November 14, 2024

Besmed Health Business Corp.
Steven Wong
Manager, Regulatory Affairs
No. 5, Lane 116
Wu-Kong 2nd Rd
Wu-Ku District
New Taipei City,
Taiwan 24888

Re: K241339
Trade/Device Name: Besmed Bacterial Filter and HMEF
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: Class II
Product Code: CAH
Dated: April 23, 2024
Received: October 15, 2024

Dear Steven Wong:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Katharine Segars -S

Katharine Segars, Ph.D.
Assistant Director
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241339

Device Name
Besmed Bacterial Filter and HMEF

Indications for Use *(Describe)*

Besmed HMEF

Besmed HME Filter (Heat and Moisture Exchange) is intended to decrease the transmission of bacteria and viruses to/from a patient, and to maintain moisture levels in the patient's respiratory tract while administering anesthesia gas, providing artificial respiration, or assisting with ventilation.

The Besmed HME Filter is typically placed at the patient's end of the breathing system, specifically between the circuits Y-piece and either the catheter mount or patient airway device. It is essential to note that the Besmed HME Filter is intended for single-use only and should be used on a single patient for up to 24 hours.

Besmed HME Filter is intended to be used within critical care and hospital/ institutional environments by qualified personnel.

Besmed Bacterial Filter

The purpose of the Besmed Bacterial Filter is to diminish the passage of bacteria and viruses to patients receiving anesthesia gas. Besmed Bacterial Filter is designed for utilization in conjunction with ventilators, anesthesia machines, and open flow systems where there is a need for filtration of inhaled gases.

The Besmed Bacterial Filter is a disposable device intended for the exclusive use of a single patient within a 24-hour timeframe. Bacterial Filter is designed for utilization in hospital environments by medical professionals who possess adequate training in the operation of mechanical ventilators, respiratory systems, and humidification systems.

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.

BESMED HEALTH BUSINESS CORP.
No. 5, Lane 116, Wu-Kong 2nd Rd, Wu-Ku District,
New Taipei City, Taiwan. 24888
☎ : +886-2-2290-3959 🖷 : +886-2-2299-9076
✉ : info@besmed.com 🌐 : www.besmed.com

510(k) Summary - K241339

Date Prepared:	14-November-2024
Company Name and Address:	Besmed Health Business Corp. No. 5, Lane 116, Wu-Kong 2nd Road, Wu-Ku District, New Taipei City, Taiwan 24888 Tel: +886-2-2290-3959 Fax: +886-2-2299-9076 www.besmed.com
Prepared and Submitted by:	Steven Wong Manager, Regulatory Affairs & Quality Affairs Tel: +886-2-2290-3959 ext 211 Email: research6@besmed.com
Official Contact:	Sarah Lu (Ms.) Vice President Tel: +886-2-2290-3959 Email: sarah.lu@besmed.com
Proprietary or Trade Name:	Besmed Bacterial Filter and HMEF
Common Name:	Filter, Bacterial, Breathing-Circuit
Classification Regulation Name:	21 CFR § 868.5260, Breathing circuit bacterial filter
FDA Product Code:	CAH
Regulatory Class:	Class II
Type of Submission:	Traditional
Predicate Device	
Trade Name:	ThermoShield HME Filter
510(k) Number:	K163300
Manufacturer Name:	Flexicare Medical Limited
Reference Device	
Trade Name:	HepaShield Bacterial Viral Breathing System Filter
510(k) Number:	K191909
Manufacturer Name:	Flexicare Medical Limited

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✉ : info@besmed.com 🌐 : www.besmed.com

1.1 Indications for Use

Besmed HMEF

Besmed HME Filter (Heat and Moisture Exchange) is intended to decrease the transmission of bacteria and viruses to/from a patient, and to maintain moisture levels in the patient's respiratory tract while administering anesthesia gas, providing artificial respiration, or assisting with ventilation.

The Besmed HME Filter is typically placed at the patient's end of the breathing system, specifically between the circuits Y-piece and either the catheter mount or patient airway device. It is essential to note that the Besmed HME Filter is intended for single-use only and should be used on a single patient for up to 24 hours.

