October 22, 2019

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

Re: K192001
Trade/Device Name: Sterilucent self-Contained Biological Indicator, Sterilucent Lumen Cycle Process Challenge Device, Sterilucent Flexible Cycle Process Challenge Device
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
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: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192001

Device Name
Sterilucent Self-Contained Biological Indicator
Sterilucent Lumen Cycle Process Challenge Device
Sterilucent Flexible Cycle Process Challenge Device

Indications for Use *(Describe)*
The Sterilucent SCBI is intended to be used as a standard method for frequent monitoring of the Sterilucent HC 80TT Sterilizer Cycles, when incorporated into a test pack.
The Sterilucent Process Challenge Device (PCD) test pack is used for routine monitoring of the Sterilucent HC 80TT Sterilizer Lumen and Flexible Cycles. The Sterilucent PCD may also be used for performance qualification of the Sterilucent HC 80TT sterilizer Lumen and Flexible Cycles during initial installation , after relocation, major repairs or mal functions, or after sterilization process failures.
Both the Sterilucent Lumen Cycle PCD and the Sterilucent Flexible Cycle PCD are intended to have greater resistance than the stand alone SCBI. Both devices are designed to have increased resistance beyond the sterilization half-cycle, but complete inactivation upon exposure to the full cycle.

Type of Use *(Select one or both,* as *applicable)*
[ ] Prescription Use (Part 21 CFR 801 Subpart D) [X] 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 Self-Contained Biological Indicator and Test Pack (K192001)

Submitted by:	Sterilucent, Inc. 1400 Marshall Street NE Minneapolis, MN 55413 USA
Contact Person:	Peter R. Kalkbrenner Director of Engineering peter.kalkbrenner@sterilucent.com Phone: 612-767-3253 Fax: 612-767-3261
Date of Summary:	22 October 2019
Device Trade Name:	Sterilucent Self-Contained Biological Indicator Sterilucent Lumen Cycle Process Challenge Device Sterilucent Flexible Cycle Process Challenge Device
Common or Usual Name:	Biological Indicator (Test Pack)
Classification Name:	Biological Sterilization Process Indicator
Classification:	21 CFR 880.2800(a)
Class:	II
Product Code:	FRC
Predicate Device(s):	STERRAD® CYCLESURE® 24 Plus BI (K140589) Sterilucent Process Challenge Device (K141312)
Device Description:	The Sterilucent Self-Contained Biological Indicator (SCBI) is a sterilization process indicator that conforms to ANSI/AAMI/ISO 11138-1, and is intended for use only with 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 SCBI is to be used in a test pack configuration, with a different test pack (Process Challenge Device) used for each sterilization cycle. Each Process Challenge Device (PCD) is designed to have greater resistance than the worst-case sterilization load, allowing for survival beyond the sterilization half-cycle, but complete inactivation upon exposure to the full cycle. The Sterilucent SCBI provides information on whether necessary conditions were met to kill a specified number of microorganisms upon exposure to either cycle of the Sterilucent HC 80TT Hydrogen Peroxide Sterilizer.
Indication for Use:	The Sterilucent SCBI is intended to be used as a standard method for frequent monitoring of the Sterilucent HC 80TT Sterilizer Cycles, when incorporated into a test pack. The Sterilucent Process Challenge Device (PCD) test pack is used for routine monitoring of the Sterilucent HC 80TT Sterilizer Lumen and Flexible Cycles. The Sterilucent PCD may also be used for performance qualification of the Sterilucent HC 80TT sterilizer Lumen and Flexible Cycles during initial

installation, after relocation, major repairs or malfunctions, or after sterilization process failures.

Both the Sterilucent Lumen Cycle PCD and the Sterilucent Flexible Cycle PCD are intended to have greater resistance than the stand alone SCBI. Both devices are designed to have increased resistance beyond the sterilization half-cycle, but complete inactivation upon exposure to the full cycle.

