March 23, 2020

Flexicare Medical Limited
Joel Biddle
Regulatory Manager
Cynon Valley Business Park
Mountain Ash, cf45 4er UK

Re: K191909
Trade/Device Name: HepaShield Bacterial Viral Breathing System Filter
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: Class II
Product Code: CAH
Dated: February 19, 2020
Received: February 24, 2020

Dear Joel Biddle:

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)*

K191909

Device Name
HepaShield Bacterial Viral Breathing System Filter

Indications for Use *(Describe)*

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K191909

510(k) Sponsor, Contact Person and Date Summary Prepared:

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Summary prepared on: March 16th, 2020. Device Name:

Trade Name: HepaShield Bacterial Viral Breathing System Filter

Common/Usual Name: Breathing circuit bacterial filter.

Classification Name: Breathing circuit bacterial filter: 21 CFR 868.5260

Product Codes: CAH (Breathing circuit bacterial filter)

Predicate Device:

Pall's Ultipor 25 Bacterial Viral Breathing System Filter (K013093)

Device Description:

Flexicare's HepaShield Bacterial Viral Breathing System Filters are designed to reduce the transmission of bacteria and viruses to and from a patient who requires aesthesia, artificial respiration or other types of assisted respiration

Flexicare's HepaShield Bacterial Viral Breathing System Filters consist of a top/bottom housing, pleated paper filter pack and a luer port cap. The Female luer-lock port allows connection of a luer-terminating monitoring line for monitoring of patient exhaled CO2 & is supplied with a tethered cap to seal port when not in use.

The patient side of the Flexicare's HepaShield Bacterial Viral Breathing System Filters feature a 22mm Male and a 15mm Female conical. The machine side features a 22mm Female and a 15mm Male conical.
All conical connectors comply with dimensions stated within BS EN ISO 5356-1 standard.

Flexicare's HepaShield Bacterial Viral Breathing System Filters are available in Adult sizes.

Flexicare's HepaShield Bacterial Viral Breathing System Filters are available in a both Sterile and non-sterile state, packaged in individually sealed polybags, or blister trays (if sterile).

Indications For Use:

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.

Technological Characteristic Comparison Table:

The table below shows the similarities and differences between the Flexicare's HepaShield Bacterial Viral Breathing System Filter and the predicate device manufactured by Pall.

	Flexicare's HepaShield Breathing System Filter	Pall's Ultipor 25 Breathing System Filter
510(k)	K191909	K013093
Components	Filter housing top Filter housing bottom Filter Media pack Tethered luer port cap Outer shrink sleeve	Filter housing top Filter housing bottom Filter Media pack Tethered luer port cap
Assembly Method	Ultrasonic welded housing	Ultrasonic welded housing
Target population	Adult	Adult
Emergency use	Yes	Yes
Environment of use	Hospital	Hospital
Patient use/Duration of use	Single use, disposable, <24hrs	Single use, disposable, <24hrs
Contraindications	-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	- Do not install the filter in either positions A or B in conjunction with heater water-bath humidifiers or nebulizers. - Do not Reuse. - Do not Soak, rinse, wash, sterilize or treat with liquid disinfectants. - Note: This Product is free of natural rubber latex.

	humidified breathing system, the HepaShield Bacterial Viral Breathing System Filter is contraindicated for use at the patient end.	
Supplied sterile	Both Non-sterile & sterile variants	Non-sterile
Product labelling	HepaShield Bacterial Viral Breathing System Filter	PALL Ultipor BREATHING SYSTEM FILTER
Indications for use	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	The Pall Ultipor Anesthesia Breathing Circuit System with a Breathing System Filter ("BSF") is intended for use in the administration of medical gases during anesthesia. The circuit connects the anesthesia gas machine to the patient, by means of an oronasal facemask or by a connection to an artificial airway, such as an endotracheal tube or laryngeal mask. The Pall Ultipor 25 BSF minimizes viral and bacterial contamination of the inspiratory and expiratory limbs of the circuit with a minimum efficiency of 99.999%.

