November 16, 2021

Pall Corporation
% Randy Prebula
Partner
Hogan Lovells U.S. LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K211286
Trade/Device Name: Ultipor U55/U55N Breathing Circuit Filter and Heat and Moisture Exchanger
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: Class II
Product Code: CAH
Dated: October 18, 2021
Received: October 18, 2021

Dear Randy Prebula:

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)*

K211286

Device Name

Ultipor® U55/U55N Breathing Circuit Bacterial Filter and Heat and Moisture Exchanger

Indications for Use *(Describe)*

The Pall® Ultipor® U55/U55N Filter is a single use bacterial/viral filter and heat and moisture exchanger (HME) for patient side or machine side installation in breathing systems. It is designed to reduce bacterial/viral transmissions between the patient, the equipment and the environment and to reduce the loss of patient heat and humidity. The Ultipor® U55/U55N breathing circuit filter has >99.999% bacterial and >99.995% viral efficiency.

The filter is for single patient use for adult patients, and is intended for use within breathing systems in healthcare and home environments where ventilation is required and for a maximum duration of 24 hours.

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 – K211286

Pall Corporation's Ultipor® U55/U55N Breathing Circuit Bacterial Filter and Heat and Moisture Exchanger

Submitter:	Pall Corporation 25 Harbor Park Drive Port Washington, NY 11050, USA
Primary Contact:	Brian Goetz Senior Manager, Regulatory Affairs Telephone Number: 516-801-9267 Fax Number: 516-801-9643
Date Prepared:	November 2, 2021
Trade Names:	**Pall® Ultipor® U55/U55N Filter**
Common Name:	Filter, Bacterial, Breathing-Circuit
Classification Regulation:	21 C.F.R. § 868.5260, Breathing circuit bacterial filter
Regulatory Class:	Class II
FDA Product Code:	CAH
Predicate Device:	Intersurgical, Inc. Hydro-Guard Mini Breathing Filter and Heat and Moisture Exchanger (Model 1745) (K092409)

Intended Use/Indications for Use

The Pall® Ultipor® U55/U55N Filter is a single use bacterial/viral filter and heat and moisture exchanger (HME) for patient side or machine side installation in breathing systems. It is designed to reduce bacterial/viral transmissions between the patient, the equipment and the environment and to reduce the loss of patient heat and humidity. The Ultipor® U55/U55N breathing circuit filter has
>99.999% bacterial and >99.995% viral efficiency.

The filter is for single patient use for adult patients, and is intended for use within breathing systems in healthcare and home environments where ventilation is required and for a maximum duration of 24 hours.

Device Description

The Pall® Ultipor® U55/U55N Breathing Circuit Bacterial Filter and Heat and Moisture Exchanger is a disposable, highly efficient, bi-directional bacterial/viral filter for patient ventilation solutions and is comprised of the following components:

- Filter housing – Is comprised of two molded halves, an inlet housing and an outlet housing that are joined and sealed together. The finished filter housing holds the pleated hydrophobic filter media and provides conical (tapered) fittings on opposing sides of the finished housing to provide connection to the conventional equipment used in the breathing circuit. One side of the finished housing has a coaxial conical fitting, with a conical fitting located on the opposing side.

- Hydrophobic filter media – Provides airborne bacterial removal efficiency of >99.999%, airborne viral removal efficiency of >99.995% and waterborne microbial contaminant removal efficiency of 100%. If the filter is used at the patient end, the filter media also acts as a heat and moisture exchanger (HME) by conserving a proportion of the heat and humidity present in the patient's exhaled air and returning it to the patient on the next inspiration.

Summary of Technological Characteristics

The subject and predicate devices have the same fundamental design, consisting of the filter media and housing. In addition, the subject and predicate filters both operate based on size exclusion (direct interception filtration) as the primary filtration mechanism, supplemented by effects of inertial impaction, and diffusion impaction, to prevent certain particles from passing through the filter to the other side.