Besmed HME Filter is intended to be used within critical care and hospital/institutional environments by qualified personnel.

Besmed Bacterial Filter

The purpose of the Besmed Bacterial Filter is to diminish the passage of bacteria and viruses to patients receiving anesthesia gas. Besmed Bacterial Filter is designed for utilization in conjunction with ventilators, anesthesia machines, and open flow systems where there is a need for filtration of inhaled gases.

The Besmed Bacterial Filter is a disposable device intended for the exclusive use of a single patient within a 24-hour timeframe. Bacterial Filter is designed for utilization in hospital environments by medical professionals who possess adequate training in the operation of mechanical ventilators, respiratory systems, and humidification systems.

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1.2 Device Description

Besmed HMEF

- The Besmed HME Filter absorbs the heat and moisture exhaled by the patients. Upon inhalation, it releases the previously retained heat and humidity to the dry inhalation gases. The HME filter is designed with electrostatic cotton for filtration, as well as a heat-preserved and moisture-absorbed paper roll for maintaining the warmth and humidity of the airway in a respiratory system. Additionally, it eliminates bacterial and viral contaminants from the breathing circuit gas. To ensure passive humidification treatment, it is recommended to install the Heat and Moisture Exchanger Filter (HMEF) on the patient's end. Besmed HME Filter is intended for adult and child patients with the tidal volume between 150ml-1000ml.

Besmed Bacterial Filter

- Besmed Bacterial Filter is for single-use purpose. The intended use is achieved through the implementation of an electrostatic filtration mechanism. Transparent and compact housing material makes it easy to check the surface of the filter media for a foreign substance.

1.3 Comparison of Technological Characteristic with the Predicate Device

The subject and predicate devices have the same technical characteristics in terms of the intended use, principle of operation, design specification, consisting of the filter media and housing. Additionally, both the subject and predicate devices utilize an electrostatic filtration mechanism, which employs electric charges to enhance particle capture.

The tables below show the similarities and differences between the subject and predicate/reference device.

Table 1. A Comparison between the Subject and Predicate Device

Device feature	Subject Device (K241339)		Predicate Device (K163300)	Comparison
Manufacturer	Besmed Health Business Corp.		Flexicare Medical Limited	N/A
Proprietary Name	Besmed HMEF with Luer Lock Port Besmed HMEF		ThermoShield HME Filter	N/A
Device models	Sterile models	Non-sterile models	Not stated in the 510(k) summary	N/A
	FL-70311 FL-70312 FL-70313	FL-70301 FL-70302 FL-70303		
Intended Patient Population	Child and Adult		Adult and Mini (Pediatric)	Similar
Color	Transparent and Green		Clear/ colorless, Blue	Different
Emergency use	Yes		Yes	Same
Primary components	Luer port cap		Tethered luer port cap	Similar
	Filter housing top		Filter housing top	
	Filter paper		Filter pad	
	HME paper medium		HME paper	
	Filter housing bottom		HME paper medium	
	Outer stickers		Outer shrink sleeve	
Assembly Method	Ultrasonic welded housing		Snap Fit casing	Different
Port diameter	22M/15F		22M/15F	Same
Configurations	Straight with luer port	Straight without luer port	Straight with luer port	Same
Filtration Method	Electrostatic		Electrostatic	Same
Placement within circuit	Patient side		Patient side	Same

