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

November 20, 2014

Medical Respiratory Devices S.L.
Mr. Paul Dryden
President, PreMedic, Inc.
Avda. de las Americas 4, Nave A7
Coslada (Madrid) 28823
SPAIN

Re: K142303
Trade/Device Name: NeumoFilt Ergo and NeumoFilt BiteOn
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: October 21, 2014
Received: October 22, 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K142303

Device Name
NeumoFilt Ergo

Indications for Use *(Describe)*

For use with pulmonary function testing (PFT) equipment only, to filter air between the patient's exhaled air and the testing equipment. Single patient use, disposable. Duration of use < 24 hours. Environment of use: Hospital, Sub-acute facilities, Clinics, Physician offices.

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)

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FOR FDA USE ONLY

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K142303

Device Name
NeumoFilt BiteOn

Indications for Use *(Describe)*

For use with pulmonary function testing (PFT) equipment only, to filter air between the patient's exhaled air and the testing equipment. Single patient use, disposable. Duration of use < 24 hours. Environment of use: Hospital, Sub-acute facilities, Clinics, Physician offices.

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

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Official Contact: Jose Alberto Hernandez
General Manager

Proprietary or Trade Name: NeumoFilt Ergo
NeumoFilt BiteOn

Common/Usual Name: Diagnostic Spirometer (Accessory)

Regulation description: Diagnostic Spirometer
Product code: BZG
Regulation number: 21 CFR 868.1840
Device class: Class II

Predicate Device: Air Safety Model 2800 PFT filter (K051712)

Device Description: The MRD NeumoFilt pulmonary function filter ("PFT filter") is a standard electrostatic filter that is placed between the patient and the pulmonary function testing equipment to keep a patient inhaled and exhaled breath from contaminating the equipment. There are 2 models with the only difference being the patient end piece which is either a biteblock shape (BiteOn) or the mouthpiece shape (Ergo).

Indications for Use: For use with pulmonary function testing (PFT) equipment only, to filter air between the patient's exhaled air and the testing equipment. Single patient use, disposable. Duration of use < 24 hours. Environment of use: Hospital, Sub-acute facilities, Clinics, Physician offices.

Contraindications: None

Substantial Equivalence Rationale:

The MRD NeumoFilt is viewed as substantially equivalent to the predicate devices because:

Indications – For use with pulmonary function testing (PFT) equipment only, to filter air between the patient's exhaled air and the testing equipment. Single patient use, disposable. Duration of use < 24 hours. Environment of use: Hospital, Sub-acute facilities, Clinics, Physician offices.
Discussion - This is identical to the predicate – Air Safety Model 2800 PFT Filter – K051712, which is intended for use with pulmonary function testing equipment, to filter air between the patient's exhaled air and the testing equipment.

Features	Proposed NeumoFilt PFT Filter	Predicate Air Safety Model 2800 PFT Filter (K051712)
Indications for use	For use with pulmonary function testing (PFT) equipment only, to filter air between the patient's exhaled air and the testing equipment. Single patient use, disposable. Duration of use < 24 hours. Environment of use: Hospital, Sub-acute facilities, Clinics, Physician offices.	Model 2800 is indicated for use with pulmonary function testing equipment, to filter air between the patient's exhaled air and the testing equipment.
Patient Use / Duration if use	Single patient use, disposable, < 24 hours	Single patient use, disposable, < 24 hours
Environment of Use	Hospital, Sub-acute facilities, Clinics, Physician offices	Hospital, Sub-acute facilities, Physician offices
Patient Population	No specific limitations	No specific limitations
Contraindications	None	None
Features, Specifications and Performance		
Can be used with several different PFT machines	Yes	Yes
Various sizes of machine side end fittings – 30, 33, 35, 36, 48 mm	Yes	Yes
Patient uses a mouthpiece or biteblock	Yes	Yes
Filtration method	Electrostatic	Electrostatic
Resistance to flow @ 1, 5, 14 l/sec per ATS standard for spirometry	0.56 cmH_2O @ 1 l/sec 0.74 cmH_2O @ 5 l/sec 1.47 cmH_2O @ 14 l/sec	0.5 cm H_2O @ 1 l/sec 0.7 cm H_2O @ 12 l/sec
Bacterial Filtration Efficiency (BFE)	99.9998%	99.9999%
Viral Filtration Efficiency (VFE)	99.9939%	99.999+%
Weight (gm)	30 grams	40 grams
Internal volume/ Dead space	70 ml – Ergo 68 ml – BiteOn	75 ml
Housing Burst Pressure	> 120 cm H_2O	Not reported
Performance	None under section 514	None under section 514
Biocompatibility	Tested per ISO 10993 Cytotoxicity Sensitization Irritation	Not reported

Technology – The MRD NeumoFilt is an electrostatic media that is equivalent in performance and the fundamental principle of operation as the predicate.
Discussion - There are no differences in technology between the proposed device and the predicate Air Safety Model 2800 PFT filter – K051712.

Environment of Use – Hospitals, Sub-acute facilities, clinics and physician offices.
Discussion - The environment of use is substantially equivalent to the predicate Air Safety Model 2800 PFT filter – K051712.

Patient Population – There are no patient specific limitations.
Discussion - This is identical to the predicate Air Safety Model 2800 PFT filter – K051712.

Performance Specifications – The performance specifications are substantially equivalent to the predicates – Air Safety Model 2800 PFT filter – K051712.

Non-clinical Testing – We performed a number of non-clinical tests to demonstrate the safety and efficacy of the MRD NeumoFilt. These tests included:

Materials – The materials have been evaluated and tested in accordance with ISO 10993-1 and G95-1. Based upon ISO 10993-1 and G95-1 the NeumoFilt filter would be considered as:

- Externally communicating (indirect gas pathway)
- Tissue contact
- Limited duration (< 24 hours)

And the housing:

- Surface Contact
- Mucosa contact
- Limited duration (< 24 hours)

We have performed the following tests:

- Cytotoxicity
- Sensitization
- Intracutaneous reactivity or Irritation

Performance Testing – We have performed the following performance data and testing:

- Resistance to flow at 1, 5, 14 l/second
- Bacterial / Viral filtration efficiency per Nelson Laboratories
    - Pre – and Post – conditioning
    - Bacterial Filtration Efficiency (BFE) - 99.9998% per MIL-M-36954C, S. aureus ATCC# 6538 of approximately 3.0 micron size, > 107 challenge.
    - Viral Filtration efficiency (VFE) – 99.9939% per MIL-M-36954C, X174 bacteriophage of approximately 2.9 micron size, > 106 challenge.
- Dead space
- Housing burst strength
- Age testing

Discussion of Differences and Similarities –
As the above table and rationale present there are no major differences between the proposed NeumoFilt and the predicate. Each filter is operates on the same filtration technology that is placed between two houses. They each connect to PFT testing equipment. The predicate may be used with a separate mouthpiece to make it easier for the user whereas the proposed Ergo design the patient end-fitting is shaped like a mouthpiece thus not requiring a separate piece. Their physical

size, design, dimensions are very similar and not considered significantly different as demonstrated by the comparative performance testing. The slight differences in BFE / VFE, weight, and Dead Space do not raise any new safety concern and thus can be considered substantially equivalent.

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.