DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 22, 2017

Flexicare Medical Limited
% Mark Job
Regulatory Technology Services, LLC
1394 25th Street North West
Buffalo, Minnesota 55313

Re: K163300
Trade/Device Name: ThermoShield HME Filter
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: Class II
Product Code: CAH
Dated: March 08, 2017
Received: March 15, 2017

Dear Mr. Mark Job:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163300

Device Name
ThermoShield HME Filter

Indications for Use *(Describe)*
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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary

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

Flexicare Medical Limited
Cynon Valley Business Park
Mountain Ash.
CF45 4ER. United Kingdom

Joel Biddle
Senior Compliance Engineer
Telephone: 00 44 1443 474 647

Summary prepared on: March 18th, 2017.

Device Name:

Trade Name:	ThermoShield HME Filters
Common/Usual Name:	Breathing System Bacterial / Viral filter with HME
Classification Name:	Filter, Bacterial, Breathing-Circuit. 21 CFR 868.5260
Product Code:	CAH
Classification:	Class 2

There have been no prior submissions for the devices included within this submission.

Legally Marketed Equivalent Device:

Flexicare's ThermoShield HME Filters are substantially equivalent to:

- Gibeck "Humid-Vent Filter Compact angled/ Humid-Vent Filter Compact Straight" which was cleared for marketing by 510(k) No K964382 for adult population.

  And,

- Gibeck "Humid-Vent Filter Pedi" which was cleared for marketing by 510(k) K952084 for pediatric population.

Device Description:

Flexicare's ThermoShield HME Filters are designed to prevent the transmission of bacteria and viruses to and from a patient who requires aesthesia, artificial respiration or other types of assisted respiration

Flexicare's ThermoShield HME Filters include a HME (Heat and Moisture Exchanger) Media in addition to a filter. The Inclusion of HME media is intended to help prevent complications due to drying of the respiratory mucosa, such as mucus plugging and endotracheal tube (ETT) occlusion. This is achieved by the HME media preventing a large amount of the water vapor from passing through the device.

Flexicare's ThermoShield HME Filters consist of a top/bottom housing, filter pad, HME media and a luer port cap. The Female luer-lock port allows 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 ThermoShield HME Filters feature a 22mm Male and a 15mm Female conical connector. The machine side features a 22mm Female and a 15mm Male conical connector.
All conical connectors comply with dimensions stated within BS EN ISO 5356-1: 2004

Flexicare's ThermoShield HME Filters have rounded housing with no sharp edges. This reduces the risk of pressure marks on the patient.

Flexicare's ThermoShield HME Filters are available in Adult and Mini (Pediatric) sizes.

Flexicare's ThermoShield HME Filters are supplied non sterile in individually sealed polybags.

Intended Use:

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.

Substantial Equivalence

Flexicare's ThermoShield HME Filters have the same intended use as the predicate devices. The indication for use are slightly different and do not affect substantial equivalence.
Flexicare's ThermoShield HME Filters, Gibeck "Humid-Vent Filter Compact angled/ Humid-Vent Filter Compact Straight" and the Gibeck "Humid-Vent Filter Pedi" are single use devices.
Supplied in Adult and Pediatric sizes. None of the devices are life supporting or life sustaining.

Patient Contact –

Skin contact (intact skin) & Externally Communicating – limited Duration (<24hrs)

Both manufacturer's filters are designed for a single patient use.

None of the devices are life supporting or life sustaining, nor are they implanted.

None of the filters use software or are electronically driven. None of the filters are sterile.

Both manufacturer's filters are intended to be used in conjunction with other devices such as catheter mounts and industry standardized conical connectors.

Both manufacturer's filters are designed for the same intended use in the same intended conditions.
Both manufacturer's filters consist of 4-5 components made from injection molded plastics, coiled paper & stamped polymer weave.

Neither manufacturer's devices are in vitro diagnostic devices.