Weight (g)	Straight with luer port 34.50g	Straight with luer port 38g	Different
Indications for Use	▪ Besmed HME Filter (Heat and Moisture Exchange) is intended to decrease the transmission of bacteria and viruses to/from a patient, and to maintain moisture levels in the patient's respiratory tract while administering anesthesia gas, providing artificial respiration, or assisting with ventilation. ▪ The Besmed HME Filter is typically placed at the patient's end of the breathing system, specifically between the circuits Y-piece and either the catheter mount or patient airway device. It is essential to note that the Besmed HME Filter is intended for single-use only and should be used on a single patient for up to 24 hours. ▪ Besmed HME Filter is intended to be used within critical care and hospital/ institutional environments by qualified personnel.	Flexicare's ThermoShield HME (Heat and Moisture Exchange) Filters are intended to reduce the transmission of bacteria and viruses. to/from a patient, and to maintain moisture levels in the patient's respiratory tract during anesthesia, artificial respiration and other types of assisted ventilation. An HMEF is normally positioned at the patient end of the breathing system between the circuit Y- piece and the catheter mount or patient airway device. Flexicare's ThermoShield HME Filters are single use devices for use on a single patient for up to 24hrs and are available in Adult and Mini (pediatric) sizes. Flexicare's ThermoShield HME Filters are designed to be used in pre-hospital, hospital and homecare environments by trained personnel. Expert clinical judgment must be used in assessing patient humidification requirements	Similar. Both devices are intended to minimize the transfer of bacteria and viruses to/from a patient. It also aids in maintaining moisture levels in the patient's respiratory tract while administering anesthesia gas, providing artificial respiration, or assisting with ventilation. Both devices are single use devices for use on a single patient for up to 24hrs, there is a difference in the intended use environment in which both devices are operated. It will not alter the device's intended purpose.
Environment of Use	Critical care and Hospital/ Institutional Environment	Pre-hospital, Hospital & Homecare Environment	Similar
Device Type	Disposable	Disposable	Same

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✉ : info@besmed.com 🌐 : www.besmed.com

Patient Usage Type		Single patient use		Single patient use		Same
Duration of contact		Limited (≤ 24 h)		Limited (≤ 24 h)		Same
Mode of application		Non-invasive		Non-invasive		Same
Supplied sterile		Sterile and Non-Sterile Variants		Non-Sterile		Differences in the device sterility have no impact on the indication for use and HMEF's principle of operation.
Technical	**Material**	Luer port cap:	PP	Tethered luer port cap:	PVC	Different
		Filter housing top:	ABS	Filter housing top:	PP	
		Filter paper:	Filter paper	Filter pad:	PP	
		HME paper medium:	Filter paper impregnated CaCl2	HME paper:	Paper	
		Filter housing bottom:	ABS	Filter housing bottom:	PP	
				Outer shrink sleeve:	LDPE	
	Latex/ DEHP content	No		No		Same
	Internal Volume/dead space as per ISO 9360-1	**19 ml deadspace model** FL-70311/FL-70301	Available for children and adult population	47ml		Different
		45 ml deadspace model FL-70312/ FL-70302				
		60 ml deadspace model FL-70313/ FL-70303	Available for adult population			

	HME moisture output (mg/L)	**19ml deadspace model rep** FL-70311 35.23 mg/L at TV 250ml 32.79 mg/L at TV 500ml 32.49 mg/L at TV 1000ml **45ml deadspace model rep** FL-70312 35.23 mg/L at TV 250ml 32.79 mg/L at TV 500ml 32.49 mg/L at TV 1000ml **60 ml deadspace model rep** FL-70313 35.23 mg/L at TV 250ml 32.79 mg/L at TV 500ml 32.49 mg/L at TV 1000ml	30.4 mg/L at TV 500ml	Different. The subject device's moisture output performance is above the clinical acceptance criteria of 30 mg/L, as well as that of the predicate device, under varying conditions of tidal volume, respiratory rate, and flow rate.
	HME moisture loss (mg/L)	**19ml deadspace model rep** FL-70311 6.81 mg/L at TV 250ml 11.71 mg/L at TV 500ml 11.06 mg/L at TV 1000ml **45ml deadspace model rep** FL-70312 6.81 mg/L at TV 250ml 11.71 mg/L at TV 500ml 11.06 mg/L at TV 1000ml **60 ml deadspace model rep** FL-70313 6.81 mg/L at TV 250ml 11.71 mg/L at TV 500ml 11.06 mg/L at TV 1000ml	6.8 mg/L at TV 500ml	Different. The subject device's moisture loss results are generally higher than those of the predicate device under varying conditions of tidal volume, respiratory rate, and flow rate.
	Tidal Volume Range (ml)	150 - 1000ml	138~800ml	Different. Tidal volume for both devices varies.
	Pressure Drop/ Flow resistance	**19ml deadspace model rep** FL-70313 At 0 hour 0.15 hPa @30L/min 0.27 hPa @60L/min 1.34 hPa @90L/min At 24 hour 0.17 hPa @30L/min 0.32 hPa @60L/min 1.41 hPa @90L/min **45ml deadspace model rep** FL-70312 At 0 hour 0.58 hPa @30L/min 1.58 hPa @60L/min	1.71 hPa @30L/min 4.31 hPa @60L/min 7.82 hPa @90L/min	Different. The pressure drop results of the subject device, are lower than those of the predicate device under varying flow rates.

