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

February 1, 2018

Crosstex/SPSmedical Supply Corp
Mr. Brent Geiger
Sr. Director, Global Regulatory Compliance
6789 W. Henrietta Road
Rush, NY 14543

Re: K171287
Trade/Device Name: SporView® VH_2O_2 BI

Regulation Number: 21 CFR 880.2800
Regulation Name: Biological Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: December 22, 2017
Received: December 26, 2017

Dear Brent Geiger:

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 yours,

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)*

K171287

Device Name

SporView® VH2O2 BI

Indications for Use *(Describe)*

The SporView® VH2O2 BI is a self-contained biological indicator intended for use in the following STERRAD® sterilization system:

- STERRAD® 100NX® (Standard Cycle)

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

1.0 Submitter

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Contact: Brent Geiger
Phone: (763) 553-3345
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510(k) Number: K171287

Date Submitted: 1/26/2018

2.0 Device

Trade Name: SporView® VH_2O_2 BI
Common Name: Biological Indicator
Classification: Biological Sterilization Process Indicator (21 CFR 880.2800)
Device Class: II
Product Code: FRC

3.0 Predicate Device

STERRAD® CYCLESURE® 24 Biological Indicator (K151971)

4.0 Device Description

The SporView® VH_2O_2 BI is a self-contained biological indicator (SCBI) designed to monitor hydrogen peroxide sterilization efficacy in healthcare facilities, specifically within a STERRAD® 100NX® Standard Cycle. Each unit consists of a glass fiber disc inoculated with a minimum of 10^6 spores of *Geobacillus stearothermophilus* ATCC® 7953 and a hermetically sealed glass ampoule of modified growth medium, both contained within a polypropylene vial with a polypropylene filter lined within the top of a polypropylene cap. A chemical process indicator on the vial label allows for differentiation between processed and unprocessed units.

Following exposure to the sterilization cycle, the BI is activated by squeezing the sides of the vial, causing the media ampoule to break and immerse the inoculated carrier in growth medium. The BI is then incubated at 55 – 60ºC for 24 hours. The growth medium, comprised of soybean casein digest broth modified with bromocresol purple (a pH

indicator), remains purple and free of turbidity if the sterilization cycle was effective. Spore growth produces acidic waste (carbonic acid) which causes a shift down in pH (acidic) within the growth medium, transitioning the media from a purple to a yellow color and/or exhibiting turbidity which both indicate a failed sterilization cycle.

5.0 Indications for Use

The SporView® VH_2O_2 BI is a self-contained biological indicator intended for use in the following STERRAD® sterilization system:

- STERRAD® 100NX® (Standard Cycle)

6.0 Comparison of Technological Characteristics with the Predicate Device

The SporView® VH_2O_2 BI and its predicate device – STERRAD® CYCLESURE® 24 Biological Indicator legally marketed under K151971 – are substantially equivalent in that they both have the same intended use, fundamental technology and general performance.

Similarities between subject and predicate devices – The subject and predicate devices are both intended to routinely monitor vaporized hydrogen peroxide sterilization of the STERRAD® 100NX® Standard Cycle. Both devices have the same self-contained biological indicator components – inoculated glass fiber disc, glass ampoule, growth media, vial, cap and liner. Both BIs have spore carriers containing ≥ 1.0×10^6 *Geobacillus stearothermophilus* and produce a growth media color change of purple to yellow in the presence of spore growth.

Differences between subject and predicate devices – The only notable difference between the subject and predicate device is that the survival and kill times are longer in duration for the SporView® VH_2O_2 BI than the predicate device. The performance testing has demonstrated that this difference raises no questions of safety or efficacy and the subject device performs equivalently to the predicate device.

The following table outlines the similarities and differences between the subject and predicate devices:

Element	Subject Device	Predicate Device
	SporView® VH_2O_2 BI	**STERRAD® CYCLESURE 24 Biological Indicator**
Biological Indicator Design	Same as predicate	Self-Contained Biological Indicator
Method of Sterilization	Same as predicate	Vaporized hydrogen peroxide
Indications for Use	The SporView® VH_2O_2 BI is a self-contained biological indicator intended for use in the following STERRAD® sterilization system: • STERRAD 100NX® (Standard Cycle)	The device is intended for use in the following STERRAD® sterilization systems: • STERRAD 100S • STERRAD 50 • STERRAD 200

		• STERRAD NX® • STERRAD 100NX (Standard, Flex and Express Cycles) – For STERRAD 100NX Duo Cycle in the United States, the STERRAD CYCLESURE 24 Biological Indicator should only be used in a test pack configuration (REF 20243)
Organism	Same as predicate	*Geobacillus stearothermophilus*, ATCC™ 7953
Viable Spore Population	Same as predicate	≥ 1.0×10^6
BI Components	Same as predicate	Inoculated glass fiber disc and glass ampoule with growth media contained within a vial and enclosed with a cap with liner
Carrier Material	Same as predicate	Glass fiber
Growth Medium Color Change	Same as predicate	Purple to yellow
Resistance Characteristics	Using 2.5 mg/L of hydrogen peroxide: • *D* value: ≥ 1 second • Survival: ≥ 6 seconds • Kill: ≤6 minutes	Using 2.5 mg/L of hydrogen peroxide: • *D* value: ≥~1 second • Survival: Calculated based on *D* value • Kill: 60 seconds
Incubation Temperature	Same as predicate	55 – 60ºC
Incubation Duration	24 hours	24 – 72 hours
Shelf Life	9 Months	12 Months

7.0 Performance Data

Testing was performed to support substantial equivalence of the SporView® VH_2O_2 BI to the predicate device.

Study Performed	Details and Acceptance Criteria	Results
Spore Population	Assay to demonstrate spore population of the BI meets specification of ≥1.0 x 10^6.	Pass
D Value Determination	Assessment to demonstrate subject device meets the D value specification of ≥1 second.	Pass
Survival and Kill Response	Assessment to demonstrate the subject device meets the survival specification of ≥ 6 seconds and the kill specification of ≤ 6 minutes.	Pass
Effect of Holding Time	Evaluation of 24 hour holding time prior to incubation on resistance characteristics of subject BI. Holding time resistance characteristics met the D value specification and were equivalent to the original resistance characteristics.	Pass
Reduced Incubation Time	Determination of the minimum incubation time for the subject device. Subject device exhibited 30% to 80% growth following partial cycle exposure, resulted in a ≥97% correlation between the results observed at 24 hours and the results observed at seven days for a reduced incubation time of 24 hours.	Pass
Verification of Growth Media Color Change	Assessment to verify stability of growth media color change. Subject device growth media exhibited a color change to yellow, which did not revert to the original color of purple following incubation.	Pass
Suitability of Carrier and Primary Packaging Materials	Suitability testing of carrier and primary packaging materials of the subject device. Carrier and primary packaging material did not absorb sterilant or show degradative effects when exposed to worst case cycle conditions.	Pass
Shelf Life Testing	Verification of subject device's performance characteristics (spore population, D value, survival and kill response, RIT, and media color change stability) for 9 month labeled product shelf life.	Pass
Sterilization Cycle Performance Validation	Simulated use test to demonstrate no growth of subject device after exposure to half and full sterilization cycles under worst case conditions.	Pass

8.0 Conclusion

Based on the intended use, technological characteristics, performance data and non-clinical tests performed, the subject device is substantially equivalent to, and is as safe and as effective as the legally marketed predicate device, STERRAD® CYCLESURE® 24 Biological Indicator cleared in K151971, Class II (21 CFR 880.2800), product code FRC.