Substantial equivalence comparison table - Adult filters

	Flexicare's ThermoShield HME Filters – Adult K: 163300	Gibeck Humid-vent Filter Compact K: 964382
Components	Filter housing top Filter housing bottom Filter pad HME paper Tethered luer port cap Outer shrink sleeve	Filter housing top Filter housing bottom Filter pad HME paper Luer port cap Outer sticker
Materials	Filter housing top – Polypropylene Filter housing bottom - Polypropylene Filter pad - Polypropylene HME paper - Paper Tethered luer port cap - PVC Outer shrink sleeve - LDPE	Filter housing top – ABS Filter housing bottom - Polypropylene Filter pad - Polypropylene HME paper - Paper luer port cap - ABS Outer sticker - Paper
Assembly Method	Snap Fit casing	Snap Fit casing
Patient population	Adult	Adult
Emergency use	Yes	Yes
Environment of use	Pre-hospital, Hospital & Homecare	Pre-hospital, Hospital & Homecare
Patient use/Duration of use	Single use, disposable, <24hrs	Single use, disposable, <24hrs
Supplied sterile	No	No
Indications for use	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.	Humid-vent filter (HMEF) are combined Heat and Moisture Exchanger (HME) and Bacterial/Viral Filter for humidification and bacterial/viral filtration during anesthesia and ventilator care. Expert clinical judgment must be used in assessing the patients humidification requirements. Source: Gibeck Humid-Vent Filter Compact IFU.
Colours	Clear/ colorless, Blue	Clear/ colorless, Blue, White

Standard 22/15mm connections in compliance with ISO 5356-1	Yes	Yes
Luer port for gas sampling in compliance with ISO 594-2	Yes	Yes
Configurations	Straight with luer port	Straight with luer port
Filtration Method	Electrostatic	Electrostatic
Placement within circuit	Patient side	Patient side
Weight (g)	Straight with luer port 38g	Straight with luer port 31g
Internal Volume/dead space as per ISO 9360-1	Straight with luer port 46ml	Straight with luer port 35ml
Bacterial/ Viral Filtration efficiency/ filter integrity (Fresh)	BFE – 99.999% VFE – 99.99%	BFE – 99.9999% VFE - 99.999%
Salt Method filtration efficiency	98.90%	Not stated
Moisture output (mg/L)	Vt 500 – 30.4mg H2O/L air	Vt 500 – 29.2mg H2O/L air
Moisture loss (mg/L)	Vt 500 – 6.8 mg H2O/L air	Vt 500 – 7.8mg H2O/L air
Tidal Volume range (ml)	138-800ml	150-1000ml
Pressure Drop/ Flow resistance	Straight filters 1.71cmH2O @ 30LPM 4.31cmH2O @ 60LPM 7.82cmH2O @ 90LPM	Straight filters 1.25cmH2O @ 30LPM 2.96cmH2O @ 60LPM 5.21cmH2O @ 90LPM
Housing Burst strength	>101kPa	>101kPa
Leakage per ISO 9360-1 6.4	No leak at 101kPa	No leak at 101kPa
Compliance per ISO 9360-1 6.5	Straight filters 14ml/kPa	Straight filters 13ml/kPa
Reuse, Cleaning & Disinfection	N/A – Single use	N/A – Single use
Shelf Life	4 years	5 years
Packaging	Non-sterile Polybag	Non-sterile Polybag
Temp/humidity req's	None stated	None stated
Non-clinical Test Results	Verification tests were performed on Flexicare's Adult ThermoShield HME Filter. These Non-clinical tests included Visual inspection/comparison, HME moisture output, HME moisture loss, Compliance testing, Pressure drop, Conical connector compliance testing, Luer lock compliance testing, shelf life verification, Biocompatibility and Filtration efficiency. Testing demonstrated that the relevant features, design and performance of each manufacturer's device are substantially equivalent.	
Conclusion	Flexicare's Adult ThermoShield HME Filter is considered to be substantially equivalent the Gibeck Humid-vent Filter Compact. The comparison of each devices features, performance, materials, intended use and intended purpose demonstrate this.	

