DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 11, 2015

Merck Millipore Ltd.
Chris Parr
Regulatory Affairs Specialist III
Tullagreen, Carrigtwohill
Co. Cork, Ireland

Re: K143583
Trade/Device Name: Cathivex®-GV Filter Units
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPB
Dated: June 29, 2015
Received: July 6, 2015

Dear Mr. Parr:

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" (21CFR 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 yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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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)*
K143583

Device Name
Cathivex®-GV Filter Units

Indications for Use *(Describe)*
Cathivex®-GV filter units are in-line 0.22µm, sterilizing-grade filters for use with intravenously administered aqueous solutions. The filters remove particulates, microbial contamination, and air bubbles in applications where venting and low protein binding membranes are required or desired.

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 K143583

Date Prepared	August 11, 2015
Name, address and telephone number of submitter	Merck Millipore Ltd. Tullagreen, Carrigtwohill Co. Cork, Ireland Phone: +353.21.4883666 / Fax: +353.21.4883048
Contact Person	Chris Parr Merck Millipore | Global Regulatory Management

Device Trade Name	Cathivex®-GV Filter Units
Device Common Name	Filter Unit
Model Number	SLGV0250S
Device Class	II
Product Code	FPB
Regulation Number	880.5440
Regulation Name	Intravascular administration sets

Device Description

Cathivex®-GV filter units are sterile, non-pyrogenic, single-use filter devices intended for sterile filtration of aqueous solutions for intravenous infusions. Cathivex®-GV filter units are designed with a Female Luer Lok™ inlet and a Male Luer Lok™ outlet. Cathivex®-GV filter units contain a 0.22µm Durapore® hydrophilic filter membrane constructed from polyvinylidene fluoride (PVDF) and a 0.03µm hydrophobic vent membrane constructed from polytetrafluoroethylene (PTFE). The filter membrane is designed to remove particles, microorganisms, microprecipitates and undissolved powders which are larger than 0.22 µm. The vent membrane is designed to prevent air locks and air emboli by automatically venting air introduced upstream. The filter housing material is molded from PVC.

Indications for Use

Cathivex®-GV filter units are in-line 0.22µm, sterilizing-grade filters for use with intravenously administered aqueous solutions. The filters remove particulates, microbial contamination, and air bubbles in applications where venting and low protein binding membranes are required or desired.

Predicate Device

Cathivex®-GV filter units are substantially equivalent to the following legally marketed predicate device, Pall Supor® AEF Filter.

Applicant	Pall Medical
Device Trade Name	Pall Supor® AEF Filter
Model Number	AEF1NTE
510(k) Number	K993379
Clearance date	12/16/1999
Device Class	II
Product Codes	FPB
Regulation Numbers	880.5440
Regulation Names	Intravascular administration sets
Indications for Use	Removal by in-line filtration of inadvertent contaminants (including bacteria, particles, and entrained air) from infused intravenous fluids.

Predicate Device Description

The Pall Supor® AEF filter is an air eliminating filter with low protein binding 0.2µm Supor membrane for up to 24 hours use, with any administration set, for the removal of inadvertent particulate debris, microbial contaminants and entrained air which may be found in solutions intended for intravenous use. The filter units are sterile, non-pyrogenic, single use filter units. Pall Supor® AEF filter is designed with a Female Luer Lok™ inlet and a Male Luer slip outlet with rotating locking collar. The filter membrane is Supor®

polyethersulfone with a pore size of 0.2µm (micron). The filter housing material is molded from acrylic polymer.

Summary of Technological Characteristics

The Intended Use for Cathivex®-GV filter units is the same as the predicate device in regards to in-line filtration of solutions administered intravenously.

Cathivex®-GV filter units and Pall Supor® AEF incorporate a common design feature of a vent membrane for venting air introduced upstream. The presence of a vent membrane in Cathivex®-GV filter units is considered a key technological similarity which is pivotal to the device achieving its intended use to prevent air locks caused by air introduced upstream and from preventing air emboli from entering the patient. Cathivex®-GV filter units and Pall Supor® AEF also include an application for low protein binding. This application is making use of the existential properties of the Durapore® PVDF filter membrane which is a low protein binding material.

