DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 9, 2015

Crosstex
SPSmedical Division
Mr. Michael Nolan
Research and Development Coordinator
6789 West Henrietta Road
Rush, NY 14543

Re: K143520
Trade/Device Name: SPSmedical VH_2O_2 External Indicators
Regulation Number: 21 CFR 880.2800(b)
Regulation Name: Physical/chemical sterilization process indicator
Regulatory Class: II
Product Code: JOJ
Dated: May 8, 2015
Received: May 12, 2015

Dear Mr. Nolan:

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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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)*
K143520

Device Name
SPSmedical VH2O2 External Indicators

Indications for Use *(Describe)*

A chemical indicator for monitoring all cycles within the STERIS® V-PRO™ 60 (Flexible, Lumen & Non-lumen). The VH_2O_2 Indicators are intended to be used by health care providers with sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed units. Colors other than blue such as yellow/green should be treated as a process failure.

CATALOG NUMBER	PRODUCT NAME
GPL-2000R	Indicator Label
5093	Indicator Card

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

SUBMITTER INFORMATION

SPSmedical Supply Corp.
a division of Crosstex International
6789 West Henrietta Road
Rush, NY 14543 U.S.A.

Contact: Michael G. Nolan
Research and Development Coordinator
Phone: (800) 722-1529 x 120
Fax: (585) 359-0167

Date of Summary: May 26, 2015

DEVICE NAME AND CLASSIFICATION

Device Trade Name:	SPSmedical VH_2O_2 External Indicators
Common Name:	Vaporized Hydrogen Peroxide Chemical Indicators
Classification Name:	Physical/chemical sterilization process indicator 21 CFR § 880.2800(b)
Review Panel:	General Hospital
Product Code:	JOJ
Device Class:	II

PREDICATE DEVICE:

SPSmedical VH_2O_2 Indicators K140566.

DEVICE DESCRIPTION:

The SPSmedical VH_2O_2 External Indicators are single use process indicators, intended for use in verifying exposure to all vaporized hydrogen peroxide cycles in the STERRAD® 100S, 200, 100NX, NX, STERIS® V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX and Sterilucent™ PSD-85 sterilizers. For purposes of this submission testing has been performed to validate the SPSmedical VH_2O_2 External Indicators for use in the Steris® V-PRO® 60 sterilizer.

Indicators will identify if an item has seen vaporized hydrogen peroxide during the Steris® V-PRO® 60 sterilization processes by changing from a pink to a blue signal color. They provide a visual indication to help distinguish between processed and unprocessed items.

Physical Properties: The SPSmedical VH_2O_2 External Indicators consist of two (2) devices, an indicator label and an indicator card. These devices have minor physical differences. The label has an adhesive backing while the card does not. They use the same manufacturing process and are printed on the same substrate.

Technical Characteristics: The chemical indicator ink utilized on the SPSmedical VH_2O_2 External Indicators has been formulated to meet the performance requirements ANSI/AAMI/ISO 11140-1 for Process Indicators.

Functional Characteristics: The SPSmedical VH_2O_2 External Indicators are designed to monitor sterilization cycles in low temperature vaporized hydrogen peroxide sterilizers. They are a reliable tool used for the monitoring of vaporized hydrogen peroxide sterilization processes and provide a visual indication that hydrogen peroxide (H_2O_2), an essential ingredient in the vaporized hydrogen peroxide sterilization process has been introduced into the sterilizer's chamber. Indicators will identify if an item has seen H_2O_2 during the sterilization process. Indicators change from an initial color of pink to a final signal color of blue.

INTENDED USE:

The SPSmedical VH_2O_2 External Indicators are intended to be used by health care providers with articles such as sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed items. Indicators change to a signal color of blue after exposure to vapor hydrogen peroxide.

510(K) SUMMARY

BIOCOMPATIBILITY

SPSmedical VH_2O_2 External Indicators are manufactured using nontoxic inks and substrates that will not alter the chemical composition of the products being sterilized and are safe for human contact. SPSmedical VH_2O_2 External Indicators can be disposed in general waste receptacles.

STORAGE CONDITIONS:

Store the SPSmedical VH_2O_2 External Indicators in a cool, dry place (15-30°C), and away from any alkaline chemicals, acids and sources of light.

NON-CLINICAL TESTING:

Since the SPSmedical VH_2O_2 External Indicators are a legally market device only the new Steris® V-PRO® 60 sterilization cycles were validated for use through simulated use testing. Three (3) lots of product were used which were all at or beyond their real time shelf life expiration of twenty four (24) months.

Simulated Use Testing: Consisted of verifying SPSmedical VH_2O_2 External Indicators turned blue in a half cycle with end of shelf life sterilant with a fully loaded chamber at Steris® by Steris® technicians. All testing was performed in triplicate in lumen, non-lumen and flexible cycles of the Steris® V-PRO® 60 sterilizer.

Shelf Life: When properly stored the SPSmedical VH_2O_2 External Indicators maintain a shelf life of up to two (2) years from the date of manufacture. The expiration date is located on every pack. Post processing indicator stability has been verified to maintain color change results for a minimum of six (6) months when properly stored.

All other concerns with the SPSmedical VH_2O_2 External Indicators have been previously validated. There have been no changes to the product since the predicate filing under K140566.