	Breathing System Filters are designed to be used in hospital environments by trained personnel.	Source: K013093 510(k) summary
Intended use	Instruction leaflet	Instruction leaflet
Patient connection	ET tube, Laryngeal Mask Airway, Catheter mount, Breathing circuit	ET tube, Laryngeal Mask Airway, Catheter mount, Breathing circuit
Standard 22/15mm connections in compliance with ISO 5356-1	Yes	Yes
Luer port for gas sampling in compliance with ISO 80369-7	Yes	Yes
Configurations	Straight with luer port	Straight with luer port
Filtration Method	Mechanical	Mechanical
Placement within circuit	Patient side Machine side	Patient side Machine side
Weight (g)	42g	26g
Internal Volume/dead space as per ISO 9360-1	47ml	35ml
Bacterial/ Viral Filtration efficiency/ filter integrity (Fresh)	BFE – 99.99999% VFE – 99.9999%	BFE - 99.999%
Salt Method filtration efficiency	99.89%	Not stated
Tidal Volume range (ml)	141ml-800ml	Not stated
Pressure Drop/ Flow resistance per BS EN ISO 23328-2/ BS EN ISO 9360-1	1.70 cmH2O @ 30LPM 3.92 cmH2O @ 60LPM 6.56 cmH2O @ 90LPM	1.43 cmH2O @ 30LPM 3.10 cmH2O @ 60LPM 4.96 cmH2O @ 90LPM
Leakage per BS EN ISO 23328-2/ BS EN ISO 9360-1	<2 ml/min	<2 ml/min
Compliance per BS EN ISO 9360-1	0.057 ml/cmH2O	0.029 ml/cmH2O
Reuse, Cleaning & Disinfection	N/A – Single use (max 24hrs)	N/A – Single use (max 24hrs)
Shelf Life	5 years	5 years
Packaging	Polybag	Polybag
Temp/humidity req's	Not stated	Not stated
Standards met	ISO 5356-1 ISO 10993-1 BS EN ISO 23328-1 BS EN ISO 80369-7	510(K) Summary does not specify
Biocompatibility	ISO 10993 compliant EN ISO 18562 compliant	Not stated

Summary of Nonclinical Testing: Flexicare's HepaShield Bacterial Viral Breathing System Filter has been evaluated in accordance with standards listed in table:

Test	Standard / Pre Determined Acceptance Criteria	Results
Visual Inspection	Pre-determined Acceptance Criteria*	Pass
Compliance testing	BS EN ISO 9360: 2009	Methodology only, no pass criteria – Comparable performance outcome between Flexicare's new devices and the predicate devices
Pressure drop	BS EN ISO 23328-2 (Refers to: BS EN ISO 9360: 2009) - Methodology only, no pass criteria – for comparison only. HME aspects not applicable.	Methodology only, no pass criteria – Comparable performance outcome between Flexicare's new devices and the predicate devices
Gas Leakage		
Conical Connector compliance	BS EN ISO 5356-1 2004	Pass
Leak testing		Pass
Drop testing		Pass
Cytotoxicity, Irritation, Sensitization, Systemic toxicity, Material Mediated Pyrogenicity,	BS EN ISO 10993-10:2010	Pass
	BS EN ISO 10993-5:2009	Pass
	BS EN ISO 10993-11:2009	Pass
Bacterial Endotoxin	(USP) guidelines <161> and <85>. ANSI/AAMI ST72:2011,	Pass
Particulate emissions (gas pathway)	EN ISO 18562-2:12017	Pass
VOC emissions (gas pathway)	EN ISO 18562-3:2017	Pass
Gauging tests on luer	BS EN ISO 80369-7:2016	Pass
Liquid leakage from luer		Pass
Air leakage from luer		Pass
Luer separation force		Pass
Luer unscrewing torque		Pass
Luer ease of assembly		Pass
Luer resistance to overriding		Pass
Luer testing for stress cracking		Pass
Shelf life testing	Standards included within this table	Pass
Filter integrity	Based on ASTM F2101 (Nelson Labs Protocol)	Methodology only, no pass criteria within standard.
	BS EN ISO 23328-1 (2008)	Methodology only, no pass criteria within standard.
Pressure Drop	BS EN ISO 23328-2 (2009)	Methodology only, no pass criteria within standard
Housing Leakage	BS EN ISO 23328-2(2009)	Methodology only, no pass criteria within standard

*** Pre-determined Acceptance Criteria - Visual inspection**
Criteria: Product packaging must remain sealed & undamaged. All components of devices must be free of flash, cracking, warping, discoloration or contamination.

Methodology: Visual inspection under normal or corrected vision of device packaging (inspection of panels, seams and welds for unsealed areas/openings, pin-holes, print quality, tares) and assembled device (inspection of device for cracking, warping, discolouration, cosmetic defects, flash and contamination within material).

Flexicare's HepaShield Bacterial Viral Breathing System Filter passed the performance testing when tested against methods and criteria from both pre-determined acceptance criteria methods and relevant FDA Recognized standards.

The results of this testing show that Flexicare's HepaShield Bacterial Viral Breathing System Filter passes all performance tests and perform at least as well as the marketed predicate device.

Consensus Standards

The recognized consensus standard for devices classified through FDA product code CAH are:

- ISO 5356-1: 2004 - *Anaesthetic And Respiratory Equipment - Conical Connectors: Part 1: Cones And Sockets.*

- EN ISO 18652: 2017 - *Biocompatibility Evaluation Of Breathing Gas Pathways In Healthcare Applications*

Conclusion:

The conclusions drawn from the nonclinical tests demonstrates that the Flexicare HepaShield Bacterial Viral Breathing System Filter device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Pall's Ultipor 25 Bacterial Viral Breathing System Filter (K013093). .