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

October 31, 2014

Sterilucent, Inc.
Mr. Peter R. Kalkbrenner
Director of Engineering
1400 Marshall Street NE
Minneapolis, MN 55413

Re: K140464
Trade/Device Name: Sterilucent PSD-85 Hydrogen Peroxide Sterilizer
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: II
Product Code: MLR
Dated: September 25, 2014
Received: October 2, 2014

Dear Mr. Kalkbrenner:

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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Office of Device Evaluation
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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)*
K140464

Device Name
Sterilucent PSD-85 Hydrogen Peroxide Sterilizer

Indications for Use *(Describe)*
The Sterilucent PSD-85 Hydrogen Peroxide Sterilizer (PSD-85) is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities. The two pre-programmed sterilization cycles, the Lumen and the Non-Lumen Cycles, operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The PSD-85 Lumen Cycle can sterilize*:
• Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
• Medical devices with a single stainless steel lumen with:
o An inside diameter of 1 mm or larger and a length of 60 mm or shorter
o An inside diameter of 2 mm or larger and a length of 250 mm or shorter
o An inside diameter of 3 mm or larger and a length of 350 mm or shorter

*The validation testing for all lumen sizes was conducted using a maximum of ten (10) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of one instrument tray with a total weight of 10.4 lbs.

The PSD-85 Non-Lumen Cycle can sterilize**:
• Non-lumen instruments including non-lumen instruments with stainless steel diffusion-restricted areas such as the hinged portion of forceps or scissors.

**The validation studies were conducted using a validation load consisting of one instrument tray with a total weight of 25.3 lbs.

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)*

510(k) Summary
for the
Sterilucent PSD-85 Hydrogen Peroxide Sterilizer

Owner: Sterilucent, Inc.
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Telephone: 612-767-3260
Fax: 612-767-3261

Contact: Peter R. Kalkbrenner
Director of Engineering

Telephone: 612-767-3253
Fax: 612-767-3261

Summary Date: 31 October, 2014

Device Name and Classification

Trade Name:	Sterilucent PSD-85 Hydrogen Peroxide Sterilizer
Common/Usual Name:	Vapor Phase Hydrogen Peroxide Sterilizer
Classification Name:	Sterilizer, Ethylene Oxide Gas
Device Class:	Class II
FDA Classification Number:	880.6860
Product Code:	MLR

Predicate Device

AMSCO® V-PRO™ 1 Plus Low Temperature Sterilization System (K083097)

Device Description

The Sterilucent PSD-85 Hydrogen Peroxide Sterilizer (PSD-85) is a self contained stand alone device, using vaporized hydrogen peroxide as the sterilant. The PSD-85 is intended for use in the terminal sterilization of cleaned, rinsed, and dried, reusable metal and non-metal medical device used in healthcare facilities. The sterilization cycle operates at low pressure and temperatures, and is therefore suitable for processing medical devices that are sensitive to heat and moisture. The hydrogen peroxide vapor is generated by heating aqueous hydrogen peroxide and injecting into a chamber.

Statement of Intended Use

The PSD-85 is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities. The two pre-programmed sterilization cycles, the Lumen and the Non-Lumen Cycles, operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The PSD-85 Lumen Cycle can sterilize*:

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Medical devices with a single stainless steel lumen with:
    - An inside diameter of 1 mm or larger and a length of 60 mm or shorter
    - An inside diameter of 2mm or larger and a length of 250 mm or shorter
    - An inside diameter of 3mm or larger and a length of 350 mm or shorter

  *The validation testing for all lumen sizes was conducted using a maximum of ten (10) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of one instrument tray with a total weight of 10.4 lbs.

The PSD-85 Non-Lumen Cycle can sterilize**:

- Non-lumen instruments including non-lumen instruments with stainless steel diffusion-restricted areas such as the hinged portion of forceps or scissors.

  **The validation studies were conducted using a validation load consisting of one instrument tray with a total weight of 25.3 lbs.

Technological Characteristics Summary Comparison

The PSD-85 has similar technological characteristics as the predicate device as shown in the detailed side by side comparison in the following table.