COMPONENTS:

Indicators are composed of commercially existing materials of synthetic paper or label stock (e.g. Tyvek ®, polypropylene, polystyrene etc…). The indicator ink is a nontoxic sterilization indicator ink that changes from an initial color of pink to a blue signal color when exposed to the stated vaporized hydrogen peroxide sterilization process described within this submission.

SUBSTANTIAL EQUIVALENCE DISCUSSION:

The predicate and subject devices are the exact same device. The predicate and subject devices are substantially equivalent in terms of their intended use, functional and technical characteristics within the vaporized hydrogen peroxide sterilization processes described within this submission.

PREDICATE I.D.

Trade Name:	SPSmedical VH_2O_2 Indicators	
Model No.:	GPS-250R	Indicator Strip
	GPS-250Y	Indicator Strip
	GPL-2000R	Indicator Label
	GPL-2000Y	Indicator Label
	HT-048	Indicator Tape
	HT-036	Indicator Tape
	5093	Indicator Card

510(K) SUMMARY

Submitter/holder: SPSmedical Supply Corp.
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Rush, NY 14543 U.S.A.
Phone: (585) 359-0130
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510(k) No.: K140566

COMPARISON OF INDICATIONS FOR USE (IFU):

Predicate IFU—A chemical indicator for monitoring all cycles within the STERRAD® 100S (Standard & Long), 200, 100NX (Standard, Flex & Express), NX (Standard & Advanced), STERIS® V-PRO™ 1, V-PRO™ 1 Plus (Lumen & Non-lumen), V-PRO® maX (Flexible, Lumen & Non-lumen) and Sterilucent™ PSD-85 (Lumen & Non-lumen). The VH_2O_2 Indicators are intended to be used by health care providers with sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed units. Colors other than blue such as yellow/green should be treated as a process failure.

Subject IFU—A chemical indicator for monitoring all cycles within the STERIS® V-PRO® 60 (Flexible, Lumen & Non-lumen). The VH_2O_2 Indicators are intended to be used by health care providers with sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed units. Colors other than blue such as yellow/green should be treated as a process failure.

CATALOG NUMBER	PRODUCT NAME
GPL-2000R	Indicator Label
5093	Indicator Card

Discussion—The Predicate Device and the Subject Device have the same IFU with the exception of cycles other than the cycles which are the principle of this 510(k) remain on the Subject IFU.

DESIGN DIFFERENCES PREDICATE VS. SUBJECT DEVICE:

The predicate and subject devices are the exact same device. The subject device seeks the Indication for Use within the Steris® V-PRO® 60.

SUBSTANTIAL EQUIVALENCE CONCLUSIONS

The subject device has the same intended use, technical characteristics and functional characteristics as the predicate device. Both provide a visual indication that the indicator has been exposed to the vaporized hydrogen peroxide sterilization process. Both are made of the exact same materials and exact same manufacturing processes. The non-clinical testing has been performed by and directed by Steris® Corporation and found to meet predetermined acceptance criteria.

510(K) SUMMARY

SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

ELEMENT	SUBJECT DEVICE (K143520)	PREDICATE (K140566)
Intended Use	Equivalent	Process Indicator
Indications for Use	A chemical indicator for monitoring all cycles within the STERIS® V-PRO™ 60 (Flexible, Lumen & Non-lumen). The VH_2O_2 Indicators are intended to be used by health care providers with sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed units. Colors other than blue such as yellow/green should be treated as a process failure. **Catalog Number** **Product Name** GPL-2000R Indicator Label 5093 Indicator Card	A chemical indicator for monitoring all cycles within the STERRAD® 100S (Standard & Long), 200, 100NX (Standard, Flex & Express), NX (Standard & Advanced), STERIS® V-PRO™ 1, V-PRO™ 1 Plus (Lumen & Non-lumen), V-PRO® maX (Flexible, Lumen & Non-lumen) and Sterilucent™ PSD-85 (Lumen & Non-lumen). The VH_2O_2 Indicators are intended to be used by health care providers with sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed units. Colors other than blue such as yellow/green should be treated as a process failure.
Device Design	Card, Label	Strip, Label, Tape, Card etc.
Endpoint Color	Equivalent	Signal Color of Blue
Indicator Agent	Equivalent	H_2O_2 Indicator Ink
Sterilization Method	Equivalent	Vaporized Hydrogen Peroxide
Device Materials	Equivalent	Synthetic Substrate
Performance—ISO 11140-1 Complete reaction cycle	Equivalent	Indicators turn to a complete reaction color of blue
Performance—ISO 11140-1 Incomplete reaction cycle	Equivalent	Indicators do not turn blue and are markedly different than the color achieved under the complete reaction cycle testing.
Biocompatibility	Equivalent	Non-toxic
Non-clinical Performance—Steris® V-PRO® 60 (Flexible, Lumen & Non-Lumen cycles)	Equivalent	Turns blue in a half cycle under worst case conditions.
Shelf-life	Equivalent	Up to 2 years

CONCLUSION:

Since the predicate device and the subject device are the exact same device, they have the same intended use, the same functional and technical characteristics; they are comprised of the same materials and performance. Non-clinical testing performed at Steris® by Steris® technicians in the Steris® V-PRO® 60 documents that based on the results from the nonclinical testing performed there are no concerns with the safety or effectiveness of the SPSmedical VH2O2 External Indicators. Based on these facts and the nonclinical tests performed the subject device is as safe, as effective, and performs as well as the predicate device [SPSmedical Vaporized Hydrogen Peroxide Chemical Indicators (K140566)].