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510(k) Summary K133004

Date Prepared	March 14, 2014
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Device Trade Names	Vented Millex®-GV, Cathivex®-GV
Device Common Name	Filter Units
Model Numbers	SLGVV255F, SLGVN250S
Device Class	II
Product Code	BSN
Regulation Number	868.5130
Regulation Name	Anesthesia conduction filter

Device Description

Vented Millex®-GV and Cathivex®-GV filter units are sterile, non-pyrogenic, single-use filter devices intended for sterilizing aqueous solutions for medical applications. Vented Millex®-GV is designed with a Female Luer Lok™ inlet and a Male Luer slip outlet, and Cathivex®-GV is designed with a Female Luer Lok™ inlet and a Male Luer Lok™ outlet. Both devices 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 by automatically venting air introduced upstream. The filter housing material is molded from PVC.

Indications for Use

Vented Millex®-GV filter units are syringe filters for sterilization of low volume aqueous solutions for direct patient injection, filtration of laboratory solutions, and filtration of clinical solutions where venting and low protein binding membrane are required or desired. Cathivex®-GV filter units are in-line gravity fed filters for the sterilization of aqueous solutions for administration via the neuraxial route, filtration of laboratory solutions, and filtration of clinical solutions where venting and low protein binding membrane are required or desired.

Predicate Device

Vented Millex®-GV and Cathivex®-GV are substantially equivalent to the following legally marketed predicate device, Millex®-GV.

Applicant	Millipore Corporation
Device Trade Name	Millex®-GV, 33mm
Model Number	SLGVM33RS
510(k) Number	K023892
Clearance date	1/17/2003
Device Class	II
Product Codes	BSN, FPB
Regulation Numbers	868.5130, 880.5440
Regulation Names	Anesthesia conduction filter, Intravascular administration sets
Indications for Use	Intended for use as a syringe filter to sterilize, ultraclean or clarify low volume solutions in direct patient care and pharmacy admixture applications.

Predicate Device Description

Millex®-GV 33mm syringe filter units are sterile, non-pyrogenic, single use syringe filter units intended for sterilizing and/or clarifying small volumes of aqueous solutions, alcohols and proteinaceous solutions. Millex®-GV 33mm is designed with a Female Luer Lok™ inlet and a Male Luer slip outlet. They are designed to remove by filtration, particles, microorganisms, microprecipitates and undissolved powders larger than the

rated pore size of the device. The filter membrane is Durapore® (PVDF) with a pore size of 0.22µm (micron). The filter housing material is molded from modified acrylic. Typical applications include the sterile filtration and/or clarification of protein pharmaceuticals, diagnostic imaging agents, chemotherapeutics and associated low volume solutions in direct patient care and pharmacy admixture applications.

Summary of Technological Characteristics

The Intended Use for Vented Millex®-GV and Cathivex®-GV is the same, and is similar to the predicate device in regards to the sterilization of solutions for medical applications. The predicate device includes additional applications in the Intended Use for ultracleaning and clarification. These applications are not part of the Intended Use for Vented Millex®-GV and Cathivex®-GV, and do not alter the intended therapeutic effect when compared to the predicate.

Vented Millex®-GV and Cathivex®-GV include an application in the Indications for Use for venting. The introduction of a vent is considered an incremental product enhancement designed to prevent air locks caused by air introduced upstream. The introduction of a vent membrane is not considered to adversely affect safety and effectiveness. Vented Millex®-GV and Cathivex®-GV also include an application in the Indications for Use for low protein binding. This application is making use of the existing properties of the Durapore® PVDF filter membrane used in the predicate device. Durapore® PVDF is a low protein binding material, and as such, the predicate device would also be considered to be low protein binding.

From a design perspective there are similarities and differences between the predicate device and the subject devices. The key similarity is the filter membrane type and pore size which is the same. The key difference is the introduction of a vent membrane for venting of air introduced upstream. The materials used in the molding of the filter housing of the predicate device are different to those of the subject devices. PVC is considered a well established material offering suitable mechanical properties for the application. Biocompatibility testing has been performed to address the differences between materials of the predicate and subject devices.

The performance of the subject devices has been verified through bench testing and the filter units have been demonstrated to perform as intended. The subject devices do not introduce new risks or adversely affect safety and effectiveness.

Summary of Nonclinical Testing

The following design verification and validation tests were conducted on Vented Millex®-GV and Cathivex®-GV post-sterilization. All specified performance requirements were met.

Device Testing

- Visual Inspection
- Filter Integrity Test
- Burst Test
- Flow Rate Test (Vented Millex®-GV only)
- Gravity Flow Test (Cathivex®-GV only)
- Housing Test (Vented Millex®-GV only)
- Bubble Point Test
- Water Intrusion Test
- Endotoxin LAL Test
- Particle Count Downstream Test
- Gravimetric Test
- Luer Insertion Test
- Bacterial Retention Test
- Simulated Use Test
- Packaging Test
- Hold Up Volume Test
- Mouse Safety Test

Packaging Testing

- Peelability Test
- Dye Test
- Strength of Blister Seal and Burst Strength Test
- Blister Seal Width
- Unit Packaging including Print Inspection
- Product Sterility Test

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,* and demonstrated acceptable results.

Sterilization

- Vented Millex®-GV and Cathivex®-GV 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.*
- Vented Millex®-GV and 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

- Vented Millex®-GV and Cathivex®-GV have a 1 year shelf life that is supported by accelerated and real-time stability studies.
- The results demonstrate that the devices maintain their performance and sterility throughout the duration of the study and support a 1 year shelf life.

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 devices for the purposes of demonstrating substantial equivalence or safety and effectiveness.

Summary and Conclusions from Non-Clinical and Clinical Testing

Vented Millex®-GV and Cathivex®-GV Filter Units are substantially equivalent to the predicate device Millex®-GV 33mm because they share the following similarities:

- Device Class (class II)
- Product Code (BSN)
- Intended Use (sterilization)
- Filter Membrane Type (Durapore® PVDF, 0.22 µm)
- Packaging Design (Blister with medical paper lid)
- High degree of similarity in design and principle of operation

Non-Clinical performance testing was conducted for Vented Millex®-GV and Cathivex®-GV 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 devices maintain sterility and performance throughout their 1 year shelf life.

Based on the data presented in this 510(k), the subject devices are 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. Any differences that do exist are deemed not to significantly affect the safety and effectiveness of the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 27, 2014

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

Re: K133004
Trade/Device Name: Vented Millex®-GV, Cathivex®-GV
Regulation Number: 21 CFR 868.5130
Regulation Name: Anesthesia Conduction Filter
Regulatory Class: II
Product Code: BSN
Dated: January 13, 2014
Received: January 16, 2014

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and

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)*
K133004

Device Name
Vented Millex®-GV, Cathivex®-GV

Indications for Use *(Describe)*
Vented Millex®-GV filter units are syringe filters for sterilization of low volume aqueous solutions for direct patient injection, filtration of laboratory solutions, and filtration of clinical solutions where venting and low protein binding membrane are required or desired.
Cathivex®-GV filter units are in-line gravity fed filters for the sterilization of aqueous solutions for administration via the neuraxial route, filtration of laboratory solutions, and filtration of clinical solutions where venting and low protein binding membrane 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)

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)*

Digitally signed by Richard C. Chapman
Date: 2014.03.26 19:26:38 -04'00'

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