September 16, 2023

Passy-Muir, Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K230483
Trade/Device Name: Passy Muir Tracheostomy Viral & Bacterial Airway Protection Filter (PM-APF15)
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing circuit bacterial filter
Regulatory Class: Class II
Product Code: CAH
Dated: September 14, 2023
Received: September 14, 2023

Dear Prithul Bom:

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,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
Division of Infection Control and Plastic and Reconstructive Surgery Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230483

Device Name
Passy Muir Tracheostomy Viral & Bacterial Airway Protection Filter (PM-APF15)

Indications for Use *(Describe)*

For non-mechanically ventilated tracheostomy patients who are awake and alert or monitored by a trained healthcare provider or caregiver, where filtration of inspired and/or expired gases is desired. Use up to 24 hours.

Environment of use – clinical settings including hospital, sub-acute, pre-hospital, and home. For adults with Tidal Volumes >300 ml and pediatrics with Tidal Volumes >80 ml. Do not use on neonate or infant patients.

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

K230483

DATE PREPARED: September 16, 2023

APPLICANT: Passy-Muir, Inc.
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Irvine, CA 92612

MANUFACTURER: Passy-Muir, Inc.
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Irvine, CA 92612

CONTACT PERSON: Donna Malter (RA/QA Manager)
Email: dmalter@passymuir.com
Tel: (949) 833-8255

PROPRIETARY NAME: Passy Muir Tracheostomy Viral & Bacterial Airway Protection Filter (PM-APF15)

COMMON NAME: Filter, bacterial, breathing-circuit

REGULATION NUMBER: 21 CFR 868.5260

PRODUCT CODE: CAH

DEVICE CLASS: Class II

REVIEW PANEL: General Hospital
Premarket Review: Surgical and Infection Control Devices (OHT4)
Infection Control and Plastic Surgery Devices (DHT4B)

PREDICATE DEVICE: Altera Filter - K192713 (Filter Only) by Meditera Tibbi Malzeme, San. ve Tic. A.S.

DEVICE DESCRIPTION: The Passy Muir Tracheostomy Viral & Bacterial Airway Protection Filter (PM-APF15) is a non-sterile, lightweight, single-patient use device for non-mechanically ventilated tracheostomy patients to filter viral, bacterial, and other particulate matter. The filter is intended to fit onto the 15mm hub of a tracheostomy tube. The filter is easy to apply and remove with a gentle twist motion.

PRINCIPLE OF OPERATION: Filtration is via the principle of electrostatic charges that attract and capture microbes in the media.

INTENDED USE: To filter a patient's inspiratory and expiratory respiratory gasses to remove bacteria and viruses.

INDICATIONS FOR USE:

For non-mechanically ventilated tracheostomy patients who are awake and alert or monitored by a trained healthcare provider or caregiver, where filtration of inspired and/or expired gases is desired. Use up to 24 hours.

Environment of use – clinical settings including hospital, sub-acute, pre-hospital, and home. For adults with Tidal Volumes >300 ml and pediatrics with Tidal Volumes >80 ml. Do not use on neonate or infant patients.

Technological Characteristics Comparison

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Description	Subject Device	Predicate Device (K192713)	Comparison
Device	Passy Muir Tracheostomy Viral & Bacterial Airway Protection Filter (PM-APF15)	Altera Filter - K192713 (Filter Only) by Meditera Tibbi Malzeme, San. Ve Tic. A.S.	N/A
Model	Passy Muir Tracheostomy Viral & Bacterial Airway Protection Filter (PM-APF15)	Not available	N/A
Classification	Class II Device, CAH - Filter, Bacterial, Breathing-Circuit (21 CFR 868.5260)	Class II Device, CAH - Filter, Bacterial, Breathing-Circuit (21 CFR 868.5260)	Same
Intended Use	To filter a patient's inspiratory and expiratory respiratory gasses to remove bacteria and viruses.	To filter a patient's inspiratory and expiratory respiratory gasses to remove bacteria and viruses.	Same

Indications for Use	For non-mechanically ventilated tracheostomy patients who are awake and alert or monitored by a trained healthcare provider or caregiver, where filtration of inspired and/or expired gases is desired. Use up to 24 hours. Environment of use – clinical settings including hospital, sub-acute, pre-hospital, and home. For adults with Tidal Volumes >300 ml and pediatrics with Tidal Volumes >80 ml. Do not use on neonate or infant patients.	[Filter Device] 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 Device] N/A Environment of use – clinical settings including hospital, sub-acute, pre-hospital and home or patients with Tidal Volumes >300 ml	Similar -Second device in K192713 is an HME and not relevant to this submission
Principle of Operation	Filtration is via the principle of electrostatic charges that attract and capture microbes in the media.	Filtration is via the principle of electrostatic charges that attract and capture microbes in the media.	Same
Patient Population	Adults Tidal Volume >300 ml Pediatrics Tidal Volume >80 ml. Do not use on neonate or infant patients.	Adults Tidal Volume >300ml	Similar
Anatomical Site	Breathing gas pathway	Breathing gas pathway	Same

