June 21, 2021

Propper Manufacturing Co., Inc.
Andrew Sharavara
Chief Technical Officer
36-04 Skillman Avenue
Long Island City, New York 11101

Re: K210866
Trade/Device Name: Steri-Dot Process Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: March 19, 2021
Received: March 23, 2021

Dear Andrew Sharavara:

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,

Clarence W. Murray, III, PhD
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k210866

Device Name
Steri-Dot Process Indicator

Indications for Use *(Describe)*
The Steri-Dot Process Indicator for EO gas sterilization is designed for use by a health care provider to demonstrate that the unit or load has been exposed to an EO gas sterilization process, and to distinguish between processed and unprocessed units or loads. The indicator dots turn from purple-red to green when exposed to EO gas sterilization conditions, thus providing an indication of processed items.

The Steri-Dot process indicator can be used in the following EO sterilization cycles:

1. 37°C, 736 mg/l EO, ≥35% RH, 3 hours exposure
2. 37°C, 759 mg/l EO, ≥35% RH, 3 hours exposure
3. 54°C, 600 mg/l EO, 40-60% RH, 45 min or longer exposure
4. 54°C, 736 mg/l EO, ≥35% RH, 1 hour exposure
5. 55°C, 759 mg/l EO, ≥35% RH, 1 hour exposure
6. 55°C, 600 mg/l EO, 40-60% RH, 4 hours exposure

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 K210866

Submitted by: Propper Manufacturing Company, Inc.
Address: 36-04 Skillman Avenue,
Long Island City, New York 11101

Contact Name: Andrew Sharavara, Ph.D., Chief Technical Officer

Telephone: (800) 832-4300 x149
Fax: (718) 482-8909
E-mail: as@proppermfg.com

Date Submitted: June 21, 2021

Device information:

Device Trade Name: Steri-Dot® Process Indicator
Classification Name: Physical/Chemical Sterilization Process Indicator
Common Name: Ethylene Oxide Gas Sterilization Indicator
Product Code: JOJ
Classification: Class II (21 C.F.R. 880.2800)

Description of the Device

The Steri-Dot Process Indicator is a single use chemical indicator designed for Ethylene Oxide (EO) sterilization monitoring. Each indicator consists of reactive EO indicator ink printed on a substrate paper circle, 3/4" or 1" in diameter, with adhesive backing. Individual indicators are printed with reactive ink only.

The indicator responds to the critical parameters of an EO sterilization cycle: exposure time, temperature, relative humidity and amount of Ethylene Oxide gas. During EO sterilization process indicator ink chemicals react forming a green compound. The degree of the reaction depends on the sterilization exposure. When the parameters achieve required level, the indicator ink chemistry changes color from purple-red to green. If the parameters do not achieve the required level, the indicator color will be brown or red.

Indications for Use

The Steri-Dot® process indicator for EO gas sterilization is designed for use by a health care provider to demonstrate that the unit or load has been exposed to an EO gas sterilization process, and to distinguish between processed and unprocessed units or loads. The indicator dots turn from purple-red to green when exposed to EO gas sterilization conditions, thus providing an indication of processed items.

The Steri-Dot process indicator can be used in the following EO sterilization cycles:

1. 37°C, 736 mg/l EO, ≥35% RH, 3 hours exposure
2. 37°C, 759 mg/l EO, ≥35% RH, 3 hours exposure
3. 54°C, 600 mg/l EO, 40-60% RH, 45 min or longer
4. 54°C, 736 mg/l EO, ≥35% RH, 1 hour exposure
5. 55°C, 759 mg/l EO, ≥35% RH, 1 hour exposure
6. 55°C, 600 mg/l EO, 40-60% RH, 4 hours exposure

Performance

The performance of the Steri-Dot process indicator meets the requirements of ANSI/AAMI/ISO 11140-1:2014 for Type 1 process indicators.

Technological Characteristic Comparison Table

Comparison of the subject device (Steri-Dot process indicator, Propper Manufacturing Co., Inc) to Predicate device (EO Gas Sterilization Process Indicator Tapes, SteriTec Products, Inc., k002861).

Product name	Steri-Dot Process Indicator	EO Gas Sterilization Process Indicator Tapes, K002861	Similar. Both devices have "process indicator" in the names according to Intended use.
Product generic name	A physical/chemical sterilization process indicator	A physical/chemical sterilization process indicator	Identical
Product code	JOJ	JOJ	Identical
Sterilization method	Ethylene Oxide gas sterilization	Ethylene Oxide gas sterilization	Identical
Intended use	Sterilization process indicator	Sterilization process indicator	Identical
Sterilization method	Ethylene Oxide Gas sterilization.	Ethylene Oxide Gas sterilization	Identical
Sterilization cycles	37°C, 736 mg/l EO, ≥35% RH, 3 hrs 37°C, 759 mg/l EO, ≥35% RH, 3 hrs 54°C, 600 mg/l EO, 40-60% RH, 45 min or longer 54°C, 736 mg/l EO, ≥35% RH, 1 hour 55°C, 759 mg/l EO, ≥35% RH, 1 hour 55°C, 600 mg/l EO, 40-60% RH, 4 hrs	54°C(130°F), 600 mg/l EO, 40-60% RH, 45 min or longer	Similar. Steri-Dot process indicator can be used in several additional cycles.
Device design	Paper dots with adhesive backing printed with indicator ink	Cured crepe paper printed with indicator ink lines. The tape is manufactured from a creped, printed, saturated and backsized 42	Similar design – substrate paper with printed indicator. Substrate papers