	PSD-85	**V-Pro 1 Plus**
Physical Characteristic	Self contained, stand alone device	Self contained, stand alone device
Design and Construction	Welded frame onto which is mounted the sterilization chamber along with a variety of instruments and components, controls, piping, and vacuum pump, all of which is housed in covered frame	Welded frame onto which is mounted the sterilization chamber along with a variety of instruments and components, controls, piping, and vacuum pump, all of which is housed in covered frame
-Chamber volume	85 L	136 L
-Weight	440 pounds (200 kg)	755 pounds (342 kg)
-Maximum Power	1650 Watts	3680 Watts
Sterilant	59% aqueous solution of hydrogen peroxide	59% aqueous solution of hydrogen peroxide

	PSD-85	V-Pro 1 Plus
Internal Process Monitors		
-Temperature	Chamber and vaporizer thermistors	Chamber and vaporizer temperature probes
-Pressure	Chamber pressure transducers	Chamber pressure transducers
-Sterilant Concentration	Real-time hydrogen peroxide vapor monitor	None
Control System	Atmel AT91SAM7 Microprocessor	Programmable logic control (PLC)
Operational Principle	Sterilization of the intended devices by exposure under controlled conditions of pressure, temperature, and time	Sterilization of the intended devices by exposure under controlled conditions of pressure, temperature, and time
Operational Parameters	Low pressure (vacuum; sub-atmospheric down to 0.4 Torr) and temperature (55 ^{o}C)	Low pressure (vacuum; sub-atmospheric down to 0.4 Torr) and temperature (50 ^{o}C)
Pre-processing requirements	Cleaned, rinsed and dried devices	Cleaned, rinsed and dried devices
Devices	Reusable metal and non-metal medical devices that are used in healthcare facilities, including those that are sensitive to heat and moisture	Reusable metal and non-metal medical devices that are used in healthcare facilities, including those that are sensitive to heat and moisture
Sterilization Cycles	Two (2) pre-programmed: Lumen (approximately 72 minutes) and Non-Lumen (approximately 40 minutes)	Two (2) pre-programmed: Lumen (approximately 63 minutes) and Non-Lumen (approximately 28 minutes)
Monitoring	Both systems have biological and chemical indicators	
- Biological Indicator	Self-contained biological indicator, *Geobacillus stearothermophilus*	Self-contained biological indicator, *Geobacillus stearothermophilus*
- Process Challenge Device / Routine Test Pack	Self-contained biological indicator, *Geobacillus stearothermophilus*	Self-contained biological indicator, *Geobacillus stearothermophilus*
-Chemical Indicator	Sterilucent CI Strips, Labels and Tape	Steris VHP – HC CI
Miscellaneous	The two sterilizers have equivalent packaging options	
- Load Packaging	Tyvek/Mylar pouches, trays wrapped with polypropylene sterilization wrap, rigid containers	Tyvek/Mylar pouches, trays wrapped with polypropylene sterilization wrap, rigid containers

Technological differences between the PSD-85 and the predicate device are minimal and mainly limited to differences in sterilization cycle parameters that do not affect the relative safety or efficacy of the two devices. The PSD-85 sterilization cycle parameters have been shown to provide a level of safety and efficacy at least equivalent to that of the predicate device. Differences include:

- The PSD-85 has a smaller sterilization chamber, smaller overall size, is lighter, and uses less energy compared to the predicate device.
- The PSD-85 chamber temperature is 55ºC versus 50ºC for the predicate device. This slightly higher temperature minimizes condensation of hydrogen peroxide vapor on the load.
- The PSD-85 conditioning phase used to detect and, if necessary, remove residual moisture from loads being sterilized, is more sophisticated than the predicate device in that the PSD-85 process takes extra steps to reduce the probability of ice formation on the load.
- The PSD-85 uses a variable dose of sterilant based on real time measured and monitored hydrogen peroxide vapor concentration versus a fixed dose of sterilant for the predicate device. Worst case biological performance, sterilant residue, and biocompatibility testing has demonstrated that the safety and efficacy of the PSD-85 is equivalent or better than that of the predicate device.
- The PSD-85 aeration period involves an extra two minute period where aeration is enhanced by actively moving air through the chamber and the sterilized load. Worst case sterilant residue, biocompatibility, and toxic residue tests and analyses indicate that the PSD-85 exposure sequence and aeration period reduces residual sterilant and other potentially toxic substances to a level of safety equal to or greater than the predicate device.

Summary of Non-clinical Performance Data

Testing was performed using the "overkill" method.

Pre-Validation Testing

Test Organism: *Geobacillus stearothermophilus*

Process Variables and Parameters: Testing was conducted to characterize the effect of process parameters on lethality. The four critical process parameters are chamber wall temperature, vaporizer temperature, injection pressure and vaporized hydrogen peroxide concentration. The level tested for each parameter was selected to provide a worst case situation for the test series and to be outside the abort levels or settings for the sterilizer. The study showed that process lethality was unaffected over the range of tested process parameters.