SCBI Technological Characteristics Table

	Proposed Sterilucent SCBI (K192001)	Predicate STERRAD CYCLESURE 24 Plus BI (K140589)	Comparison
Intended Use	Single use sterilization process indicator	Single use sterilization process indicator	Same
Indications for Use	The STERRAD® CYCLESURE® 24 PLUS Biological Indicator is intended to be used as a standard method for frequent monitoring of STERRAD ® Sterilizer Cycles.	The Sterilucent SCBI is intended to be used as a standard method for frequent monitoring of the Sterilucent HC 80TT Sterilizer Cycles, when incorporated into a test pack.	Similar
Organism	Geobacillus stearothermophilus ATCC 7953	Geobacillus stearothermophilus ATCC 7953	Same
Viable Spore Population	Equal or greater than 1.0×10^6	Equal or greater than 1.0×10^6	Same
Sterilization Agent	Hydrogen Peroxide Vapor	Hydrogen Peroxide Vapor	Same
Culture Conditions	Crushable glass ampoule containing modified Tryptic Soy Broth with a pH indicator	Crushable glass ampoule containing modified Tryptic Soy Broth with a pH indicator	Same
Carrier Material	Quartz Fiber Disc	Quartz Fiber Disc	Same
Primary Packaging	Polypropylene vial with a white polypropylene cap. The cap filter is Tyvek non-woven polyethylene	Polypropylene vial with a white polypropylene cap. The cap filter is Tyvek non-woven polyethylene	Same
D-Value	5.7 – 9.1 sec.	1.93 – 2.28 sec.	Similar
Survival/Kill Window	25.0 sec. (All survive) 140 sec. (All kill)	Not calculated or determined	Different
Shelf Life	12 months from date of manufacture	12 months from date of manufacture	Same
Storage Conditions	2-25°C (35-77°F) under dry conditions	2-25°C (35-77°F) under dry conditions	Same
Manufacturer	MESA Laboratories, Inc.	MESA Laboratories, Inc.	Same

PCD Test Pack Technological Characteristics Table

	Proposed Sterilucent HC 80TT PCD (K192001)	Predicate Sterilucent PSD-85 PCD (K141312)	Comparison
Intended Use	Single use sterilization process indicator	Single use sterilization process indicator	Same
Indications for use	The Sterilucent Process Challenge Device is used for performance qualification of the Sterilucent PSD-85 sterilizer Lumen and Non-Lumen Cycles during initial installation, after relocation, major repairs or malfunctions, or after sterilization process failures. The Sterilucent	The Sterilucent Process Challenge Device (PCD) test pack is used for routine monitoring of the Sterilucent HC 80TT Sterilizer Lumen and Flexible Cycles. The Sterilucent PCD may also be used for performance qualification of the Sterilucent HC 80TT sterilizer Lumen	Similar

	Proposed Sterilucent HC 80TT PCD (K192001)	Predicate Sterilucent PSD-85 PCD (K141312)	Comparison
	Process Challenge Device may also be used for routine monitoring of the PSD-85 sterilizer Lumen and Non-Lumen Cycles.	and Flexible Cycles during initial installation, after relocation, major repairs or malfunctions, or after sterilization process failures. Both the Sterilucent Lumen Cycle PCD and the Sterilucent Flexible Cycle PCD are intended to have greater resistance than the stand alone SCBI. Both devices are designed to have increased resistance beyond the sterilization half-cycle, but complete inactivation upon exposure to the full cycle.	
SCBI	Sterilucent HC 80TT SCBI, quartz fiber carrier inoculated with > 10^6 Geobacillus sterathermophilus spores per disc, K192001 (current submission)	Sterilucent PSD-85 SCBI, stainless steel carrier inoculated with > 10^6 Geobacillus sterathermophilus spores per disc, K141238	Similar
Packaging	Clear polymer vial with polymer caps and a challenge tube on one end.	Clear polymer vial with polymer caps and a challenge tube on one end.	Same
Diffusion Restrictor	Tube of various inner diameter and lengths tailored to individual sterilization cycle	Tube of various inner diameter and lengths tailored to individual sterilization cycle	Same
Integrated Process Indicator	SPSmedical VH_2O_2 Chemical Indicator placed on the outside of the vial	SPSmedical VH_2O_2 Chemical Indicator placed on the outside of the vial	Same
Relative Resistance	Greater than stand-alone SCBI; greater than most difficult to sterilize device in each respective cycle; all kill at full cycle	Greater than stand-alone SCBI; greater than most difficult to sterilize device in each respective cycle; all kill at half cycle	Similar
D-Value	28.69 sec. (PCD-F)	18.18 sec. (PCD-NL)	Different
Manufacturer	Sterilucent, Inc.	Sterilucent, Inc.	Same

