DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 3, 2016

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

Re: K160636
Trade/Device Name: iPEP System and vPEP
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: Class II
Product Code: BWF
Dated: July 2, 2016
Received: July 6, 2016

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. 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.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
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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 on last page.

510(k) Number *(if known)*
K160636

Device Name

iPEP System and vPEP

Indications for Use *(Describe)*

The D R Burton iPEP Therapy System or vPEP is intended for use as a Positive Expiratory Pressure (PEP) by patients capable of generating an exhalation flow of 10 lpm for 3-4 seconds and an Incentive Spirometer as an inspiratory, deep breathing positive exerciser.

Intended for single-patient, multi-use.

iPEP System for hospital and clinical settings
vPEP for hospital, clinical, and home care setting

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
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Company	D R Burton Healthcare LLC 3936 South Fields Street Farmville, NC 27828 Tel – 847-641-0500
Official Contact:	Dennis Cook President & CEO
Proprietary or Trade Name:	iPEP System and vPEP
Common/Usual Name:	Spirometer, therapeutic (incentive)
Product Code:	BWF, Class II
Classification / CFR:	21CFR 868.5690
Device:	iPEP System and vPEP
Predicate Devices:	K991561 – Roadrunner PEP Device (DHD Healthcare Corp.) K002768 – Acapella (DHD Healthcare Corp.) K003146 – Cliniflo Incentive Spirometer (DHD Healthcare Corp.)

Device Description:
D R Burton Healthcare as indicated above proposes to offer 2 devices which we will refer to as the:

- iPEP (integrated Incentive spirometer with PEP) system and
- vPEP which is a standalone PEP therapy device

iPEP system

- Volumetric Incentive Spirometer up to 4000 cc
- Oscillatory PEP module (cartridge)

The design of the iPEP system permits the PEP cartridge to be removed and used as an independent PEP device, which we refer to as the Pocket PEP.

In order to use the Pocket PEP the iPEP system includes a separate mouthpiece, carrying / storage case and dust cover which are needed when one wants to use the PEP cartridge independent of the iPEP systems (Pocket PEP).

When the PEP cartridge is removed from the iPEP system, one can insert a cover where the PEP cartridge has been removed to allow the incentive spirometer to be used one its own.

vPEP

- The vPEP is the standalone device that is pre-assembled and is not intended to be used in the iPEP System. The vPEP incorporates the identical internal components of the PEP cartridge of the iPEP system.

Indications for Use:
The D R Burton iPEP Therapy System is intended for use as a Positive Expiratory Pressure (PEP) by patients capable of generating an exhalation flow of 10 lpm for 3-4 seconds and an Incentive Spirometer as an inspiratory, deep breathing positive exerciser.

Intended for single-patient, multi-use.

iPEP System for hospital and clinical settings
vPEP for hospital, clinical, and home care setting

Patient Population:
Patients requiring inspiratory exercise and capable of generating an exhalation flow of 10 lpm for 3-4 seconds.

Environment of Use:
iPEP System for hospital and clinical settings
vPEP for hospital, clinical, and home care setting

Substantial Equivalence Discussion

Table 1 and **Table 2** compare the key features of the proposed D R Burton iPEP with incentive spirometer and vPEP with the identified predicates. The comparison demonstrates that the devices can be found to be substantially equivalent to the identified predicates. We based this conclusion upon the following:

Indications for Use –
The indications for use are similar for the proposed device when compared to the predicates – K991561 / K002768 – DHD Acapella for PEP and K003146 – DHD Cliniflo as an Incentive Spirometer.
Discussion – We note that the indications for use wording have changed with time. Recent PEP devices have added language related to patients capable of generating an exhalation flow of 10 lpm for 3-4 seconds. This specific wording of the indications for use statement can be found in K123400 – Trudell Aerabika Oscillating Positive Expiratory Pressure. We do not believe that the additional language changes the intent of the indications for use but provides clarity for the user and patient population.

Patient Population –
The patient population is defined as patients requiring inspiratory exercise and / or PEP therapy is equivalent to the predicates – K991561 / K002678 – DHD Acapella for PEP and K003146 – DHD Cliniflo as an Incentive Spirometer .
Discussion – The patient populations are equivalent to the predicates – K991561 / K002678 – DHD Acapella for PEP and K003146 – DHD Cliniflo as an Incentive Spirometer. We note that the indications for use wording have changed with time. Recent PEP devices have added language related to patients capable of generating an exhalation flow of 10 lpm for 3-4 seconds. This specific wording of the indications for use statement can be found in K123400 – Trudell Aerabika Oscillating Positive Expiratory Pressure. We do not believe that the additional language changes the intent of the indications for use but provides clarity for the user and patient population.