		g/m2 paper, with a natural rubber, C-5 tackifier, antioxidant adhesive on the back.	are different.
Device purposes	1.Designed to work as process indicators to distinguish between unprocessed and processed items after EO Gas exposure.	1.Designed to work as process indicators to distinguish between unprocessed and processed items after EO Gas exposure. 2. The purpose includes use as a tape to wrap a sterilizable article together as a pack.	1. Identical. 2. Significant difference.
Back side of indicators	Adhesive	Adhesive	Identical
Initial color	Purple-red	Brown	Similar
End point color	Green	Green	Identical
FDA indicator	Process indicator	Process indicator	Identical
ISO Indicator type	Type 1, process indicator	Type 1, process indicator	Identical
Single use	Yes	Yes	Identical
Shelf life	42 months	36 months	Similar
Indications for use	The Steri-Dot® process indicator for EO gas sterilization is designed for use by a health care provider to demonstrate that the unit or load has been exposed to an EO gas sterilization process, and to distinguish between processed and unprocessed units or loads. The indicator dots turn from purple-red to green when exposed to EO gas sterilization conditions, thus providing an indication of processed items. The Steri-Dot process indicator can be used in the following EO sterilization cycles: 37°C, 736 mg/l EO, ≥35% RH, 3 hrs 37°C, 759 mg/l EO, ≥35% RH, 3 hrs 54°C, 600 mg/l EO, 40-60% RH, 45 min or longer 54°C, 736 mg/l EO, ≥35% RH, 1 hr 55°C, 759 mg/l EO, ≥35% RH, 1 hr 55°C, 600 mg/l EO, 40-60% RH, 4 hrs	The EO Sterilization Indicator Tape is for use in ethylene oxide sterilizers operating at 600 mg/l EO gas, 40-60% relative humidity, 130°F, for 45 minutes or longer. The word “gas” turns green after exposure to a EO gas sterilization process, thus providing identification of processed items.	Similar. Steri-Dot process indicator can be used in several additional cycles.

Propper BI-OK® EO Gas Biological Test Pack, K972747, was used as a reference device for stability and shelf-life review because the reference device includes EO sterilization

record card – a paper sheet printed with EO indicator ink similar to the ink of Steri-Dot process indicator.

Summary of Non-clinical Testing

Provided below is the non-clinical testing that was performed to demonstrate that the subject device met the acceptance criteria for each standard or test method.

Test	Purpose	Acceptance Criteria	Result
ANSI/AAMI/ISO 11140-1:2014 testing for Type 1 indicator.	To demonstrate conformance of Steri-Dot indicator to the requirements specified in ISO 11140-1:2014 for process indicators.	37°C, RH 60%, EO 600mg/l, 3 min: no color change or color markedly different compared to green 37°C, RH 60%, EO 600mg/l, 25 min: green color 54°C, RH 60%, EO 600mg/l, 2 min: no color change or color markedly different compared to green 54°C, RH 60%, EO 600mg/l, 20 min: green color 60°C, RH ≥85%, EO - none, 90 min: no change	Passed
Testing in EO cycles with parameters used in healthcare sterilization.	To demonstrate that Steri-Dot Process indicator achieves specified end color in typical cycles.	Color change from purple-red to green	Passed
Biocompatibility study and ink transfer test	To demonstrate that the indicator does not create biocompatibility issues to health care professionals and patients. The exposure to health care professional is minimal and well below any identified toxic thresholds for the compounds.	Evaluation of individual components for biocompatibility and indicators with similar formulation with long history of on the market. Testing according to ISO 11140-1:2014. Requirement: 6.2.2. No ink transfer should be observed on unprocessed and EO processed samples.	Passed
End point stability and shelf- life study	To confirm that Steri-Dot process indicator has acceptable stability after processing when achieved and not achieved end point color ("Pass" and "Fail" conditions). To demonstrate that Steri-Dot indicator meet the performance	Steri-Dot indicators processed in Pass and Fail cycles at various time points after production and at the end of shelf life should demonstrate stable color for 140 days. Met specifications after 42 months of real time shelf-life exposure.	Passed

	parameters when tested using real-time shelf-life exposure method.		
Adhesive test – healthcare applications	The purpose of the test is to evaluate if the adhesive is suitable for its function and does not deteriorate during sterilization process.	The test is considered a pass if at least 95% of the indicators at different stages of shelf life remain on surfaces of sterilization packaging materials before and after Steri processing.	Passed

Conclusion

The conclusion drawn from the nonclinical test demonstrate that the Steri-Dot process indicator is as safe, as effective, and performs as well as or better that the legally marketed predicate device.