October 21, 2019

Sterilucent, Inc.
Peter Kalkbrenner
Director of Engineering
1400 Marshall St. NE
Minneapolis, Minnesota 55413

Re: K191999
Trade/Device Name: Sterilucent VH2O2 Chemical Indicators
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: July 25, 2019
Received: July 26, 2019

Dear Peter 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191999

Device Name

Sterilucent VH2O2 Chemical Indicator

Indications for Use *(Describe)*

A chemical indicator for monitoring all cycles within the Sterilucent™ HC 80TT Hydrogen Peroxide Sterilizer (Lumen & Flexible), STERRAD® 100S (Standard & Long), 200, 100NX (Standard, Flex & Express), NX (Standard & Advanced), STERIS® VPRO™ 1, V-PRO™ 1 Plus (Lumen & Non-Lumen), VPRO® maX (Flexible, Lumen & Non-Lumen) and Sterilucent PSD-85 (Lumen & Non-Lumen). The VH2O2 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.

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 for the Sterilucent VH2O2 Chemical Indicator

Submitted by: Sterilucent, Inc.
Contact Person: Peter R. Kalkbrenner
Director of Engineering
peter.kalkbrenner@sterilucent.com
Phone: 612-767-3253
Fax: 612-767-3261

Date of Summary: 21 October 2019
Device Trade Name: Sterilucent VH_2O_2 Chemical Indicator
Common or Usual Name: Chemical sterilization process indicator
Classification: 21 CFR 880.2800(b)
Class: II
Product Code: JOJ
Predicate Device(s): SPSmedical VH_2O_2 Indicators (K140566/ K110152)

Device Description:

The Sterilucent VH_2O_2 Chemical Indicator is a Class 1/Type 1 process indicator that conforms to ANSI/AAMI/ISO 11140-1:2014, and is intended to be used with currently cleared hydrogen peroxide sterilizers (STERRAD® 100S, 200, 100NX, NX, STERIS® VPRO™ 1, V-PRO™ 1 Plus, VPRO® maX and the Sterilucent PSD-85) and the Sterilucent HC 80TT Hydrogen Peroxide Sterilizer. The HC 80TT Hydrogen Peroxide Sterilizer has two pre-programmed sterilization cycles ("Lumen" and "Flexible") which both utilize vaporized hydrogen peroxide (VHP) to rapidly sterilize a variety of reusable medical devices.

The Sterilucent VH_2O_2 Chemical Indicator is provided in two different formats: Strip and Label. Both formats consist of a polymeric material on which indicator ink is deposited. A pressure-sensitive adhesive is provided on the back of the Label, which allows the process indicator to be adhered to various substrates including containers, pouches, tamper-proof arrows or locks, etc.

The Sterilucent VH_2O_2 Chemical Indicator provides a visual indication that a sterilization load has been exposed to the VHP sterilization process. The indicator works by means of a chemical reaction, which results in a recognizable color change from red to blue.

Indication for Use:

A chemical indicator for monitoring all cycles within the Sterilucent™ HC 80TT Hydrogen Peroxide Sterilizer (Lumen & Flexible), STERRAD® 100S (Standard & Long), 200, 100NX (Standard, Flex & Express), NX (Standard & Advanced), STERIS® VPRO™ 1, V-PRO™ 1 Plus (Lumen & Non-Lumen), VPRO® maX (Flexible, Lumen & Non-Lumen) and Sterilucent PSD-85 (Lumen & Non-Lumen). The VH2O2 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.

