



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 3, 2014

Besmed Health Business Corporation
C/O Mr. Paul Dryden
President
ProMedic, Inc.
No. 5, Lane 116, Wu-Kong 2nd Rd,
Wu-Ku District, New Taipei City
TAIWAN

Re: K141355

Trade/Device Name: Besmed Volumetric Incentive Spirometer
Regulation Number: 21 CFR 868.5690
Regulation Name: Spirometer, therapeutic (incentive)
Regulatory Class: Class II
Product Code: BWF
Dated: August 4, 2014
Received: August 5, 2014

Dear Mr. 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" (21CFR 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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Erin I. Keith, M.S.
Director
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K141355

Device Name

Besmed Volumetric Incentive Spirometer

Indications for Use (Describe)

The Besmed Volumetric Incentive Spirometer is intended as an inspiratory deep breathing positive exerciser. Intended for single-patient, multi-use in a hospital or home care 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)



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Date Prepared: 20-Aug-2014

Besmed Health Business Corp.

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Wu-Ku District, New Taipei City, Taiwan

Tel - 011-886-2-2290-3959

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Official Contact: Winnie Chung, Regulatory Affairs

Proprietary or Trade Name: Volumetric Incentive Spirometer

Common/Usual Name: Incentive spirometer

Classification Name: 21CFR 868.5690, Class 2
BWF - spirometer, therapeutic (incentive)

Predicate Devices: K801199 – Hudson RCI Voldyne

Device Description:

The Besmed Volumetric Incentive Spirometer has a flexible tube and mouthpiece which the patient inhales through. This tube connects to the inspiration port of the unit. The chamber has a ball and piston which upon the patient inhaling, creates a vacuum, which causes the ball and piston to rise, the piston reflects the inspiratory volume while the ball is an indicator for the user to maintain the optimum inspiratory flow rate. Two (2) models are offered – 2500 cc and 5000 cc. It is a single patient, multi-use, disposable, non-sterile device. The mouthpiece may be removed and cleaned by the user as needed but the main device is not to be cleaned.

As a patient improves their respiratory capacity or gets stronger they improve their inspiratory volume raising the piston. The principle of the ball indicator is to provide the user a visual indicator of their inspiratory flow rate and help them to improve the respiratory function with repeated uses. Incentive spirometers are commonly referred to as “lung exercisers”.

The Besmed Volumetric ICS achieves the therapeutic intent by helping the patient to improve their inspiratory volume. It is a relative improvement device that as described offers the patient the “incentive” to improve. This is the identical therapeutic intent of the predicate volume based incentive spirometer.

Indications for Use:

The Besmed Volumetric Incentive Spirometer is intended as an inspiratory deep breathing positive exerciser. Intended for single-patient, multi-use in a hospital or home care setting.

Patient Population:

Patients requiring inspiratory exercise.

Environments of use:

Hospital and home care settings

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Comparison to Predicates

Attribute	Hudson RCI K801199	Proposed Besmed Volumetric ICS
Indications for Use	Intended as an inspiratory deep breathing positive exerciser. Intended for single-patient, multi-use in a hospital or home care setting.	The Besmed Volumetric Incentive Spirometer is intended as an inspiratory deep breathing positive exerciser. Intended for single-patient, multi-use in a hospital or home care setting.
Environments of use	Home care settings and hospitals	Home care settings and hospitals
Prescriptive	Yes	Yes
Patient population	Patients requiring inspiratory exercise	Patients requiring inspiratory exercise
Single patient, multi-use	Yes	Yes
Patient interface	Mouthpiece (maybe removed and cleaned)	Mouthpiece (maybe removed and cleaned)
Basic components	Housing 1 ball / piston Tubing Mouthpiece	Housing 1 ball / piston Tubing Mouthpiece
Volume range	2500 and 5000 cc	2500 and 5000 cc
Accuracy	Not reported but ~ 21% when comparative testing performed	+/- 15%
Performance testing	Volume accuracy 2500 cc – 14 – 21% 5000 cc – 16 – 21%	Volume accuracy 2500 cc – 4 – 15% 5000 cc – 3 - 12%
		Age Testing Pre and post- exposure Environmental Testing High / Low and Humidity conditions Drop test

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Substantial Equivalence Discussion

Table 1 compares the key features of the proposed Besmed Volumetric incentive spirometer with the identified predicate and demonstrates that the device can be found to be substantially equivalent.

In summary one can conclude that substantial equivalence is met based upon the following:

Indications for Use –

The indications for use are identical for the proposed device when compared to the predicate – K801199 – Hudson RCI Voldyne incentive spirometer.

Discussion – Each device is indicated for use volumetric inspiratory deep breathing positive exerciser.

Technology and construction –

The design, components, shape, size, etc., are equivalent to the predicate – K801199 – Hudson RCI Voldyne incentive spirometer.

Discussion – The design is a 1 ball / piston volume based system that upon the patient inhaling raises the piston to indicate the volume of inspired air while there is a ball which indicates the inspiratory flow rate that the patient should try and maintain.

Environment of Use –

The environments of use are identical to predicate - K801199 – Hudson RCI Voldyne incentive spirometer.

Discussion – The environments of use are identical to the predicate K801199 – Hudson RCI Voldyne incentive spirometer.

Patient Population –

The patient population of patients requiring inspiratory exercise is equivalent to the predicate – K801199 – Hudson RCI Voldyne incentive spirometer.

Discussion – The patient populations are equivalent to the predicate – K801199 – Hudson RCI Voldyne incentive spirometer.

Non-Clinical Testing Summary –

Materials:

The materials are identical to our reference Besmed TriBall ICS cleared under K133873. We consider the device as External Communicating (Indirect gas pathway) and Surface Contact (direct skin) with limited duration of use (< 24 hours). The following tests were performed.

- Cytotoxicity
 - Sensitization
 - Intracutaneous / Irritation
-

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Environmental:

The proposed device was exposed to various environmental conditions of high and low temperatures over time and the performance evaluated and compared before and after these tests to confirm that the proposed device met its performance specifications.

Performance Testing including Comparative:

We performed volume accuracy / repeatability and comparative volume accuracy and the results demonstrated equivalent (or better) performance demonstrating the proposed device is equivalent to the – K801199 – Hudson RCI Voldyne incentive spirometer.

Multiple samples of each device were tested multiple times and then evaluated for consistency of performance.

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 be substantially equivalent.