The Sterilucent SCBI is similar to the STERRAD CYCLESURE 24 Plus Biological Indicator (K140589), manufactured by MESA Laboratories (Bozeman, MT). The Sterilucent SCBI and predicate device are both single-use sterilization process indicators intended to monitor exposure to sterilization cycles utilizing VHP as a sterilant. Both devices have the same intended use, materials, specifications, and mode-of-action, and are manufactured using the exact same production methods.

The Sterilucent HC 80TT PCD (Lumen and Flexible) is similar to the Sterilucent PSD-85 PCD (Lumen and Non-Lumen), which is intended for use in routine monitoring of the Sterilucent PSD-85 sterilization cycles (K141312). Both devices are designed to increase resistance beyond that measured with a SCBI and to represent a challenge to the sterilization process that is equal to or greater than the routinely processed item that is most difficult to sterilize in each respective cycle (ref. AAMI TIR31:2008).

Summary of Non-Clinical Testing (Bench): Performance testing was conducted to demonstrate the functionality of the Sterilucent SCBI either alone or when incorporated into a PCD. Testing was completed in accordance with FDA Guidance ("Biological Indicator (BI) Premarket Notification [510(k)] Submissions" dated October 2007), ANSI/AAMI/ISO 11138-1, and/or ANSI/AAMI/ISO 11140-1. Resistance characterization of the SCBI was performed using a resistometer compliant with the requirements of ANSI/AAMI/ISO 18472. A summary of nonclinical

tests performed to demonstrate the safety and effectiveness of both the Sterilucent SCBI and PCD are as follows:

Test	Purpose	Acceptance Criteria	Result
SCBI Resistance Evaluation (D-Value & Survival/Kill Window)	Determination of resistance characteristics under conditions representative of the subject intended sterilizer	Meaningful value	Passed
SCBI Holding Time Assessment (24 hours)	Determination of time period exposed SCBI can be held before incubation.	Meaningful value	Passed
SCBI Reduced Incubation Time (24 hours)	Determination of reduced incubation time	Value less than seven (7) days based on FDA RIT protocol	Passed
SCBI Growth Inhibition (none allowed)	Demonstrate sterilant absorption does not inhibit spore growth	Spore growth	Passed
SCBI Population Stability & 12-month Shelf Life	Demonstrate spore population is maintained throughout the labeled shelf life	Spore population remains between 1.0-4.0 x 10^6 throughout	Passed
SCBI Integrated Chemical Indicator Verification	Demonstrate compliance to ISO 11140-1 pass/fail criteria	ISO 11140-1 Section 8.7, Table 6	Passed
PCD Resistance Characterization	Demonstrate test packs are more difficult to sterilize than the SCBI	Greater resistance as demonstrated by fractional kill	Passed
PCD Functionality	Demonstrate challenge to the sterilization process is equal to or greater than the most difficult item routinely processed	Fractional kill at half-cycle; all kill at full cycle	Passed

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

Conclusions: The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective and performs as well as or better than the legally marketed predicate device.