	Subject Device	**Predicate Device**
Element	**Pall® Ultipor® U55 and U55N Breathing Circuit Bacterial Filter and Heat and Moisture Exchanger**	**Intersurgical 1745 Hydro-Guard Mini Breathing Filter and Heat and Moisture Exchanger (K092409)**
Indications for Use	The Pall® Ultipor® U55/U55N Filter is a single use bacterial/viral filter and heat and moisture exchanger (HME) for patient side or machine side installation in breathing systems. It is designed to reduce bacterial/viral transmissions between the patient, the equipment and the environment and to reduce the loss of patient heat and humidity. The Ultipor® U55/U55N breathing circuit filter has >99.999% bacterial and >99.995% viral efficiency. The filter is for single patient use for adult patients, and is intended for use within breathing systems in healthcare and home environments where ventilation is required and for a maximum duration of 24 hours.	The Intersurgical Hydro-Guard Mini Filter and Heat and Moisture Exchanger is for use at the patient and equipment connections. It is designed to reduce bacterial/viral transmissions between the patient and equipment and to reduce the loss of patient heat and humidity. The filter is for single patient use for an adult target population, is intended for use within breathing systems in healthcare and home environments where ventilation is required and a maximum duration of 24 hours.
Installation positions	Patient and machine ends	Patient and machine ends
Filtration efficiency (%)	>99.999% bacterial; >99.995% viral	>99.999%
Filtration efficiency – waterborne bacterial removal (%)	100	Not available
Minimum tidal volume (mL)	150 *(See Note 1 below)*	>200
Maximum tidal volume (mL)	1000	1000
Pressure drop (cmH_2O) @ 60 L/min	2.5	2.9
Heat and moisture exchanger loss H_2O @ 500 mL tidal volume (mg/L)	15	23

Compressible volume (dead space) (mL) approx.	50	63
Gas Leakage (mL/min)	< 4	<5
Compliance (ml/kPa)	<1	<1
Connections patient side (mm)	22 male/15 female	22 male/15 female
Connections machine side (mm)	22 female	22 female/15 male
Dry weight (g)	50	30
Filter Life (hrs)	24	24

NOTE: *1.* Lowest tidal volume while providing adequate patient ventilation should be determined by the physician by clinical assessment, internal filter volume, ventilation settings and breathing circuit configuration.

Performance Data

Testing was performed on the subject device or on representative filters reflecting the same fundamental design and materials, and the same manufacturing methods. The following non-clinical tests were performed to demonstrate the performance of the subject Ultipor® U55/U55N Filter and support the proposed indications for use:

Methodology	**Purpose**	**Acceptance Criteria**	**Results**
Biocompatibility	Evaluate device's biological safety for the intended use, in accordance with ISO 10993-1 and FDA's corresponding guidance document	• Cytotoxicity (L929 MEM elution) per ISO 10993-5; • Sensitization and intracutaneous injection per ISO 10993-10; • Acute systemic toxicity per ISO 10993-11 with both polar and non-polar solvents (in lieu of testing to ISO 18562-4); and • Material-mediated pyrogenicity per ISO 10993-11.	All results were acceptable.
Microbial retention	Evaluate aerosol bacterial and viral removal	>99.999% effectiveness for bacteria removal and >99.995% for virus removal	Unaged and aged (5 years) filters demonstrated bacterial effectiveness of >99.999% and viral effectiveness of >99.995%.
	Evaluate liquid bacterial removal	100% retention	No bacteria were recovered from the water placed on the machine side following the challenge for any unaged or aged (3 & 5 years) filters. This testing also supports filter media integrity and hydrophobicity.
Poly-alpha-olefin (PAO) Removal[1]	Evaluate filtration efficiency	Penetration of ≤0.09%,	All unaged and 5-year aged filters had a penetration of 0.09%.
Sodium Chloride Particulate Removal		Pre- and post-conditioning penetrations of <1%	Unaged and 5-year aged filters had acceptable performance for pre-conditioning and post-conditioning penetration.