Substantial equivalence comparison table - Mini filters

	Flexicare's ThermoShield HME Filters - Mini K: 163300	Gibeck Humid-vent Filter Pedi K:952084
Components	Filter housing top Filter housing bottom Filter pad HME paper Tethered luer port cap Outer shrink sleeve	Filter housing top Filter housing bottom Filter pad HME paper Luer port cap Outer sticker
Materials	Filter housing top – Polypropylene Filter housing bottom - Polypropylene Filter pad - Polypropylene HME paper - Paper Tethered luer port cap - PVC Outer shrink sleeve - LDPE	Filter housing top – ABS Filter housing bottom - Polypropylene Filter pad - Polypropylene HME paper - Paper luer port cap - ABS Outer sticker - Paper
Assembly Method	Snap Fit casing	Snap Fit casing
Patient population	Pedi	Pedi
Emergency use	Yes	Yes
Environment of use	Pre-hospital, Hospital & Homecare	Pre-hospital, Hospital & Homecare
Patient use/Duration of use	Single use, disposable, <24hrs	Single use, disposable, <24hrs
Supplied sterile	No	No
Indications for use	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.	Humid-Vent Filter Pedi is a combined heat and moisture exchanger (HME) and bacterial/viral filter for humidification and bacterial/viral filtration during anesthesia and intensive care. With luer lock port for $ETCO_2$, anesthetic agent or pressure monitoring V_T50-250ml. It reduces hypothermia and post-operative shivering as well as the risk of bacterial/viral contamination. Source: Gibeck Humid-Vent Filter Pedi IFU.
Colours	Clear/ colorless, Blue	Clear/ colorless, Blue, White
Standard 22/15mm connections in compliance with ISO 5356-1	Yes	Yes

Luer port for gas sampling in compliance with ISO 594-2	Yes	Yes
Configurations	Straight with luer port	Straight with luer port
Filtration Method	Electrostatic	Electrostatic
Placement of device within circuit	Patient end	Patient end
Weight (g)	Straight with luer port 25g	Straight with luer port 14.5g
Internal Volume/dead space as per ISO 9360-1	Straight with luer port 25ml	Straight with luer port 12ml
Bacterial/ Viral Filtration efficiency/ filter integrity (Fresh)	BFE – 99.99 VFE – 99.9	BFE – 99.9999 VFE – 99.9
Salt Method filtration efficiency	97.71%	Not stated
Moisture output (mg/L)	Vt 200 – 30.3mg H2O/L air	Vt 200 – 30.4mg H2O/L air
Moisture loss (mg/L)	Vt 200 – 6.9 mg H2O/L air	Vt 200 – 6.9mg H2O/L air
Tidal Volume Range (ml)	75-600ml	50-250ml
Pressure Drop/ Flow resistance	Straight filters 2.02cmH2O @ 30LPM 4.86cmH2O @ 60LPM 8.61cmH2O @ 90LPM	Straight filters 1.90cmH2O @ 30LPM 4.72cmH2O @ 60LPM 7.98cmH2O @ 90LPM
Housing Burst strength	>101kPa	>101kPa
Leakage per ISO 9360-1 6.4	No leak at 101kPa	No leak at 101kPa
Compliance per ISO 9360-1 6.5	Straight filters 10ml/kPa	Straight filters 10ml/kPa
Reuse, Cleaning & Disinfection	N/A – Single use	N/A – Single use
Shelf Life	4 years	5 years
Packaging	Non-sterile Polybag	Non-sterile Polybag
Temp/humidity req's	None stated	None stated
Non-clinical Test Results	Verification tests were performed on Flexicare's Mini ThermoShield HME Filter. These Non-clinical tests included Visual inspection/comparison, HME moisture output, HME moisture loss, Compliance testing, Pressure drop, Conical connector compliance testing, Luer lock compliance testing, shelf life verification, Biocompatibility and Filtration efficiency. Testing demonstrated that the relevant features, design and performance of each manufacturer's device are substantially equivalent.	
Conclusion	Flexicare's Mini ThermoShield HME Filter is considered to be substantially equivalent the Gibeck Humid-vent Filter Pedi. The comparison of each devices features, performance, materials, intended use and intended purpose demonstrate this.	