Technological Characteristics Table:

	Proposed **Sterilucent VH_2O_2 Chemical Indicators**	**Predicate** **SPSmedical VH_2O_2 Indicators (K140566/ K110152)**	**Comparison**
Manufacturer	Crosstex-SPSmedical	Crosstex-SPSmedical	Same

	Proposed **Sterilucent VH_2O_2 Chemical Indicators**	**Predicate** **SPSmedical VH_2O_2 Indicators (K140566/ K110152)**	**Comparison**
Intended Use	Single use sterilization process indicator	Single use sterilization process indicator	Same
Indications for Use	A chemical indicator for monitoring all cycles within the **Sterilucent™ HC 80TT Hydrogen Peroxide Sterilizer (Lumen & Flexible)**, STERRAD® 100S (Standard & Long), 200, 100NX (Standard, Flex & Express), NX (Standard & Advanced), STERIS® VPRO™ 1, V-PRO™ 1 Plus (Lumen & Non-Lumen), VPRO® maX (Flexible, Lumen & Non-Lumen) and Sterilucent PSD-85 (Lumen & Non-Lumen). The VH2O2 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.	A chemical indicator for monitoring all cycles within the STERRAD® 100S (Standard & Long), 200, 100NX (Standard, Flex & Express), NX (Standard & Advanced), STERIS® VPRO™ 1, V-PRO™ 1 Plus (Lumen & Non-Lumen), VPRO® maX (Flexible, Lumen & Non-Lumen) and Sterilucent™ PSD-85 (Lumen & Non-Lumen). The VH2O2 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.	Similar
Device Design	Strip, Label	Strip, Label, Tape	Similar
Endpoint Specifications - Color Change Upon Exposure to H2O2	Red/Pink changes to Blue	Red/Pink changes to Blue	Same
Indicator Agent	Tetraethylammonium Bromide(ammonium salt)	Tetraethylammonium Bromide(ammonium salt)	Same
Indicator Ink Components	Water-based Carrier; Activator, Indicator Agent, & Modulator	Water-based Carrier; Activator, Indicator Agent, & Modulator	Same
Substrate	Polymer (Tyvek, Polypropylene, polystyrene)	Polymer (Tyvek, Polypropylene, polystyrene)	Same
Conformance Testing under ISO 11140-1 for VH_2O_2 Indicators	Comply with Standard	Comply with Standard	Same
Full Cycle In-Use Validation Testing of CI with listed sterilizers	Yes	Yes	Same
Shelf Life	Up to 2 years from date of manufacture	Up to 2 years from date of manufacture	Same
Distributor	Sterilucent & SPSmedical	Sterilucent & SPSmedical	Same
Storage Conditions	Dry area, ambient temperature of 15º to 30º C, away from alkaline chemicals, acids, and sources of light	Dry area, ambient temperature of 15º to 30º C, away from alkaline chemicals, acids, and sources of light	Same

The Sterilucent VH2O2 Chemical Indicator and predicate device are both single-use process indicators intended to monitor exposure to sterilization cycles utilizing vaporized hydrogen peroxide as a sterilant. Both devices have the same intended use, design, materials, specifications, and mode-of-action, and are manufactured using the exact same production methods.

Summary of Non-Clinical Testing:

Performance testing was conducted to demonstrate the functionality of the Sterilucent VH_2O_2 Chemical Indicator and general conformance with the requirements for Class 1/Type 1 vaporized hydrogen peroxide sterilization indicators as detailed in ANSI/AAMI/ISO 11140-1:2014. A summary of nonclinical tests performed follows:

Test	*Standard Used*	*Goal*	*Result*
ISO 11140-1 compliance	ISO 11140-1	Demonstrate compliance to ISO 11140-1 pass/fail criteria	Passed
Shelf-life	ISO 11140-1	Demonstrate compliance to ISO 11140-1 pass/fail criteria on devices at the stated shelf life	Passed
Sterilucent VH_2O_2 Chemical Indicator Functionality	NA	Demonstrate appropriate color change in applicable sterilizer	Passed
Endpoint Color Stability	NA	Demonstrate processed indicator endpoint color stability	Passed
Biocompatibility	NA	Demonstrate CI does not release any know toxic substances	Passed

Summary of Clinical Testing:

Clinical evaluations were not required and therefore are not submitted with this 510(k).

Overall Performance Conclusion:

Based on the nonclinical tests performed, the subject device, the Sterilucent VH_2O_2 Chemical Indicator, is as safe, as effective and performs as well as or better than the legally marketed predicate device, the SPSmedical VH_2O_2 Indicators.