Methodology	Purpose	Acceptance Criteria	Results
Filter Media Integrity with 50 cm hydrostatic head	Evaluate hydrophobicity (resistance to penetration by a measured column of liquid)	No water breakthrough of the filter media for 60 seconds after application of a 50 cm head of sterile water	No unaged or 3-year aged filter showed water breakthrough.
Air Flow Resistance (Pressure Drop) Pre- and Post-hydrostatic head	Evaluate any changes in the filter's resistance to air flow before and after being subjected to a 15 cm hydrostatic head.	At 60 L/min, average inspiratory/expiratory flow resistance should be $\leq$2.5 cm H2O pre-hydrostatic head and ≤6.0 cm H2O post-hydrostatic head, and no evidence of water breakthrough within 60 seconds of the 15 cm hydrostatic head.	The pre-hydrostatic head and post-hydrostatic maximum flow resistance were passing across all unaged, 3-year aged, and 5-year aged filters.
Heat and Moisture Exchange efficiency	Evaluate moisture loss for tidal volumes of 250 mL, 500 mL, 750 mL, and 1000 mL	<12 mg/L (10-12 mg H2O/L) at 250 ml tidal volume; <16 mg/L (13-16 mg H2O/L) at 500 ml tidal volume; <20 mg/L (19 mg H2O/L) at 750 ml tidal volume; <22 mg/L (19-22 mg H2O/L) at 1000 ml tidal volume.	The average moisture loss met the acceptance criteria for the specified tidal volumes for unaged, and aged (1, 3, & 5 years filters.
	Evaluate pressure drop pre and post moisture loss testing	The inspiratory/expiratory flow resistance should be <2.5 cm H2O at 60 L/min	For unaged as well as 1, 3 & 5 year aged filters, the maximum inspiratory and expiratory flow resistance were passing, showing that the pressure drop does not increase when conditioned for the length of filter use or when challenged with liquid.
	Evaluate leakage (pressure decay) under an applied pressure pre and post moisture loss testing	ISO 9360-1 Section 6.4 does not specify acceptance criteria, only to record the volume of air required; however, Pall has specified an internal acceptance criteria for leakage of <25 mL/min at 7 ± 0.5 kPa.	The maximum leakage values for unaged as well as for 1, 3 & 5 year aged filters met predefined criteria both pre- and post-moisture loss.
	Evaluate compliance in accordance with ISO 9360 pre- and post- moisture loss testing	ISO 9360-1 Section 6.5 does not specify an acceptance criterion, only to record the volume of air required.	There was no significant increase in flow rate following filter conditioning. All test values for unaged and aged (1, 3, & 5 years) filters were acceptable.
Housing Integrity (for pressure decay)	Evaluate filter leakage at two different pressures	Leakage <4 ml/min for unaged filters at 70 mbar (7 kPa) and 150 mbar (15 kPa); leakage <25 ml/min at 70 mbar (7 kPa) for aged filters.	Unaged as well as 1 & 3 year aged filters had leakage values meeting the predefined acceptance criteria at the evaluated pressures.
Connector Compliance	Demonstrate inlet and outlet ports comply with ISO 5356-1	All ports must comply with ISO 5356-1	For both 15 mm and 22 mm connectors, axial force and rotation for unaged and 1 & 3 year aged filters were in accordance with the standard.

Methodology	Purpose	Acceptance Criteria	Results
Nebulization	Evaluate changes in air flow resistance across filter when used with nebulized drugs at patient and machine ends of breathing circuit	Air flow resistance <6 cm H2O at 60 L/min airflow after 24 hours of nebulization	Unaged & 3 year aged filters: Highest flow resistance values were within specification for both filter locations and for drugs delivered by air-driven and ultrasonic nebulizers as well as drugs delivered by metered dose inhalers, as applicable.
Particulate Analysis	Assess if airborne particulate is emitted into the gas stream in accordance with ISO 18562	Particulate category PM2.5 and PM10 acceptable concentrations: 12 µg/m^3 and 150 µg/m^3, respectively	The minimum, maximum, and average particulate concentrations are all below acceptable limits
Volatile Organic Compounds (VOCs) Analysis	Assess if airborne VOCs are emitted from the filter into the gas stream per ISO 18562	Threshold of Toxicological Concern (TTC) of 360 µg/d for the first 24 hours and a limit of 120 µg/d for the remaining 24 hours	Exposure of the individual VOCs released are all below pre-defined TTC
Shelf life (stability / maintained performance)[1]	Evaluate shelf life	3 years from the date of manufacture based on the stability testing	Stability of device confirmed from performance testing conducted on 3-year real-time aged and 5-year accelerated aged devices.

[1] Testing also performed during filter manufacturing process.
[2] The subject filter is not supplied sterile and therefore does not have an expiry date based on validation of the integrity of a sterile barrier seal.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Intersurgical Inc.'s Model 1745 Hydro-Guard Mini Breathing Filter and Health and Moisture Exchanger (K092409).