March 16, 2020

Meditera Tibbi Malzeme San. ve Tic. A.S.
% Paul Dryden
Consultant
Meditera Tibbi Malzeme San. ve Tic. A.S. % ProMedic, LLC
131 Bay Point Dr NE
St. Petersburg, Florida 33704

Re: K192713
Trade/Device Name: Altera Filter and HME/Filter
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: Class II
Product Code: CAH
Dated: February 25, 2020
Received: February 26, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elizabeth Claverie, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*

K192713

Device Name

Altera Filter and HME / Filter

Indications for Use *(Describe)*

Filter only - For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and/or expired gases is desired. Use up to 24 hours.

HME / Filter - For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and/or expired gases is desired and to maintain moisture levels in the patient's respiratory tract during anesthesia, artificial respiration and other types of assisted ventilation. Use up to 24 hours.

Environment of use – clinical setting including hospital, sub-acute, pre-hospital and home

For patient with Tidal Volumes > 300 ml.

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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510k Summary

Date Prepared: 16-March-2020

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Quality Assurance Team Leader

Proprietary or Trade Name: Altera Filter and HME/Filter

Common/Usual Name: Filter, bacterial, breathing circuit

Classification Name: 21CFR 868.5260
CAH - filter, bacterial, breathing circuit
Class II

Predicate Devices: K151498 – Zhejiang Haisheng Medical Device Co. Ltd.

Device Description:
The subject device is provided in two (2) configurations.

- Filter only
- HME / Filter combination

The common features are:

- Standard conical 15 mm / 22 mm fittings for connections
- Female luer lock port for gas sampling for end-tidal CO_2

Principle of Operation:

There are two principles of operation with the subject devices:

- Filtration is via the principle of electrostatic charges that attract and capture the microbes in the spun-fiber polypropylene media.
- Passive humidification is the use of a "treated" media (paper or foam) which absorbs the patient's exhaled heat and moisture and upon inhales the retained heat and humidity is released to the dry inhalation gases.

Indications for Use:

Filter only - For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and/or expired gases is desired. Use up to 24 hours.

HME / Filter - For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and/or expired gases is desired and to maintain moisture levels in the patient's respiratory tract during anesthesia, artificial respiration and other types of assisted ventilation. Use up to 24 hours.

Environment of use – clinical setting including hospital, sub-acute, pre-hospital and home or patient with Tidal

Volumes > 300 ml.

Technological Characteristic Comparison Table:

The following table presents a comparison of the subject device to the predicate.

Attribute	Predicate Zhejiang Haisheng Medical Device Co. Ltd	Proposed Altera Filter and HME / Filter	Comparison
510k number	K151498	K192713	N/A
Classification	CAH – Breathing Circuit bacterial filter and HME 21 CFR 868.5260	CAH – Breathing Circuit bacterial filter and HME 21 CFR 868.5260	Same
Indications for Use	For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and/or expired gases is desired and to add, maintain, retain moisture for the exhaled breath of the patient. Use up to 24 hours.	Filter only - For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and/or expired gases is desired. Use up to 24 hours. HME / Filter - For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and/or expired gases is desired and to maintain moisture levels in the patient's respiratory tract during anesthesia, artificial respiration and other types of assisted ventilation. Use up to 24 hours. Environment of use – clinical setting including hospital, sub-acute, pre-hospital and home For patient with Tidal Volumes > 300 ml.	Similar
Principle of Operation	Filtration is via the principle of electrostatic charges in the media Passive humidification is the use of a "treated" media which absorbs the patient's exhaled heat and moisture and upon inhales the retained heat and humidity is released to the dry inhalation gases.	Filtration is via the principle of electrostatic charges in the media Passive humidification is the use of a "treated" media which absorbs the patient's exhaled heat and moisture and upon inhales the retained heat and humidity is released to the dry inhalation gases.	Same
Patient Population	Adults Tidal Volume >150 ml Pediatrics	Adults Tidal Volume >300 ml	Similar
Environments of use	Hospitals, sub-acute, pre-hospital and home	Hospitals, sub-acute, pre-hospital and home	Similar

Attribute	Predicate Zhejiang Haisheng Medical Device Co. Ltd	Proposed Altera Filter and HME / Filter	Comparison
Compatibility with environment and other devices	Intended for use with ventilators, anesthesia gas machines	Intended for use with ventilators, anesthesia gas machines	Same
Prescriptive	Yes	Yes	Similar
Packaged	Sterile	Non-sterile	Similar
Single patient use, disposable	Yes, up to 24 hours	Yes, up to 24 hours	Similar
Basic components	Filter media HME has HME media Sampling port for expired gas sampling	Filter media HME has HME media Sampling port for expired gas sampling	Similar
Characteristics			
Biocompatibility	Not known	Externally communicating, Tissue, Limited Cytotoxicity Sensitization Irritation Leachable and Extractables with TRA Acute Systemic Toxicity Volatile Organic Compound Testing Particulate Matter Testing	Similar
Performance testing	ISO 9360-1 Flow resistance – <3 cmH_2O @ 60 Lpm Humidification – 32 mg/l @ TV 1000 ml	ISO 9360-1 Flow resistance – <1.7 cmH_2O @ 60 Lpm Humidification – 39 mg/l @ TV 1000 ml Leakage - 0 ml/min	Similar
Dead space	< 65 ml	45 ml – Filter 55 ml – HME/Filter	Similar
Filtration efficiency	BFE - 99.999% VFE – 99.99%	BFE - 99.998% VFE – 99.96%	Similar
Connectors	Standard ISO 80369 small bore luer fittings Conical 15/22 mm	Standard ISO 80369 small bore luer fittings Conical 15/22 mm	Similar
Shelf-life	3 years	3 years	Similar

Summary of Nonclinical Testing

The following table lists the non-clinical testing and the results.

Test Method	Purpose	Acceptance Criteria	Results
ISO 9360-1	Resistance to Flow (cmH_2O)	Equivalent to a predicate	<1.7 cmH_2O @ 60 lpm
	Dead Space (Internal Compressible Volume ml)	Equivalent to a predicate	45 ml for filter only 55 ml for HME
	Leakage	No leak @ 1 psi for 2 min	0.002 ml leak
	Housing Burst Pressure	No pass/fail criteria reported value	>76 kPa
ISO 80369-7 Luer ISO 5356-1 Conical	Connectors	Passes Requirements	Meets the Standards
ASTM F2101	Bacterial Filtration Efficiency (BFE) %	Equivalent to predicate	>99.998%
ASTM F2101	Viral Filtration Efficiency (VFE) %	Equivalent to predicate	>99.96%
ISO 9360-1	HME Performance	Moisture Output equivalent to predicate	Moisture Output Vt = 1000 ml @ 24 hours 39 mg/L
ISO 10993 and ISO 18562	Cytotoxicity Sensitization Irritation Chemical Characterization TRA Acute Systemic Toxicity Volatile Organic Compound Particulate Matter	Non-cytotoxic Non-sensitizer Non-irritant Margin of Safety > 1 Non-systemic Identified VOC <12 micrograms/ m^3PM	Non-cytotoxic Non-sensitizer Non-irritant Margin of Safety > 1 Non-systemic Identified VOC <12 micrograms/ m^3
ASTM 1980-16	Accelerated Aging	Device meets it performance specification post-conditioning	Device met performance specifications

Conclusion:
The conclusions drawn from the nonclinical tests that demonstrate that the Altera Filter and HME / Filter device is as safe, as effective, and performs as well as or better than the legally marketed device.