be more than 24 hours total combined time. The environment of use is for hospital and clinical setting.	Boeing is indicated for the treatment and prevention of atelectasis. Boing facilitates opening of airways in patients requiring prevention or treatment of atelectasis. Boeing also has the ability to provide supplemental oxygen when used with compressed oxygen.	VersaPAP™ is indicated for the treatment and prevention of atelectasis. VersaPAP™ also has the ability to provide supplemental oxygen when used with compressed oxygen.	To provide visual indication of a patient's airway pressure during ventilation. It may be attached to the manometer port or proximal port on ventilation devices such as resuscitation bags, hyperinflation bags, CPAP mask, or CPAP circuits.
Patient Population	Patients (ages 5 years and above) who are capable of following directions for positive airway pressure (PAP) therapy.	Patients requiring therapy for treatment and prevention of atelectasis who are capable of following directions for PAP therapy	Patients (ages 5 years and above) who are capable of following directions for positive airway pressure (PAP) therapy.	No population
Environments	Hospital and clinical settings	Hospital and clinical settings	Hospital and clinical settings	Hospital and clinical settings

	Proposed OxyPAP	Predicate DHD EzPAP	Reference Trudell VersaPAP	Reference Ambu Pressure Manometer
Operating principles	• Venturi principle created by compressed gas source • Supplemental oxygen port • Measures airway pressure with manometer • Adjustable pressure	• Venturi principle created by compressed gas source • Supplemental oxygen port	• Venturi principle created by compressed gas source • Supplemental oxygen port • Measures airway pressure with manometer • Adjustable pressure	• Measures airway pressure with manometer
Single patient, multi-use	Yes. Typical use is < 14 days, less than 24 hours cumulative use			
Ability to adjust flow rate	Yes			N/A
Ability to adjust pressure during exhalation	Yes, via a "PEEP" type valve	Yes via an adjustable opening and via flow rate	Yes adjustable	N/A
Maximum recommended pressure	< 20 cmH_2O			N/A
Pressure manometer range	0-20 cmH_2O	No manometer	0-20 cmH_2O	0-20 cmH_2O
PAP Flow rate	5-15 Lpm			N/A
Pressure			N/A	N/A
Mean PEEP (cmH_2O) @800 ml TV	2.81 @ 5 Lpm 12 @ 10 Lpm 12.75 @ 15 Lpm	2 @ 5 Lpm 8 @ 10 Lpm 16 @ 15 Lpm	N/A	N/A
Mean Peak Expiratory Pressure (cmH_2O) @800 ml TV	15 Lpm / 15 cmH_2O 20 (400 TV) / 21 (800 TV)	15 Lpm / 15 cmH_2O 22 (400 TV) / 26 (800 TV)	N/A	N/A

	Proposed OxyPAP	Predicate DHD EzPAP	Reference Trudell VersaPAP	Reference Ambu Pressure Manometer
Mean Inspiratory Pressure (cmH_2O) @800 ml TV	-0.7 @ 5 Lpm -4.7 @ 10 Lpm -3.46 @ 15 Lpm	Not known	Not known	
Mean Expiratory Pressure (cm H_2O) @ 800 ml TV	3.1 @ 5 Lpm 12.1 @ 10 Lpm 13 @ 15 Lpm	5 @ 5 Lpm 11 @ 10 Lpm 20 @ 15 Lpm	N/A	
Shelf-life	1 year	N/A	N/A	N/A
Biocompatibility	Externally communicating, tissue and Surface Contact, mucosal contact, limited duration (< 24 hours)			
	Use of material certification confirmed materials and processing were identical to a legally marketed device.	N/A	N/A	N/A

The OxyPAP device is substantially equivalent to the predicate device because:

Indications –
The proposed indications for use for the treatment and prevention of pulmonary atelectasis and has the ability to provide supplemental oxygen when used with compressed oxygen are similar.
Discussion –
The subject device has similar indications for use as the predicate.

Patient Population –
The patient population is similar, where we have specified the age, the predicate did not.
Discussion –
The subject device has similar population as the predicate.

Environment of Use –
Hospital and healthcare setting due to the requirement for compressed air / oxygen source.
Discussion –
The subject device has similar environments of use as the predicate.

Technology –
The technology for generating PAP is similar to the predicate. The ability to adjust pressure and measure airway pressure is similar to the reference K173918 – Trudell VersaPAP.

The technology of measuring and monitoring pressure via a spring pressure manometer is similar to the references K173918 and K040991.
Discussion –
The subject device has similar technology and principle of operation, interface with the patient as the predicate.

The predicate was not cleared with the ability to attach a pressure manometer, yet the reference K173918 which has similar indications for use does have this feature.

Performance –
The differences in performance features is compared to the predicate and reference for pressure monitoring and they were not significant and can be found to be substantially equivalent.
Discussion –
The subject device has substantially equivalent performance to the predicate and applicable reference devices.

Non-clinical Comparative Performance

Biocompatibility –
The materials in patient contact are considered as having 2 types of patient contact:

- External communicating, tissue contacting, limited duration and
- Surface contact, mucosal contact, limited duration for the mouthpiece
- Use of material certification confirmed materials and processing were identical to a legally marketed device.

Bench Testing -
Performance testing included:

- Comparative performance testing to the predicate across the range of performance

- Comparative performance of the pressure manometer to the reference
- Drop testing
- Effects of aging

Discussion of Differences

The subject device incorporates a pressure manometer which the predicate does not. However, we provide a reference device, K173819, which has the same indications for use and incorporates a pressure manometer. We evaluated and compared the performance of the pressure manometer to another reference device, K040991, as K173819 did not include performance data and samples were not available to test.

There were no differences which would 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 be substantially equivalent.