From a design perspective there are similarities and differences between the predicate device and the subject device. The key similarity is the filter membrane pore size which is the same. The key difference is the introduction of the Durapore® PVDF filter membrane. Biocompatibility testing has been performed to address the difference between the filter membrane of the predicate and subject device. The material used in the molding of the filter housing of the predicate device (acrylic polymer) is different to that of the subject device (PVC). Biocompatibility testing has been performed to address the difference between the housing materials of the predicate and subject devices which offers suitable mechanical properties for the application.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Filter unit for in-line filtration.
- Intended to remove particles, microbial contaminants, and air.
- 0.22µm filter membrane pore size.
- Sterile, single use device.
- Hydrophobic vent membrane.
- Luer inlet and outlet connections.

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The following technological differences exist between the subject and predicate devices:

- Use of a different filter membrane type.
- Materials used in molding the filter housing.

The performance of the subject device has been verified through bench testing and the filter units have demonstrated to perform as intended.

Summary of Nonclinical Testing

The following performance data were provided in support of the substantial equivalence determination. All specified performance requirements were met.

Device Testing

- Visual Inspection
- Filter Integrity Test
- Burst Test
- Gravity Flow Test
- Bubble Point Test
- Water Intrusion Test
- Endotoxin LAL Test
- Particle Count Downstream Test
- Gravimetric Test
- Luer Insertion Test
- Bacterial Retention Test
- Packaging Test
- Hold Up Volume Test
- USP Mouse Safety Test
- Physical Testing (ISO 8436-4)
- Chemical Testing (ISO 8536-4)

Packaging Testing

- Peelability Test
- Dye Test
- Strength of Blister Seal and Burst Strength Test

- Blister Seal Width
- Unit Packaging including Print Inspection

Biocompatibility

Biocompatibility testing was conducted in accordance with standard ISO 10993-1:2009 *Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process,* and the FDA Blue Book Memorandum #G95-1 *Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*. The battery of testing included the following tests:

- Cytotoxicity.
- Sensitization.
- Intracutaneous reactivity.
- Systemic toxicity (acute).
- Haemocompatibility.

Sterilization

Cathivex®-GV filter units are sterilized with ethylene oxide (EO) gas using a validated sterilization cycle. Sterilization validation was conducted in accordance with ISO 11135-1:2007 *Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* and FDA Guidance *Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA.*

Cathivex®-GV filter units are sterilized using Ethylene Oxide (EO) at 100% gas concentration in a 3 hour 30 min exposure cycle at the target parameters for temperature, relative humidity and gas concentration. The sterilization cycle has been validated to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Shelf Life

Cathivex®-GV filter units have a 3 year shelf life that is supported by accelerated and real-time stability studies.

The results demonstrate that the device maintains its performance and sterility throughout the duration of the study and supports a 3 year shelf life.

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Summary of Clinical Testing

This 510(k) premarket notification does not contain any clinical performance testing data obtained from clinical investigations or from literature sources with the predicate or subject device for the purposes of demonstrating substantial equivalence.

Summary and Conclusions from Non-Clinical and Clinical Testing

Cathivex®-GV filter units are substantially equivalent to the predicate device Pall Supor® AEF because they share the following similarities:

- Device Class (class II)
- Product Code (FPB)
- Intended Use (in-line filtration of solutions administered intravenously)
- Filter Membrane Pore Size (0.22µm)
- Vent Membrane Type (hydrophobic membrane)
- High degree of similarity in design and principle of operation

Non-Clinical performance testing was conducted for Cathivex®-GV filter units in order to demonstrate that the filter units perform as intended and meet user needs and intended uses. All specified performance requirements were met for Device Testing and Packaging Testing. Biocompatibility testing was conducted in accordance with ISO 10993-1 and Blue Book Memorandum #G95-1, and demonstrated acceptable results. Sterilization Validation was completed in accordance with ISO 11135-1:2007 to achieve a Sterility Assurance Level (SAL) of 10^{-6}. Shelf life testing demonstrated that the device maintains its performance throughout the proposed 3 year shelf life.

Based on the data presented in this 510(k), the subject device is sufficiently similar in design and intended use to the predicate device that they are considered to be substantially equivalent as supported by Non-Clinical performance testing.

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