PSD-85 Process Validation

Demonstration of Dose-Response Relationship to Increasing Hydrogen Peroxide Concentration

Dose response testing was performed using various materials (representative of materials used in medical devices) as spore carriers.

Geobacillus stearothermophilus death kinetics data obtained for each material tested demonstrate a positive "dose response" to increasing concentration of hydrogen peroxide injected under half cycle conditions in the PSD-85. There were no spore survivors on any material at concentrations lower than the standard exposure concentration for the Lumen and Non-Lumen Cycles. The result demonstrates that the dose response observed in not limited to a single substrate and in each case >6 Spore Log Reduction (SLR) was observed for a half cycle exposure.

Surface Sterilization

The purpose of the study was to demonstrate sterilization of medical device surfaces. *Geobacillus stearothermophilus* spores were inoculated on a wide variety of material coupons that were representative of materials used in re-usable medical devices. The coupons were inoculated with at least 10^6 *Geobacillus stearothermophilus* spores and then exposed to ½ cycle sterilization parameters.

Results from this testing demonstrate a Sterility Assurance Level (SAL) of at least 10^{-6} for medical device surface sterilization in the PSD-85 for all materials listed as recommended for use in the PSD-85.

Mated Surface Sterilization

The purpose of the study was to demonstrate sterilization of mated medical device surfaces using the PSD-85. *Geobacillus stearothermophilus* spores were inoculated on a variety of medical device materials. The materials were than mated to the same material and exposed to ½ cycle sterilization parameters. An SAL of least 10^{-6} was demonstrated for mated material sterilization.

Lumen Sterilization

The purpose of this validation test was to demonstrate that the PSD-85 could effectively sterilize specific dimensions of rigid stainless steel lumened medical devices. Testing was completed by placing at least 10^{-6} *Geobacillus stearothermophilus* spores in the center of the lumens and exposing them to ½ cycle sterilization parameters. There were no spore survivors after multiple ½ cycle exposure tests.

Results from this testing demonstrate an SAL of at least 10^{-6} for lumen sterilization in the PSD-85 for the lumen dimensions listed as indicated for use in the PSD-85.

Bacteriostasis Testing

This purpose of bacteriostasis testing is to determine if materials exposed to the PSD-85 full sterilization cycle inhibit the growth of *Geobacillus stearothermophilus* spores. Bacteriostasis testing was performed with coupons of representative materials. The materials were exposed to three consecutive full sterilization cycles. Following exposure, the coupons were transferred to growth media and were inoculated with 100 colony-forming units of *Geobacillus stearothermophilus*. All test materials demonstrated the desired outgrowth within the 7 day incubation period. The test data indicates no bacteriostatic effect from materials processed in the PSD-85.

Simulated Use Testing

Simulated use testing was performed to confirm sterilization of medical device outer surface and lumens after processing in the PSD-85. Representative lumen and non-lumen devices were inoculated with at least 10^{-6} *Geobacillus stearothermophilus* spores, suspended in an inorganic and organic challenge soil and exposed to a full sterilization cycle. This process was repeated in triplicate for devices that were not clean for both the Lumen and Non-Lumen Cycles. The results showed sterility of all tested devices.

In-Use Testing

Devices representative of surface-features and lumen claims for the PSD-85 were selected for sterility testing. Devices tested were used in routine surgeries at a hospital and included stainless steel devices with open surfaces, mated or hinged surfaces and representative stainless steel lumen devices. The used devices were washed and dried by the hospital according to hospital protocol and transported to the PSD-85 location for processing. The results of the in-use testing demonstrated that the PSD-85 successfully sterilizes surgical instruments used in clinical cases.

Supporting Microbiological Testing

Sterilizing agent efficacy (Sporicidal Activity of a Disinfectant) testing was performed in the PSD-85 in accordance with the guidelines provided in AOAC Official Method 966.04, Sporicidal Activity of Disinfectants. None of the carriers demonstrated growth.

Software Validation

Software validation was performed according to FDA's moderate level of concern recommendations provided in the document "Guidance for the Content for Premarket Submissions for Software Contained in Medical Devices".

Overall Performance Conclusion Statement

The non-clinical studies demonstrated that the PSD-85 is as safe and effective for the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities, including heat and moisture sensitive medical devices, within the indications for use for the sterilizer, and established substantial equivalence of the PSD-85 to the predicate device, the AMSCO® V-PRO™ 1 Plus Low Temperature Sterilization System.