Although very similar in design and function, there are some differences (described below) between Flexicare's ThermoShield HME Filters and the predicate devices manufactured by Gibeck. However, these differences do not raise new safety or effectiveness issues.
One difference between manufacturers HME filters in both adult and pediatric sizes is the luer cap. Flexicare's ThermoShield HME Filters in both adult and pediatric size (with a luer port) feature a tethered flexible PVC cap that pushes onto and plugs the luer port. Gibeck's adult and pediatric HME Filters (with a luer port) feature an ABS screw on luer cap which plugs the luer port.

Flexicare's ThermoShield HME Filters also differ from the Gibeck predicate devices in their housing materials.

Flexicare's ThermoShield HME Filters (both adult and pediatric) housing is manufactured from Polypropylene (both top and bottom parts), whilst Gibeck's adult filter housing consists of an ABS top half and a Polypropylene bottom half. Gibeck's Pediatric filter consists of ABS top & bottom halves.

Summary of testing:

Flexicare's ThermoShield HME Filters have been evaluated in accordance with standards listed in Table below:

Test	Standard / Pre Determined Acceptance Criteria	Outcome
Visual Inspection	Pre-determined Acceptance Criteria*	Pass
Co2 monitoring function test	Pre-determined Acceptance Criteria**	Pass
HME moisture output	BS EN ISO 9360: 2009 - Methodology only, no pass criteria – for comparison only.	Methodology only, no pass criteria – Comparable performance outcome between Flexicare's new devices and the predicate devices
HME moisture loss		
Compliance testing		
Pressure drop		
Gas Leakage		
Conical Connector compliance	BS EN ISO 5356-1 2004	Pass
Leak testing		Pass
Drop testing		Pass
Cytotoxicity, Implant, Sensitization, Genotoxicity	BS EN ISO 10993-10:2010	Pass
	BS EN ISO 10993-5:2009	Pass
	BS EN ISO 10993-3: 2014	Pass
	BS EN ISO 10993-6:2009	Pass
Dimensional inspection of luer	ISO 594-1	Pass
Gauging tests on luer	ISO 594-2 (BS EN 1707:1997)	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	All 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.

*** 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).

**** Pre-determined Acceptance Criteria - Co2 monitoring function test**

Criteria: Flexicare's HME Filters with monitoring ports must provide a positive consistent CO2 reading when connected to a Capnograph CO_2 analyzing machine via a monitoring line.

Methodology: Test subject device is connected to a Capnograph CO_2 analyzing machine via a monitoring line with BS EN 1707:1997 compliant luer lock connectors. A test volunteer is required to breathe through the filter from the patient side steadily over a 1-minute period. Test conductor to note whether a positive, consistent CO_2 reading has been achieved.

All Samples passed the performance testing when tested against methods and criteria from pre-determined acceptance criteria in-house test methods and relevant BS EN & ISO FDA recognized standards.

The results of this testing show that Flexicare's ThermoShield HME Filters pass all performance tests and performs at least as well as marketed predicate devices "Humid-Vent Filter Compact angled/ Humid-Vent Filter Compact Straight" and "Humid-Vent Filter Pedi" by Gibeck.

The conclusions drawn from the nonclinical performance testing demonstrate that Flexicare's ThermoShield HME Filters are as safe, as effective, as the legally marketed predicate devices "Humid-Vent Filter Compact angled/ Humid-Vent Filter Compact Straight" and "Humid-Vent Filter Pedi" by Gibeck.