		3.25 hPa @90L/min At 24 hour 0.58 hPa @30L/min 1.60 hPa @60L/min 3.45 hPa @90L/min **60 ml deadspace model rep** FL-70312 At 0 hour 0.58 hPa @30L/min 1.60 hPa @60L/min 4.03 hPa @90L/min At 24 hour 0.57 hPa @30L/min 1.63 hPa @60L/min 3.94 hPa @90L/min		
	Gas leakage per ISO 9360-1, 6.4	FL-70313 2.29 ml/min @7kpa 2.65 ml/min @15kpa	1.53 ml/min @7kpa 1.67 ml/min @15kpa	Different. The pressure gas leakage results of the subject device at 7kPa and 15kPa are below than 4 ml/min as per the requirements.
	Leakage by pressure decay per ISO 80369-7:2021, 6.1.2	FL-70313 0.00048 Pa·m³/s	0.00054 Pa·m³/s	Different. The subject device's leakage rate did not exceed 0.005 Pa·m³/s, as per ISO 80369-7 requirements.
	Sub-atmospheric pressure air leakage per ISO 80369-7:2021, 6.2	FL-70313 0.00053 Pa·m³/s No leak at 101 kPa	0.00048 Pa·m³/s No leak at 101 kPa	Different. The sub-atmospheric pressure leakage rate for the subject device did not exceed leak of 0.005 Pa·m³/s in luer connector.
	Compliance per ISO 9360-1 6.5	0.83 ml/kPa	14.02 ml/kPa	Different than the predicate.
	Standard 22/15mm connections in compliance with ISO 5356-1	Yes	Yes	Same
	Luer port for gas sampling in compliance with ISO 80369-7	Yes	Yes	Same
	Bacterial filtration efficiency-ASTM F2101	FL-70313 BFE – 99.99 % VFE – 99.99 %	BFE – 99.99 % VFE – 99.99 %	Same
	Salt test method -	Available for childre n	FL-70312 At 0 hour 99.99% @15 LPM	

	filtration performance ISO 23328-1	and adult population	99.98% @30 LPM At 24 hour 99.99% @15 LPM 99.99% @30 LPM	98.90%	Different. The filtration efficiency for the subject device is higher than the predicate device.
		Available for adult population	FL-70313 At 0 hour 99.98% @30 LPM At 24 hour 99.98% @30 LPM		
	Operation temperature	25±5 °C, Room Temperature		25±5 °C, Room Temperature	Same
	Storage condition	-20~60 °C, 30-70% RH		-20 to 60 °C, 15-95% RH	Similar. The storage humidity for the subject device is within the range of the predicate device.
	Packaging	RST 80/XPA film		Non-Sterile Primary – Polybag – (LDPE) Sterile Primary – Top Web – EO Permeable Paper Blister Pack –(PVC)	Different
	Sterilization method	Ethylene oxide sterilization		N/A	Different
	Shelf life	5 years		4 years	Different. The stability of the subject device was verified by conducting a 5-year real time aging test and 5-year accelerated aging test.
	Biocompatibility test in compliance with ISO 10993-1	Cytotoxicity, Skin Irritation, Sensitization, Acute Systemic toxicity - All test Pass		Cytotoxicity, Implant, Sensitization, Genotoxicity- All test pass	Biocompatibility testing for both devices was conducted in accordance with use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

Table 2. A Comparison between the Subject and Reference Device

Device feature	Subject Device (K241339)		Reference Device (K191909)	Comparison
Manufacturer	Besmed Health Business Corp.		Flexicare Medical Limited	N/A
Proprietary Name	Besmed Bacterial Filter with Luer Lock Port Besmed Bacterial Filter		HepaShield Bacterial Viral Breathing System Filter	N/A
Device models	Sterile models	Non-sterile models	Not stated in the 510(k) summary	N/A
	FL-70210 FL-70220 FL-70226	FL-70211 FL-70221 FL-70223		
Intended Patient Population	Child and Adult		Adult	Different
	Transparent and Green			Different
Emergency use	Yes		Yes	Same
Port diameter	22M/15F		22M/15F	Same
Assembly Method	Ultrasonic welded housing		Ultrasonic welded housing	Same
Type of use	Prescription Use		Prescription Use	Same
Primary components	Luer port cap		Tethered luer port cap	Same
	Filter housing top		Filter housing top	
	Filter		Filter Media pack	
	Filter housing bottom		Filter housing bottom	
Configurations	Straight with luer port	Straight without luer port	Straight with luer port	Same
Filtration Method	Electrostatic		Mechanical	Different. In both devices filtration mechanism are used to trap particles, including bacteria and virus, as air or liquid passes through a filter medium.
Patient connection	Breathing circuit, manual resuscitator, Air cushion mask, resuscitation		ET tube, Laryngeal Mask Airway, Catheter mount, Breathing circuit	Different

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☎ : +886-2-2290-3959 🖷 : +886-2-2299-9076
✉ : info@besmed.com 🌐 : www.besmed.com

Placement within Circuit	Patient side	Patient side Machine side	Different. The predicate device includes an additional machine side placement.
Weight (g)	Straight with luer port 23.60g	Straight with luer port 42g	Different
Indications for Use	▪ The purpose of the Besmed Bacterial Filter is to diminish the passage of bacteria and viruses to patients receiving anesthesia gas. Besmed Bacterial Filter is designed for utilization in conjunction with ventilators, anesthesia machines, and open flow systems where there is a need for filtration of inhaled gases. ▪ The Besmed Bacterial Filter is a disposable device intended for the exclusive use of a single patient within a 24-hour timeframe. Bacterial Filter is designed for utilization in hospital environments by medical professionals who possess adequate training in the operation of mechanical ventilators, respiratory systems, and humidification systems.	Flexicare's HepaShield Bacterial Viral Breathing System Filters are intended to reduce the transmission of bacteria and viruses to/from a patient during anesthesia. For use with ventilators, anesthesia machines and open flow systems where filtration of inspired and/or expired gases is desired. Flexicare's HepaShield Bacterial Viral Breathing System Filters are single use devices for use on a single patient for up to 24hrs and are available in Adult size. Flexicare's HepaShield Bacterial Viral Breathing System Filters are designed to be used in hospital environments by trained personnel.	Similar. There is no distinction in the intended purpose, clinical usage, and intended use environment of both devices.

Contraindications		▪ Avoid positioning the Besmed Bacterial filter between a humidification device or nebulizing device and the patient end. ▪ This device is strictly restricted to single patient use, do not attempt to re- sterilize or reuse the device. ▪ Do not try to cleanse or decontaminate this device using any method, such as rinsing, washing, or subjecting it to gas, heat, steam, or boiling water.		▪ DO NOT place the HepaShield Bacterial Viral Breathing System Filter between a humidification device or nebulizing device and the patient. ▪ Single Use. Do not reuse. ▪ DO NOT attempt to decontaminate this product in any way. This includes rinsing, washing or decontamination using gas, heat, steam, or boiling water. ▪ When used in conjunction with a humidified breathing system, the HepaShield Bacterial Viral Breathing System Filter is contraindicated for use at the patient end.		Similar
Environment of Use		Hospital Environments		Hospital		Similar
Device Type		Disposable		Disposable		Same
Patient Usage Type		Single patient use		Single patient use		Same
Duration of contact		Limited (≤ 24 h)		Limited (≤ 24 h)		Same
Mode of application		Non-invasive		Non-invasive		Same
Supplied sterile		Both Non-sterile & sterile variants		Both Non-sterile & sterile variants		Same
Technical	**Materials**	Luer port cap:	PP	Tethered luer port cap:	PVC	Different
		Filter housing top:	ABS	Filter housing top:	ABS	
		Filter :	Filter Paper	Filter Media pack:	Hydro-phobic pleated paper	
		Filter housing bottom	ABS	Filter housing bottom:	ABS	

	Latex/ DEHP content	No		No	Same
	Internal Volume / dead space as per ISO 9360-1	**32ml deadspace model** FL-70210/FL-70211/FL-70226/FL-70223	Available for children and adult population	47ml	Different. The subject device offers lower limit for the recommended tidal volume range use for the identified patient population.
		73ml deadspace model FL-70220/FL-70221	Available for adult population		
	Tidal Volume Range (ml)	150 - 1000ml		141~800ml	Different
	Pressure Drop/ Flow resistance	**32ml deadspace model rep** FL-70210 At 0 hour 0.65 hPa @30L/min 1.57 hPa @60L/min 2.69 hPa @90L/min At 24 hour 0.64 hPa @30L/min 1.57 hPa @60L/min 2.54 hPa @90L/min		1.70 hPa @30L/min 3.92 hPa @60L/min 6.56 hPa @90L/min	Different. The pressure drop results for the subject device, are lower than those of the predicate device under varying flow rates.
		73ml deadspace model rep FL-70220 At 0 hour 0.70 hPa @30L/min 1.62 hPa @60L/min 2.79 hPa @90L/min At 24 hour 0.75 hPa @30L/min 1.74 hPa @60L/min 2.89 hPa @90L/min			
	Gas leakage	1.49 ml/min @7kpa 2.24 ml/min @15kpa		1.61ml/min @7kpa 2.03 ml/min @15kpa	Different

	Leakage by pressure decay per ISO 80369 - 7:2021, 6.1.2	FL-70210 0.00051 Pa·m³/s		0.00059 Pa·m³/s	Different. The subject device's leakage rate did not exceed 0.005 Pa·m³/s as per ISO 80369-7 requirements.
	Sub-atmospheric pressure air leakage per ISO 80369-7:2021, 6.2	FL-70313 0.00051 Pa·m³/s No leak at 101 kPa		0.00051 Pa·m³/s No leak at 101 kPa	Same
	Compliance per ISO 9360-1 6.5	0.63 ml/kPa		0.06 ml/kPa	Different. The subject device's compliance results are higher than the predicate device, but leakage performance are similar to predicate device.
	Standard 22/15mm connections in compliance with ISO 5356-1	Yes		Yes	Same
	Luer port for gas sampling in compliance with ISO 80369-7	Yes		Yes	Same
	Bacterial filtration efficiency ASTM F2101	FL-70210 BFE – 99.999 % VFE – 99.99 %		BFE – 99.99999% VFE – 99.9999%	Same
	Salt test method - filtration performance ISO 23328-1	Available for children and adult population	FL-70210 At 0 hour 99.98% @15 LPM 99.98% @30 LPM At 24 hour 99.98% @15 LPM 99.98% @30 LPM	99.89%	Different. The subject device's filtration efficiency is > 99.9%.
		Available for adult population	FL-70220 At 0 hour 99.97% @30 LPM At 24 hour 99.98% @30 LPM		

	Operation temperature	25±5 °C, Room Temperature	25±5 °C, Room Temperature	Same
	Storage condition	-20~60 °C, 30-70% RH	-20 to 60 °C,15-95% RH	Similar
	Packaging	RST 80/XPA film	Polybag	Different
	Sterilization method	Ethylene oxide sterilization	Non-sterile	Different
	Shelf life	5 years	5 years	Same
	Biocompatibility test in compliance with ISO 10993-1	Cytotoxicity, Skin Irritation, Sensitization, Acute Systemic toxicity - All test Pass	Cytotoxicity, Irritation, Sensitization, Systemic toxicity, Material Mediated Pyrogenicity- All test pass	Testing was conducted in accordance with use of International Standard ISO 10993- 1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".
	Biocompatibility test in compliance with ISO 18562	Compliant	Compliant	Same

1.4 Summary of Nonclinical Testing

Table 3. Summary of non-clinical Testing

Test Standards	Test Performed	Acceptance Criteria	Results
Packaging for Terminally Sterilized Medical Devices			
ISO 11737-2:2020	Sterility test	Negative	Pass
ISO 10993-7:2008	EO/ ECH/ EG residual test	Non-Detected	Pass
ASTM F1929-23	Dye Penetration Test	No Penetration	Pass
ASTM F1140/F1140M-13(2020)e1	Burst test	Package successfully held for creep duration	Pass
	Creep test	It should maintain the specified pressure for 30 seconds	Pass
ASTM F88/F88M-23	Seal strength of flexible barrier materials test	Seal strength shall not greater than ± 2SD compare to pre transit package	Pass
ASTM F1608-21	Microbial Ranking Test	LRV>3.0 (99.9%)	Pass
ISTA 2A:2011	Packaged products test	No visible damage	Pass
Shelf Life Test			
ASTM F1980-21	Accelerated aging test	No visible damage after aging simulation	Device meets its performance specification
Performance Test			
ISO 9360-1:2000	Measurement of moisture loss	<16 mg/l at 250 ml/500 ml/1000 ml tidal volume	The average moisture loss met the acceptance criteria for the specified tidal volumes
	HME moisture output	Greater than 30 mg/L	Pass
	Measurement of pressure drop	Pressure drop at 30L/min, 60L/min and 90L/min should not be greater than 5hPa.	Pass
	HMEF gas leakage	Leakage less than 4ml/min @ 7kpa, and 15kpa	Pass
	Compliance	Methodology only, no acceptance criteria	Meets requirements
ISO 23328-1:2008	Salt test method to assess filtration performance	Bacterial filter and HMEF efficiency shall be > 99.9% @15 LPM and 30 LPM under 0 hour and 24 hour conditioning	Pass

ISO 80369-7:2021	Leakage by pressure decay	Leakage rate should not exceed 0.005 Pa·m³/s @ 330 kPa for 20 s	Pass
	Sub-atmospheric pressure air leakage	Leakage rate should not exceed 0.005 Pa·m³/s @ 101kPa for 20 s	Pass
	Stress cracking	No signs of seal break and leakage @101 kPa after being stress	Pass
	Resistance to separation from axial load	No disconnections observed at an axial force of 35 N	Pass
	Resistance to separation from unscrewing	No disconnections observed at unscrewing torque of 0.020Nm	Pass
	Resistance to overriding	No override the threads observed at torque of 0.17 Nm	Pass
ISO 5356-1:2015	Security of engagement	No disconnections observed at axial separation force of (50 ± 5) N for 10 s	Pass
	Leakage from 22 mm latching sockets	No signs of leakage at (8 ± 0.5) kPa	Pass
	Drop procedure for 22 mm latching sockets	No signs of damage during the test	Pass
ASTM F2101-19	Bacterial / Virus Filtration Efficiency test	Evaluate BFE/VFE filter efficiency shall be greater than 90%	Pass
Biocompatibility Test			
ISO 10993-5:2009	In Vitro Cytotoxicity test	Not more than 50 % of the cells are round	Pass
ISO 10993-10:2021	Skin sensitization tests (Maximization Test)	Did not produce skin sensitization on Guinea pig	Pass
ISO 10993-23:2021	Tests for irritation	Did not cause intracutaneous irritation	Pass
ISO 10993-11:2017	Acute systemic toxicity study	Did not cause systemic toxicity reaction or death	Pass
USP 151	Pyrogenicity Test	Did not induce pyrogenic response	Pass
ISO 18562-2:2024	Emissions of particulate matter	Measured concentrations of particulate matter PM2.5 ≤ 35μg/m³ PM10 ≤ 150μg/m³	Pass
ISO 18562-3:2024	Emissions of VOCs	The MOS (Margin Of Safety) value shall be higher than 1 for identified substances.	Pass

1.5 Summary of Clinical Testing

Clinical test study was neither included nor required for this submission.

2. Conclusion

Based on the intended use, technological characteristics and the non-clinical performance tests, the subject device is as safe, as effective, and performs at least as safely and effectively as the predicate device.