Environment of Use –
The environments of use are similar to predicates - K991561 / K002768 – DHD Acapella for PEP and K003146 – DHD Cliniflo as an Incentive Spirometer.
Discussion – We have defined the environment of use for the iPEP System to be hospital and clinical settings and the vPEP, standalone PEP device to be hospital, clinical and home care setting. These environments of use are similar to the predicates - K991561 / K002768 – DHD Acapella for PEP and K003146 – DHD Cliniflo as an Incentive Spirometer.

Principle of Operation and Technology -
The design, components, and principle of operation of the PEP mechanism, a rocker method, that generates oscillations during exhalation and the incentive spirometer in which a float rises during inhalation have been shown to be equivalent to the predicates – K991561 / K002768 – DHD Acapella for PEP and K003146 – DHD Cliniflo as an Incentive Spirometer.
Discussion – The Incentive Spirometer design is a 1 ball / piston volume based system for incentive spirometer that upon the patient inhaling raises the ball to indicate the volume of inspired air and the method of a rocker means that generates oscillations during exhalation for PEP are equivalent to the predicates - K991561 / K002768 – DHD Acapella for PEP and K003146 – DHD Cliniflo as an Incentive Spirometer.

The proposed iPEP system is different from the predicates in that is allows both therapies to be housed in the same unit so the user can receive both therapies during one treatment period. This difference is a matter of convenience for the user; the performance and function of the individual technologies are substantially equivalent to the predicates. Any differences do not raise any new safety or effectiveness concerns.

Non-Clinical Testing Summary –

Comparative Bench Testing
We performed comparative testing of the PEP functions including frequency and amplitude (pressure) as well as volume accuracy / repeatability for the incentive spirometer portion as well. Each technology was compared to the applicable predicates. The results demonstrated equivalent performance**.** These results demonstrated that the proposed device is equivalent to the predicates - K991561 / K002768 – DHD Acapella for PEP and K003146 – DHD Cliniflo as an Incentive Spirometer.

Testing that was performed included:

- Aging, Simulated Life (cleaning), Drop Testing, Cleaning
  - Pre- and post- exposure
- PEP amplitude (resistance) and frequency
  - Testing was performed at minimum and maximum expected flow rates of 5 lpm and 25 lpm
  - Mean Frequency (Hz)
  - Mean Amplitude (cmH_2O)
  - Pressure at Minimum and Maximum levels (cmH_2O)
- Comparative PEP performance
- Volumetric Accuracy – repeatability
- Comparative Volumetric accuracy

Usability Studies
Usability testing was performed with 2 users groups, lay users and Healthcare Providers, with at least 15 users per identified group. Testing included the appropriate tasks based upon the risk analysis. Testing found that the design of the device and instructions for use were appropriate for the intended user groups.

Biocompatibility Materials –
We tested the materials in direct and indirect patient contact based upon the duration of contact, for a cumulative exposure (<24 hours). The testing performed was cytotoxicity, sensitization, and irritation.

Clinical Testing Summary –
There was no clinical testing performed.

Discussion of Differences

The differences between the proposed devices and predicates are:

- Combining 2 technologies into 1 package
    - We have placed the PEP module inside the incentive spirometer housing, yet each device serves as a standalone. The incentive spirometer is performed upon user inhalation and PEP is performed upon user exhalation. Instead of performing these therapies in 2 separate and independent devices we have combined them into a convenient configuration
- iPEP System can be separated into 2 separate devices
    - The ability to remove the PEP module and use it as an independent PEP device, referred to as PocketPEP, is unique. However, the performance of the PEP device is similar to the predicate.

These differences to do raise new risk or safety concerns and thus we can conclude the proposed iPEP System and vPEP devices are substantially equivalent to predicates.