Description	Subject Device	Predicate Device (K192713)	Comparison
Environments of Use	Hospitals, sub-acute, pre-hospital, and home	Hospitals, sub-acute, pre-hospital, and home	Same
Compatibility with environment and other devices	Intended for use with open tracheostomy tube with a 15mm conical connector	Intended for use with ventilators, anesthesia gas machines and open flow systems that utilize a 15mm or 22mm conical connector	Similar
Prescriptive	Yes	Yes	Same
Packaging	Non-sterile	Non-sterile	Same
Single patient use, disposable	Yes, up to 24 hours	Yes, up to 24 hours	Same
Filter Media	Media –polypropylene media	Media –polypropylene media	Similiar
Housing Material	Medical grade ABS	Unknown	N/A
Biocompatibility	Externally Communicating, Tissue, Limited Cytotoxicity Sensitization Irritation Leachable and Extractables with TRA Acute Systemic Toxicity Volatile Organic Compound Testing Particulate Matter Testing	Externally Communicating, Tissue, Limited Cytotoxicity Sensitization Irritation Leachable and Extractables with TRA Acute Systemic Toxicity Volatile Organic Compound Testing Particulate Matter Testing	Same
Performance Testing	Flow Resistance <1.7 cmH_2O @ 60 LPM Leakage - 0 ml/min	Flow Resistance <1.7 cmH_2O @ 60 LPM Leakage - 0 ml/min	Similar
Dead space	6 ml	45 ml	Different
Particulate Filtration Efficiency ASTM F2299 @ 0.1 µm (PFE)	>99.0%	Not available	N/A
Bacterial Filtration Efficiency (BFE)*	>99.9%	99.998%	Similar
Viral Filtration Efficiency (VFE)*	>99.9%	99.96%	Similar
Connector	15mm conical connector ISO 5356-1	15mm and 22mm conical connectors ISO 5356-1	15mm conical connector same 22mm N/A
Shelf Life	Unknown	3 years	N/A

*ASTM F2100. Bacterial and Viral Filtration Efficiency test method adapted from ASTM F2101.

NON-CLINICAL TESTING OF SUBJECT DEVICE:

Test Method	Test Performed	Acceptance Criteria	Results
FDA Recognized Consensus Standard No. 1-62, ISO 5356-1 Third Edition 2004-05-15	Conical Connector Compliance	Meet the Standard	Met the Standard
Pre-determined Acceptance Criteria	Leak Testing	No leak at 1 psi for 2 minutes	Leakage – 0 ml/min
Pre-determined Acceptance Criteria	Dead Space	Better than predicate (45 ml)	6 ml
FDA Recognized Consensus Standard No. 2-245, ISO 10993-5 Third edition 2018-08	Cytotoxicity	Non-cytotoxic	Non-cytotoxic
FDA Recognized Consensus Standard No. 2-296, ISO 10993-10 Fourth Edition 2021-11	Skin Sensitization	Not a contact skin sensitizer	Not a contact skin sensitizer
FDA Recognized Consensus Standard No. 2-291, ISO 10993-23 First Edition 2021-11	Irritation	Non-Irritant	Non-Irritant
FDA Recognized Consensus Standard No. 1-135, ISO 18562-2 First Edition 2017-03	Particulate Matter Testing	<12 micrograms / m^3PM	<12 micrograms / m^3PM
FDA Recognized Consensus Standard No. 1-136, ISO 18562-3 First Edition 2017-03	Volatile Organic Compounds (VOC) Testing	Identify and confirm VOCs within safe levels	Identified and confirmed VOCs within safe levels
FDA Recognized Consensus Standard No. 1-137, ISO 18562-4 First Edition 2017-03	Leachables in Condensate Testing	Meet Standard	Met Standard
ASTM F2299/F2299M	Particle Filtration Efficiency	Particle efficiency ≥ 99% 0.1 µm (PFE) for 0.1 micron particle	99.0% 0.1 µm (PFE) for 0.1 micron particle
ASTM F2299/F2299M	Flow Resistance	<1.7 cmH_2O @ 60 LPM Leakage – 0 ml/min	<1.7 cmH_2O @ 60 LPM Leakage – 0 ml/min

Test Method	Test Performed	Acceptance Criteria	Results
ASTM F2101	Viral Filtration Efficiency (VFE) %	Viral filtration efficiency is equivalent to predicate	>99.9%
ASTM F2101	Bacterial Filtration Efficiency (BFE) %	Bacterial filtration efficiency is equivalent to predicate	>99.9%
FDA Recognized Consensus Standard No. 14-497, ASTM 1980-16	Accelerated Aging	Device meets its performance specifications post-conditioning	Device met its performance specifications post-conditioning

CONCLUSION:

The conclusions drawn from the non-clinical performance testing demonstrate that the Passy Muir Tracheostomy Viral & Bacterial Airway Protection Filter (PM-APF15) is as safe, as effective, and perform as well as or better than the legally marketed predicate device.