DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 23, 2017

Medinet SRL
% Maurizio Pantaleoni
C.E.O.
Isemed Srl
Via A.bonetti 3/A
Imola, 40026
ITALY

Re: K160837
Trade/Device Name: Medinet Incentive Spirometers - Respiprogram
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: II
Product Code: BWF
Dated: January 23, 2017
Received: January 25, 2017

Dear Maurizio Pantaleoni:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160837

Device Name
MEDINET INCENTIVE SPIROMETER - RESPIPROGRAM

Indications for Use *(Describe)*
MEDINET INCENTIVE SPIROMETER – RESPIPROGRAM is intended as an inspiratory deep breathing positive exerciser.
MEDINET INCENTIVE SPIROMETER - RESPIPROGRAM is intended for single-patient, single 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary for the MEDINET INCENTIVE SPIROMETER

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter: MEDINET s.r.l. is located at:
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Summary Preparation Date: February 13, 2016

2. Names

Device Name: MEDINET INCENTIVE SPIROMETER- RESPIPROGRAM
Classification Name: Incentive spirometer
Product Code: BWF
Regulation number: 868.5690
CLASS II

3. Predicate Devices

The MEDINET INCENTIVE SPIROMETER RESPIPROGRAM is substantially equivalent to the following device:

Applicant	Device name	510(k) Number	Product code
BESMED Health Business Corp.	TriBall incentive spirometer	K133873	BWF

4. Device Description

The RESPIPROGRAM is an inspiratory device used as breathing exerciser; RESPIPROGRAM is a FLOW exerciser

The following model is available:

- RESPIPROGRAM – code 15 10 002 600

The RESPIPROGRAM is intended as an inspiratory deep breathing positive exerciser.
It is intended for single-patient, single use both in a hospital or for home care therapy.

RESPIPROGRAM is a single patient, single use, disposable, non-sterile device.

RESPIPROGRAM is a single use device that allows the patient to indicate visually the capacity of inhaling, even though RESPIPROGRAM doesn't have a specific measuring function.
The device is a stimulator for inspiration; therefore it is indicated in all situations for when it is necessary to stimulate the patient's inhalation, under the prescription of a physician.
The patient inspires through a mouthpiece that is connected to 3 chambers that have 3 balls of different colors (red, yellow and green) each one indicating a different approximate flow rate (respectively 600, 900 and 1200 ml per second).

5. Indications for Use

MEDINET INCENTIVE SPIROMETER – RESPIPROGRAM is intended as an inspiratory deep breathing positive exerciser.
MEDINET INCENTIVE SPIROMETER - RESPIPROGRAM is intended for single-patient, single use in a hospital or home care setting.

6. Performance Data

The following comparative tests have been performed for the MEDINET incentive spirometer RESPIPROGRAM in comparison with its predicate device, to support the substantial equivalence

FLOW ACCURACY TESTS between

- RESPIPROGRAM and BESMED TRIBALL

The tests have been performed using new and aged samples and considering various humidity conditions. The results showed that all the samples tested, met the pre-determined acceptance criteria defined in the performance test protocol.

DROP TEST between:

- RESPIPROGRAM and BESMED TRIBALL

The results showed that the samples tested met the pre-determined acceptance criteria without any breakage or crack.

The following biocompatibility tests were performed:

- Cytotoxicity
- Irritation
- Sensitization

7. Substantial Equivalence Discussion & Summary of Technological Characteristics

The indications for use of the MEDINET Incentive Spirometer can be considered substantially equivalent to the identified predicate devices.

The design features, the technological characteristics and the performances are equivalent to that of the predicate devices as shown in the table below:

	Subject Device	Predicate Devices	Substantially Equivalent
	MEDINET INCENTIVE SPIROMETER RESPIPROGRAM	**BESMED TriBall - K133873**	
Regulation Number:	868.5690	868.5690	Same
Classification	II	II	Same
Product Code	BWF	BWF	Same
Indications for use	MEDINET INCENTIVE SPIROMETER RESPIPROGRAM is intended as an inspiratory deep breathing positive exerciser. MEDINET INCENTIVE SPIROMETER is intended for single-patient, single use in a hospital or home care setting.	The Besmed Incentive Spirometer is intended as an inspiratory deep breathing positive exerciser. Intended for single-patient, multi-use in a hospital or home care setting.	Equivalent. The only difference is that Medinet Incentive spirometer Respiprogram is single use, while predicate device is multi-use
Users			
Prescription devices	YES	YES	Same
Population	Patients requiring inspiratory exercise	Patients requiring inspiratory exercise	Same
Single Patient, Single Use	YES	No, Single patient, Multi Use	Equivalent. The only difference is that Medinet Incentive spirometer Respiprogram is single use, while predicate device is multi-use
Environment of use	Home care settings and hospitals	Home care settings and hospitals	Same
Design features			
Basic components	Housing 3 balls Tubing Mouthpiece	Housing 3 balls Tubing Mouthpiece	Same
Patient Interface	Mouthpiece	Mouthpiece	Same
Available Models	One model with three balls	One model with 3 balls	Same
Biocompatibility			
Cytotoxicity	Conforming to ISO 10993 testing (ISO 10993-5)	Conforming to ISO 10993 testing	Same
Sensitization	Conforming to ISO 10993 testing (ISO 10993-10)	Conforming to ISO 10993 testing	Same
Intracutaneous irritation	Conforming to ISO 10993 testing (ISO 10993-10)	Conforming to ISO 10993 testing	Same
Performances			
Flow	600/900/1200 cc/sec	600/900/1200 cc/sec	Same
Accuracy	+/- 5%	+ /- 5%	Same
Resistance	Drop Test results: no breakage or crack at the end of the test	Drop Test	Same

	Subject Device	Predicate Devices	Substantially Equivalent
	MEDINET INCENTIVE SPIROMETER RESPIPROGRAM	**BESMED TriBall - K133873**	
Condition of testing and results	±5% accuracy is maintained in the following test conditions: - Age Testing (products recently manufactured and expired products) - Low Humidity Testing (products recently manufactured and expired products tested with humidity < 40%) - High Humidity Testing (products recently manufactured and expired products tested with humidity > 80%). Low humidity test results (cc/sec): Test at 600 cc/sec: 604,6±5,5 Test at 900 cc/sec: 925,2±3,28 Test at 1200 cc/sec:1222,8±10,0 High humidity test results (cc/sec) Test at 600 cc/sec: 593,5±4,9 Test at 900 cc/sec: 887,3±3,7 Test at 1200 cc/sec:1177,3±7,5	Accuracy specification ±5% verified in the following test conditions: Age Testing High / Low Humidity conditions Inspiratory rate / Volume accuracy declared : 600 – 0,5% 900 – 0,3% 1200 – 0,1% Test results using the MEDINET test method - Low humidity (cc/sec): Test at 600 cc/sec: 624,0±10,1 Test at 900 cc/sec: 886,8±10,2 Test at 1200 cc/sec:1210,5±12,89	Same

Summary of Technological Characteristics:

Both subject and predicate device are incentive spirometers. The fundamental technology of the subject and predicate device are based on the following same technological elements:

- Housing containing 3 balls
- Mouthpiece as a patient interface
- Flow rate of 600, 900 and 1200 ml/second
- Non Sterile Device

The following technological difference exists between the subject and the predicate device:

- Respiprogram is single use, while predicate device is multi-use.

8. Conclusion

Based on technological characteristics (intended use, dimensions and features) and performance data (comparative tests and biocompatibility tests) included in this submission, the MEDINET INCENTIVE SPIROMETER RESPIPROGRAM has been shown to be substantially equivalent to the listed predicate device.