Table 1 – Comparison of Proposed Device vs. Predicates

Attribute	**Predicate** **DHD Acapella** **K991561 / K002768**	**Proposed** **iPEP System and vPEP**
Indications for Use	indicated for use as a Positive Expiratory Pressure (PEP) Device • improves clearance of secretions • may reduce the need for postural drainage • facilitates opening of airways in patients with Cystic Fibrosis, COPD, asthma, and lung diseases with secretory problems • may be used to prevent or reverse atelectasis	The D R Burton iPEP Therapy System is **intended for use as a Positive Expiratory Pressure (PEP) by patients capable of generating an exhalation flow of 10 lpm for 3-4 seconds** and an Incentive Spirometer as an inspiratory, deep breathing positive exerciser.
Environments of use	Home care settings and hospitals	iPEP System for hospital and clinical settings vPEP for hospital and home care setting.
Prescriptive	Yes	Yes
Patient population	Patients requiring PEP therapy	Patients requiring inspiratory exercise and capable of generating an exhalation flow of 10 lpm for 3-4 seconds.
Single patient, multi-use	Yes	Yes
Patient interface	Mouthpiece	Mouthpiece
Basic components	Rocker which generates oscillation during exhalation One-way valve Mouthpiece	Flap valve which generates oscillation during exhalation One-way valve Mouthpiece
Mean Frequency range (Hz) Criteria within 15%	7.0 @ 5 lpm 13.7 @ 25 lpm	8.0 @ 5 lpm 13.0 @ 25 lpm
Mean Amplitude / Pressure (cmH_2O) Criteria within 15%	5.9 @ 5 lpm 23.2 @ 25 lpm	5.5 @ 5 lpm 22.7 @ 25 lpm
Mean Pressure (cmH_2O)at Min and Max settings Criteria within 15%	Min – 0 @ 5 lpm Min – 2.9 @ 25 lpm Max – 5.9 @ 5 lpm Max – 26.1 @ 25 lpm	Min – 0 @ 5 lpm Min – 2.5 @ 25 lpm Max – 5.5 @ 5 lpm Max – 25.1 @ 25 lpm
Has means to adjust amplitude / pressure	Yes, variable exhalation opening	Yes, variable exhalation opening

Attribute	Predicate DHD Acapella K991561 / K002768	Proposed iPEP System and vPEP
Cleaning method	Rinse, soap and water	Rinse, soap and water
Performance testing		Age Cleaning / simulated life Drop test Frequency (Hz) Amplitude (cmH_2O) Pressure at min / max settings (cmH_2O)
Type of Patient contact with materials	Externally communicating / Tissue Surface contact / mucosa Limited duration (< 24 hours)	Externally communicating / Tissue Surface contact / mucosa Limited duration (< 24 hours)

Table 2 – Comparison for Incentive Spirometer

Attribute	DHD Cliniflo /Coach K003146	Proposed iPEP with Incentive Spirometer
Indications for Use	Intended as an inspiratory deep breathing positive exerciser	The D R Burton iPEP Therapy System is intended for use as a Positive Expiratory Pressure (PEP) by patients capable of generating an exhalation flow of 10 lpm for 3-4 seconds and **an Incentive Spirometer as an inspiratory, deep breathing positive exerciser.**
Environments of use	Home care settings and hospitals	iPEP System for hospital and clinical settings
Prescriptive	Yes	Yes
Patient population	Patients requiring inspiratory exercise	Patients requiring inspiratory exercise
Single patient, multi-use	Yes	Yes
Patient interface	Mouthpiece with flex-tubing	Mouthpiece with flex-tubing
Basic components	Housing 1 ball / piston Tubing Mouthpiece	Housing 1 ball / piston Tubing Mouthpiece

Attribute	DHD Cliniflo /Coach K003146	Proposed iPEP with Incentive Spirometer
Volume range	2500 and 5000 cc	4000 cc
Performance testing	Volume accuracy 2500 cc (14 – 21%) 5000 cc (16 – 21%)	Volume accuracy 4000 cc (1.6 to 2.2%) Age Testing Pre and post- exposure Drop test Cleaning
Type of Patient contact with materials	Externally communicating / Tissue Surface contact / mucosa Limited duration (< 24 hours)	Externally communicating / Tissue Surface contact / mucosa Limited duration (< 24 hours)

Substantial Equivalence Conclusion

As detailed, the indications for use, patient population, environment of use, technology or principle of operation, and performance are substantially equivalent to the predicates.

The identified differences between the proposed D R Burton iPEP system or vPEP and the predicates – K991561 / K002768 – DHD Acapella for PEP and K003146 – DHD Cliniflo as an Incentive Spirometer based upon the comparative performance testing allows us to conclude that there are no new safety or effectiveness concerns that raise new risks and thus the proposed device can be determined to be substantially equivalent.