January 11, 2018

Besmed Health Business Corp.
Paul Dryden
Consultant
No.5, Lane 116, Wu-Kong 2nd Rd
Wu-Ku District, Tw

Re: K172804
Trade/Device Name: Besmed Peak Flow Meter
Regulation Number: 21 CFR 868.1860
Regulation Name: Peak-Flow Meter For Spirometry
Regulatory Class: Class II
Product Code: BZH
Dated: December 14, 2017
Received: December 15, 2017

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.

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.

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,

Tara A. Ryan -S

Digitally signed by Tara A. Ryan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Tara A. Ryan -S, 0.9.2342.19200300.100.1.1=1300030749
Date: 2018.01.11 08:20:45 -05'00'

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)*

K172804

Device Name

Besmed Peak Flow Meter

Indications for Use *(Describe)*

The intended device measures a patient's peak expiratory flow rate liters/minute.

Patient Population – Patients 5 years and older requiring the measurement of peak expiratory flow rate.

Environment – Anywhere a patient may require the measurement of peak expiratory flow.

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

Prescription Use (Part 21 CFR 801 Subpart D) XX☐ 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: 04-Jan-2018

Besmed Health Business Corp.
No. 5, Lane 116, Wu-Kong 2nd Rd, Tel - 011-886-2-2290-3959
Wu-Ku District, New Taipei City, Taiwan Fax - 011-886-2-2299-9076

Official Contact: Sarah Lu
Vice President / Sales Manager

Proprietary or Trade Name: Besmed Peak Flow Meter

Common/Usual Name: Peak Flow Meter

Classification Name: 21CFR 868.1860
BZH - Meter, Peak Flow, Spirometry
Class II

Predicate Device: Vitalograph Peak Flow Meter, K781922

Reference Device: MINI WRIGHT LR AFS, K952713

Device Description: The Besmed Peak Flow Meter is a hand-held monitoring device that measures Peak Expiratory Flow (PEF) generated by the patient during a forced exhalation maneuver. The proposed device can be used to measure PEF by tracking day-to-day changes in breathing patterns.

Indications for Use:
The intended device measures a patient's peak expiratory flow rate liters/minute.

Patient Population – Patients 5 years and older requiring the measurement of peak expiratory flow rate.

Environment – Anywhere a patient may require the measurement of peak expiratory flow.

Comparison to Predicate

Device Comparison	**Besmed Peak Flow Meter**	**Predicate** **Vitalograph Peak Flow Meter, K781922**
Model	PF-29100 (Full Range for Adult) PF-29200 (Low Range for Child)	43800 AsmaPLAN 43800 AsmaPLAN+
Indicated Use Target Population Environment of Use	The intended device measures a patient's peak expiratory flow rate liters/minute. Patient Population – Patients 5 years and older requiring the measurement of peak expiratory flow rate. Environment – Anywhere a patient may require the measurement of peak expiratory flow.	The intended device simply measures a patient's peak expiratory flow rate in liters/minute. Patient population: Patients requiring the measurement of peak expiratory flow rate. Environment of use: Anywhere a patient may require the measurement of peak expiratory flow.
OTC	Yes	Yes
Design	Single Patient. Multi Use	Single Patient Use
Components	Mouthpiece, disposable	
Measuring Principle	Tension Spring Piston/Pointer	Tension Spring Piston/Pointer
Biocompatibility	Surface Contact, Mucosa and Externally Communicating Tissue Limited duration (<24 hr.) Cytotoxicity Sensitization Intracutaneous reactivity	Surface Contact, Mucosa and Externally Communicating Tissue Limited duration (<24 hr.) Cytotoxicity Sensitization Intracutaneous reactivity
Range	50~800 L/min (PF-29100, adult) 50~300 L/min (PF-29200, child)	50~800 L/min
ISO 23747 requirements		
Accuracy	+/- 10%	+/- 10%
Intra device Precision	+/- 5%	+/- 5%
Inter device Precision	+/- 5%	+/- 5%
Performance		
Effects of Aging	No change in performance	Unknown
Drop test	No change in performance	Unknown
Environmental conditions	10-40°C	10-40°C
Storage conditions	10-40°C	10-40°C
Cleaning	Proper cleaning with mild detergent in warm tap water.	unknown

The Besmed Peak Flow Meter is viewed as substantially equivalent to the predicate device because:

Indications for Use / Patient Population / Environment of Use–
The indications for use are similar between both devices.
Discussion -
The indications for use are similar for the proposed device and the predicate – Vitalograph Peak Flow Meter, K781922

Technology –
The technology is simple spring tension, that when the user exhales the indicator moves and the spring has been calibrated to represent the flow rate of the user. The proposed device includes a mouthpiece with one-way valve to prevent the user from inhaling through the measurement portion and thus prevent the necessity of cleaning that portion of the device. Only the mouthpiece with one-way valve needs to be cleaned between uses.
Discussion –
The technology is similar for the proposed device as compared to the predicate - Vitalograph Peak Flow Meter, K781922

Non-Clinical Testing Summary –

Biocompatibility of Materials –
The components in patient contact are characterized similar for the proposed device and the predicate, which is:

- External Communicating
- Tissue / Bone / Dentin
- And
- Surface Contact
- Mucosa
- Duration of Use – limited (< 24 hours)

Discussion -
The type and duration of patient contact is similar for the proposed and predicate device. We have performed ISO 10993-1 testing for the materials in patient contact.

Performance Testing including Comparative:
We performed peak flow accuracy and the results demonstrated equivalent (or better) performance showing the Besmed Peak Flow Meter is equivalent to the predicate – Vitalograph Peak Flow Meter, K781922. The testing included:

- Accuracy
- Repeatability of accuracy
- Ageing
- Storage / Environmental conditions
- Mechanical – drop test

Substantial Equivalence Conclusion:

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent