March 27, 2022

Great Group Medical Co., Ltd.
Kiki Hung
Regulatory Affairs
No. 168, Xingong 2nd Rd., Tianzhong Township
Changhua County, 520
Taiwan

Re: K210352
Trade/Device Name: GGM Breathing Circuit Bacterial Filter
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: Class II
Product Code: CAH
Dated: March 18, 2022
Received: March 23, 2022

Dear Kiki Hung:

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,

Clarence W. Murray, III, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210352

Device Name
GGM Breathing Circuit Bacterial Filter

Indications for Use *(Describe)*
GGM Breathing Circuit Bacterial Filter contains two types of bacterial filters, namely "Bacterial Filter" with only filtering function and "HME Filter" with heat and moisture exchanger function.

Intended patient population: VF-2160, VF-2160-1 and VH-3110 are intended for adult patients with the tidal volume between 250ml-1500ml; VH-3210 is intended for adult patients with the tidal volume between 250ml-1000ml.

Bacterial Filter (VF-2160, VF-2160-1) –
The Bacterial Filter is intended to reduce the transmission of bacteria and viruses to a patient during anesthesia. For use with ventilators, anesthesia machines and open flow systems where filtration of inspired gases is desired.
The Bacterial Filter is single use device for use on a single patient for up to 24hrs. The Bacterial Filter is designed to be used in hospital environments by trained personnel.

HME Filter (VH-3110, VH-3210) –
HME (Heat and Moisture Exchange) Filter is 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.
HME Filter is normally positioned at the patient end of the breathing system between the circuits Y-piece and the catheter mount or patient airway device. HME Filter is a single use device for use on a single patient for up to 24hrs.
HME Filter is designed to be used in hospital environments by trained personnel.

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

K210352

5.1 Type of Submission: Traditional

5.2 Date of Summary: 03/18/2022

5.3 Submitter:

Address:	Great Group Medical Co., Ltd. No. 168, Xingong 2nd Rd., Tianzhong Township, Changhua County 520, Taiwan (R.O.C.)
Phone:	+886-4-875-8181
Fax:	+886-4-875-6161
Contact:	Kiki Hung (liting@greatgroup.com.tw)

5.4 Identification of the Device:

Proprietary/Trade name:	GGM Breathing Circuit Bacterial Filter
Classification Product Code:	CAH
Regulation Number:	868.5260
Regulation Description:	Breathing circuit bacterial filter
Review Panel:	General Hospital
Device Class:	II

5.5 Identification of the Predicate Device I:

Predicate Device Name:	HepaShield Bacterial Viral Breathing System Filter
Manufacturer:	Flexicare Medical Limited
Classification Product Code:	CAH
Regulation number:	868.5260
Device Class:	II
510(k) Number:	K191909

5.6 Identification of the Predicate Device II:

Predicate Device Name:	ThermoShield HME Filter
Manufacturer:	Flexicare Medical Limited
Classification Product Code:	CAH
Regulation number:	868.5260
Device Class:	II
510(k) Number:	K163300

5.7 Indications for Use of the Device

GGM Breathing Circuit Bacterial Filter contains two types of bacterial filters, namely "Bacterial Filter" with only filtering function and "HME Filter" with heat and moisture exchanger function.

Intended patient population: VF-2160, VF-2160-1 and VH-3110 are intended for adult patients with the tidal volume between 250ml-1500ml; VH-3210 is intended for adult patients with the tidal volume between 250ml-1000ml.

Bacterial Filter (VF-2160, VF-2160-1) –

The Bacterial Filter is intended to reduce the transmission of bacteria and viruses to a patient during anesthesia. For use with ventilators, anesthesia machines and open flow systems where filtration of inspired gases is desired.

The Bacterial Filter is single use device for use on a single patient for up to 24hrs. The Bacterial Filter is designed to be used in hospital environments by trained personnel.

HME Filter (VH-3110, VH-3210) –

HME (Heat and Moisture Exchange) Filter is 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.

HME Filter is normally positioned at the patient end of the breathing system between

the circuits Y-piece and the catheter mount or patient airway device. HME Filter is a single use device for use on a single patient for up to 24hrs.

HME Filter is designed to be used in hospital environments by trained personnel.

5.8 Device Description

GGM Breathing Circuit Bacterial Filter contains two types of bacterial filters, namely "Bacterial Filter" with only filtering function and "HME Filter" with heat and moisture exchanger function.

Bacterial Filter (models VF-2160, VF-2160-1):
Bacterial Filter is a single-used medical device, which is used for filtering the bacteria and virus in the respiratory gas to the patient during the respiratory therapy. VF-2160 and VF-2160-1 are all intended for adult patients with the tidal volume between 250ml-1500ml.

HME Filter (models VH-3110, VH-3210):
HME Filter is a kind of breathing circuit bacterial filter with the function of passive heat and moisture exchanger (artificial nose). It is a breathing circuit bacterial filter that contains electrostatic cotton for filtration and contains heat preserved and moisture absorbed paper roll for airway heat preservation and humidification. The Heat and Moisture Exchanger Filter (HMEF) should be installed on the patient's end based on the principle of passive humidification treatment. VH-3110 is intended for adult patients with the tidal volume between 250ml-1500ml, and VH-3210 is intended for adult patients with the tidal volume between 250ml-1000ml.

5.9 Technological Characteristic Comparison Table

The GGM Breathing Circuit Bacterial Filter, including Bacterial Filters and HME Filters, submitted in this 510(k) file is substantially equivalent in intended use, has similar technology/principles of operation, and similar performance to the cleared HepaShield Bacterial Viral Breathing System Filter (K191909) and ThermoShield HME Filter (K163300).

5.9.1 For Bacterial Filters:

Item / Feature	Subject device		Predicate device	Comparison
Submitter	Great Group Medical Co., Ltd.		Flexicare Medical Limited	
Proprietary Name	GGM Breathing Circuit Bacterial Filter - Bacterial Filters		HepaShield Bacterial Viral Breathing System Filter	
510(k) No.	K210352		K191909	
Models	VF-2160	VF-2160-1	N/A	N/A
Intended Use	The Bacterial Filter is intended to reduce the transmission of bacteria and viruses to a patient during anesthesia. For use with ventilators, anesthesia machines and open flow systems where filtration of inspired gases is desired. The Bacterial Filter is single use device for use on a single patient for up to 24hrs. The Bacterial Filter is designed to be used in hospital environments by trained personnel.		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	Same

Item / Feature	Subject device		Predicate device	Comparison
Submitter	Great Group Medical Co., Ltd.		Flexicare Medical Limited	
Proprietary Name	GGM Breathing Circuit Bacterial Filter - Bacterial Filters		HepaShield Bacterial Viral Breathing System Filter	
510(k) No.	K210352		K191909	
Models	VF-2160	VF-2160-1	N/A	N/A
			System Filters are designed to be used in hospital environments by trained personnel.	
Intended patient population	For Adult patients with the tidal volume between 250ml-1500ml		Adult	Same
Type of use	Prescription Use		Prescription Use	Same
Components	Filter housing top Filter housing bottom Filter cotton (electrostatic cotton) Luer port cap		Filter housing top Filter housing bottom Filter Media pack Tethered luer port cap Outer shrink sleeve	Similar
Assembly Method	Ultrasonic welded housing		Ultrasonic welded housing	Same
Emergency Use	Yes		Yes	Same
Environment of Use	Hospital		Hospital	Same
Patient use/ Duration of use	Single use, disposable, <24hrs		Single use, disposable, <24hrs	Same
Supplied sterile	Sterile		Both Non-sterile & sterile variants	Similar
Patient Connection	ET tube, Laryngeal Mask Airway, Catheter mount, Breathing circuit		ET tube, Laryngeal Mask Airway, Catheter mount, Breathing circuit	Same
Colors	Clear/ colorless, Green		Clear/ colorless, Blue	Different

Item / Feature	Subject device		Predicate device	Comparison
Submitter	Great Group Medical Co., Ltd.		Flexicare Medical Limited	**Comparison**
Proprietary Name	GGM Breathing Circuit Bacterial Filter - Bacterial Filters		HepaShield Bacterial Viral Breathing System Filter	
510(k) No.	K210352		K191909	
Models	VF-2160	VF-2160-1	N/A	N/A
Standard 22/15mm connections in compliance with ISO 5356-1	Yes		Yes	Same
Luer port for gas sampling in compliance with ISO 594-2/ISO 80369-7	Yes		Yes	Same
Configurations	Straight without luer port	Straight with luer port	Straight with luer port	Similar
Filtration	Electrostatic		Mechanical	Different
Placement with Circuit	Machine side		Patient side Machine side	Similar

Item / Feature	Subject device		Predicate device	Comparison
Submitter	Great Group Medical Co., Ltd.		Flexicare Medical Limited	
Proprietary Name	GGM Breathing Circuit Bacterial Filter - Bacterial Filters		HepaShield Bacterial Viral Breathing System Filter	
510(k) No.	K210352		K191909	
Models	VF-2160	VF-2160-1	N/A	N/A
Weight	21g	23g	42g	Different
Internal Volume/ Dead space as per ISO 9360-1	30ml		47ml	Similar
Bacterial/ Viral Filtration Efficiency/ Filter Integrity (Fresh)	BFE - 99.9% VFE - 99.9%		BFE- 99.99999% VFE- 99.9999%	Similar
Salt Method Filtration Efficiency	99.61%		99.89%	Similar
Tidal Volume Range	250~1500ml		141~800ml	Different

Item / Feature	Subject device		Predicate device	Comparison
Submitter	Great Group Medical Co., Ltd.		Flexicare Medical Limited	
Proprietary Name	GGM Breathing Circuit Bacterial Filter - Bacterial Filters		HepaShield Bacterial Viral Breathing System Filter	
510(k) No.	K210352		K191909	
Models	VF-2160	VF-2160-1	N/A	N/A
Pressure Drop/ Flow resistance per BS EN ISO 23328-2/ EN ISO 9360-1	0.47 hPa @30L/min 0.98 hPa @60L/min 1.47 hPa @90L/min		1.70 hPa @ 30LPM 3.92 hPa @ 60LPM 6.56 hPa @ 90LPM	Different
Leakage per BS EN ISO 23328-2/ BS EN ISO 9360-1	< 10 ml/min		< 2 ml/min	Different
Compliance per BS EN ISO 9360-1	0.3ml/kPa		0.057ml/kPa	Different
Reuse, Cleaning & Disinfection	N/A- Single use (max 24hrs)		N/A- Single use (max 24hrs)	Same
Shelf Life	3 years		5 years	Different
Packaging	Sterile paper film		Polybag	Different ISO 11607-1

5.9.2 For HME (Heat and Moisture Exchange) Filters:

Item / Feature	Subject device		Predicate device	Comparison
Submitter	Great Group Medical Co., Ltd.		Flexicare Medical Limited	
Proprietary Name	GGM Breathing Circuit Bacterial Filter – HME (Heat and Moisture Exchange) Filters		ThermoShield HME Filter	
510(k) No.	K210352		K163300	
Models	VH-3110	VH-3210	N/A	N/A
Intended Use	HME (Heat and Moisture Exchange) Filter is 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. HME Filter is normally positioned at the patient end of the breathing system between the circuits Y-piece and the catheter mount or patient airway device. HME Filter is a single use device for use on a single patient for up to 24hrs. HME Filter is designed to be used in hospital environments by trained 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	Same

Item / Feature	Subject device		Predicate device		Comparison
Submitter	Great Group Medical Co., Ltd.		Flexicare Medical Limited		
Proprietary Name	GGM Breathing Circuit Bacterial Filter – HME (Heat and Moisture Exchange) Filters		ThermoShield HME Filter		
510(k) No.	K210352		K163300		
Models	VH-3110	VH-3210	N/A		N/A
			environments by trained personnel. Expert clinical judgment must be used in assessing patient humidification requirements.		
Intended Patient Population	For Adult patients with the tidal volume between 250ml-1500ml	For Adult patients with the tidal volume between 250ml-1000ml	Adult		Same for adult
Type of use	Prescription Use		Prescription Use		Same
Components	Filter housing top Filter housing bottom Filter cotton (electrostatic cotton) HME paper roll Luer port cap Outer stickers		Filter housing top Filter housing bottom Filter pad HME paper Tethered luer port cap Outer shrink sleeve		Similar
Materials	Filter housing top	Polypropylene/ K-Resin	Filter housing top	Polypropylene	Similar
	Filter housing bottom	Polypropylene/ K-Resin	Filter housing bottom	Polypropylene	
	Filter cotton (electrostatic cotton)	Polypropylene	Filter pad	Polypropylene	
	HME paper roll	Paper	HME paper	Paper	
	Luer port cap	PP	Tethered luer port	PVC	

Item / Feature	Subject device		Predicate device		Comparison
Submitter	Great Group Medical Co., Ltd.		Flexicare Medical Limited		
Proprietary Name	GGM Breathing Circuit Bacterial Filter – HME (Heat and Moisture Exchange) Filters		ThermoShield HME Filter		
510(k) No.	K210352		K163300		
Models	VH-3110	VH-3210	N/A		N/A
			cap		
	Outer stickers	Paper	Outer shrink sleeve	LDPE	
Assembly Method	Ultrasonic welded housing		Snap Fit casing		Different
Emergency Use	Yes		Yes		Same
Environment of Use	Hospital		Pre-hospital, Hospital & Homecare		Similar
Patient use/ Duration of use	Single use, disposable, <24hrs		Single use, disposable, <24hrs		Same
Supplied sterile	Sterile		Non-sterile		Different
Patient Connection	connections in compliance with ISO 5356-1		connections in compliance with ISO 5356-1		Same
Colors	Clear/ colorless, White		Clear/ colorless, Blue		Different

Item / Feature	Subject device		Predicate device	Comparison
Submitter	Great Group Medical Co., Ltd.		Flexicare Medical Limited	
Proprietary Name	GGM Breathing Circuit Bacterial Filter – HME (Heat and Moisture Exchange) Filters		ThermoShield HME Filter	
510(k) No.	K210352		K163300	
Models	VH-3110	VH-3210	N/A	N/A
Standard 22/15mm connections in compliance with ISO 5356-1	Yes		Yes	Same
Luer port for gas sampling in compliance with ISO 594-2	Yes		Yes	Same
Configurations	Straight with luer port		Straight with luer port	Same
Filtration	Electrostatic		Electrostatic	Same
Placement with Circuit	Patient side		Patient side	Same
Weight	31g	25g	38g	Different
Internal Volume/ Dead space as per ISO 9360-1	45ml	29ml	46ml	Similar

Item / Feature	Subject device		Predicate device	Comparison
Submitter	Great Group Medical Co., Ltd.		Flexicare Medical Limited	
Proprietary Name	GGM Breathing Circuit Bacterial Filter – HME (Heat and Moisture Exchange) Filters		ThermoShield HME Filter	
510(k) No.	K210352		K163300	
Models	VH-3110	VH-3210	N/A	N/A
Bacterial/ Viral Filtration Efficiency/ Filter Integrity (Fresh)	BFE - 99.9% VFE - 99.9%	BFE - 99.9% VFE - 99.7%	BFE- 99.999% VFE- 99.99%	Similar
Salt Method Filtration Efficiency	99.05%	98.34%	98.90%	Similar
Moisture Output (mg/L)	36.7 at Vt=500ml	35.9 at Vt=500ml	30.4, vt=500ml	Similar
Moisture Loss (mg/L)	7.3 at Vt=500mL	8.1 at Vt=500mL	6.8, vt=500ml	Similar
Tidal Volume Range	250~1500ml	250~1000ml	138~800ml	Different

Item / Feature	Subject device		Predicate device	Comparison
Submitter	Great Group Medical Co., Ltd.		Flexicare Medical Limited	
Proprietary Name	GGM Breathing Circuit Bacterial Filter – HME (Heat and Moisture Exchange) Filters		ThermoShield HME Filter	
510(k) No.	K210352		K163300	
Models	VH-3110	VH-3210	N/A	N/A
Pressure Drop/ Flow resistance	1.0 hPa @30L/min 2.3 hPa @60L/min 4.1 hPa @90L/min	1.5 hPa @30L/min 3.4 hPa @60L/min 5.7 hPa @90L/min	1.71 hPa @ 30LPM 4.31 hPa @ 60LPM 7.82 hPa @ 90LPM	Similar
Housing Burst Strength	>101kPa		>101kPa	Same
Leakage per ISO 9360-1	No leak at 101kPa		No leak at 101kPa	Same
Compliance per ISO 9360-1	0.9 ml/kPa	0.4 ml/kPa	14 ml/kPa	Different
Reuse, Cleaning & Disinfection	N/A- Single use (max 24hrs)		N/A- Single use (max 24hrs)	Same
Shelf Life	3 years		4 years	Different
Packaging	Sterile paper film		Non- sterile Polybag	Different

5.10 Non-clinical Testing

Test Methodology	Purpose	Acceptance Criteria	Results
Packaging for Terminally Sterilized Medical Devices			
ISO 10993-7	EO/ ECH/ EG residual test	Non-Detected	PASS
ISO 11737-2	Sterility test	Negative	PASS
ASTM F1608	Microbial Ranking Test	LRV>3.0 (99.9%)	PASS
ASTM F1929	Dye Penetration Test	No Penetration	PASS
ASTM F1140	Burst and Creep Test	Package successfully held for creep duration	PASS
ASTM F88	Seal Peel Strength Test	>0.1kg/cm	PASS
Shelf Life Test			
ISO 9360-1	Moisture Loss, Pressure Drop, Leakage, Compliance	Methodology only, no acceptance criteria	Meet the requirements of the clinical application

ISO 5356-1	Test for Security of Engagement of Latching Sockets to Cones, Housing Burst Strength, Drop Test	Does not fall off and crack	PASS
ASTM F2101	Filtration Efficiency Test	Methodology only, no acceptance criteria	Meet the requirements of the standard
Biocompatibility Test			
ISO 10993-5	In Vitro Cytotoxicity test	Cell viability is greater than 70%	PASS
ISO 10993-10	Skin Sensitization Study (Maximization Test)	Did not produce skin sensitization	PASS
ISO 10993-10	White Rabbit Intracutaneous Reactivity Test	Did not cause intracutaneous irritation	PASS
ISO 10993-11	Acute Systemic Toxicity Study	Did not cause systemic toxicity reaction or death	PASS
ISO 10993-11	Repeat- Dose Subchronic Systemic Toxicity Study	No significant adverse effects.	PASS
ISO 10993-3	In Vitro Mammalian Cell Gene Mutation Test	No genotoxic effects	PASS
ISO 10993-3	Salmonella Reverse Mutation Test	Did not cause mutagenic	PASS
ISO 10993-3	Mice Erythrocyte Micronucleus Test	Does not produce micronuclei	PASS
ISO 10993-6	Muscle Implant Study	Nonirritant (Score < 2.9)	PASS
ISO 18562-2	Emissions of Particulate Matter	PM2.5 ≤ 12 μg/m3 PM10 ≤ 150 μg/m3	PASS
ISO 18562-3	Emissions of VOCs and Aldehydes	Risk Assessment	PASS
ISO 18562-4	Leachable in Condensate	Risk Assessment	PASS
Performance Test			
ASTM F2101	Bacterial / Virus Filtration Efficiency test	Methodology only, no acceptance criteria	Meet the requirements of the standard

ISO 9360-1	Moisture Loss, Pressure Drop	Methodology only, no acceptance criteria	Meet the requirements of the clinical application

A series of safety and performance tests were conducted on the subject device, GGM Breathing Circuit Bacterial Filter.

- Sterilization validation test
  - EO/ ECH/ EG residual test
  - Biological Indicator (BI) validation test
  - Bioburden test
  - Sterility test

- Shelf life test
  - Moisture Loss Test
  - Pressure Drop Test
  - Leakage Test
  - Compliance Test
  - Test for Security of Engagement of Latching Sockets to Cones
  - Housing Burst Strength
  - Drop Test
  - Filtration Efficiency Test

- Biocompatibility test
  - In Vitro Cytotoxicity test
  - Skin Sensitization Study (Maximization Test)
  - White Rabbit Intracutaneous Reactivity Test
  - Acute Systemic Toxicity Study
  - Repeat- Dose Subchronic Systemic Toxicity Study
  - In Vitro Mammalian Cell Gene Mutation Test
  - Salmonella Reverse Mutation Test
  - Mice Erythrocyte Micronucleus Test

- Muscle Implant Study
- ISO 18562 Biocompatibility Evaluation
- Emissions of Particulate Matter
- Emissions of VOCs and Aldehydes
- ISO 18562-4 Leachable in Condensate Study
- ISO 18562-4 Biocompatibility Evaluation

- Performance test
  - Bacterial Filtration Efficiency test
  - Virus Filtration Efficiency test
  - Moisture Loss and Pressure Drop test
  - Life Time test

All the test results demonstrate GGM Breathing Circuit Bacterial Filter meets the requirements of its pre-defined acceptance criteria.

5.11 Clinical and Usability Testing

No clinical test data was used not needed for this submission

5.12 Conclusion

The conclusions drawn from the nonclinical test demonstrate that the GGM Breathing Circuit Bacterial Filter is as safe, as effective, and performs as well as or better than the legally marketed device.