May 19, 2021

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

Re: K210553
Trade/Device Name: Steam-Dot Process Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: February 19, 2021
Received: February 25, 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,

for Clarence W. Murray, III, PhD
Acting 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

4. Indications for Use Statement

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)*

K210553

Device Name
Steam-Dot Process Indicator

Indications for Use *(Describe)*

The Steam-Dot Process Indicator for steam sterilization is designed for use by a health care provider to demonstrate that the unit or load has been exposed to a steam sterilization process, and to distinguish between processed and unprocessed units or loads. The indicator dots turn from white to dark brown/black when exposed to steam sterilization conditions, thus providing an indication of processed items.

The Steam-Dot process indicator can be used in the following steam sterilization cycles:

*Gravity: 121 C/250 F - 30 minutes
*Vacuum assisted (pre-vacuum): 132 C/270 F - 3 minutes
*Vacuum assisted (pre-vacuum): 132 C/270 F - 4 minutes
*Vacuum assisted (pre-vacuum): 134 C/273 F - 3 minutes
*Vacuum assisted (pre-vacuum): 134 C/273 F - 4 minutes
*Vacuum assisted (pre-vacuum): 135 C/275 F - 3 minutes

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
K210533

510(k) Summary

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
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Date Submitted: February 19, 2021

Device information:

Device Trade Name: Steam-Dot™ Process Indicator
Classification Name: Physical/Chemical Sterilization Process Indicator
Common Name: Steam Sterilization Indicator
Product Code: JOJ
Classification: Class II (21 C.F.R. 880.2800)

Description of the Device

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

The indicator responds to the critical parameters of a steam sterilization cycle: exposure time, temperature, and presence of saturated steam. During steam sterilization process indicator ink chemicals react forming a black compound. The degree of the reaction depends on the sterilization exposure. When the parameters achieve required level, the indicator ink chemistry changes color from white to black/dark brown. If the parameters do not achieve the required level, the indicator color will be light brown or crème.

Indications for Use

The Steam-Dot Process Indicator for steam sterilization is designed for use by a health care provider to demonstrate that the unit or load has been exposed to a steam sterilization process, and to distinguish between processed and unprocessed units or loads. The indicator dots turn from white to dark brown/black when exposed to steam sterilization conditions, thus providing an indication of processed items.

The Steam-Dot process indicators can be used in the following steam sterilization cycles:

*Gravity: 121° C/250° F - 30 minutes
*Vacuum assisted (pre-vacuum): 132° C/270° F - 3 minutes
*Vacuum assisted (pre-vacuum): 132° C/270° F - 4 minutes
*Vacuum assisted (pre-vacuum): 134° C/273° F - 3 minutes
*Vacuum assisted (pre-vacuum): 134° C/273° F - 4 minutes
*Vacuum assisted (pre-vacuum): 135° C/275° F - 3 minutes

Performance

The performance of the Steam-Dot process indicator meets the requirements of ANSI/AAMI/ISO 11140-1:2014 for Type 1 process indicators and the requirements of FDA guidance for industry and FDA Staff: Pre-market notification [510(k)] submissions for chemical indicators, 2003.

Technological Characteristics Comparison Table

Comparison of the subject device (Steam-Dot process indicator, Propper Manufacturing Co., Inc) to Predicate device (Process indicator tape for steam sterilization, Canadian Technical Tape, Ltd).

	Subject device (K210553)	Predicate device (K140940)	Comparison
Product name	Steam-Dot™ Process Indicator	Process indicator tape for steam sterilization	Similar. Both use "Process indicator" 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	Steam sterilization	Steam sterilization	Identical
Intended use	Sterilization process indicator	Sterilization process indicator	Identical
Sterilization method	The Steam-Dot indicator is intended for use as a steam sterilization cycle process indicator in gravity and pre- vacuum steam sterilizers.	The tape is intended for use as a steam sterilization cycle process indicator in gravity and pre- vacuum steam sterilizers.	Identical
Sterilization cycles	121°C-30 min gravity 132°C-3 min pre-vacuum 132°C-4 min pre-vacuum 134°C-3 min pre-vacuum 134°C-4 min pre-vacuum 135°C-3 min pre-vacuum	121°C-30 min gravity 132°C-4 min pre-vacuum 135°C-3 min pre-vacuum	Similar. Steam-Dot Process Indicator can be used in additional cycles: 132°C-3 min pre-vacuum, 134°C-3 min pre-vacuum 134°C-4 min pre-vacuum.

End-point specification	121°C-10 min 132°C-135°C-2 min	121°C-10 min 132°C-135°C-2 min	Identical
Device design	Paper dots printed with indicator ink	Crepe paper printed with indicator ink lines	Similar
Back side of indicators	Adhesive	Adhesive	Identical
Indicator agent	Sulfur, lead carbonate hydroxide and magnesium oxide	Sulfur, lead carbonate hydroxide and magnesium oxide	Identical
Initial color	White	White	Identical
End point color	Black, Dark brown	Black, Dark brown	Identical
Performance	ANSI/AAMI/ISO 11140-1:2014	ANSI/AAMI/ISO 11140-1:2005 (R)2010	Identical requirements for Process indicator.
ISO Indicator type	Type 1	Type 1	Identical
Single use	Yes	Yes	Identical
Shelf life	4 years	3 years	Similar
Indications for use	The Steam-Dot process indicator for steam sterilization is designed for use by a health care provider to demonstrate that the unit or load has been exposed to a steam sterilization process, and to distinguish between processed and unprocessed units or loads. The indicator dots turn from white to dark brown/black when exposed to steam sterilization conditions, thus providing an indication of processed items. The Steam-Dot process indicator can be used in the following steam sterilization cycles: Gravity: 121°C/250°F - 30 min Pre-vacuum: 132°C/270°F -3min Pre-vacuum: 132°C/270°F -4min Pre-vacuum: 134°C/273°F -3 min Pre-vacuum: 134°C/273°F -4 min Pre-vacuum: 135°C/275°F -3 min	The Process Indicator Tape for Steam Sterilization is indicated for use in holding sterilization packs together and can be used in gravity sterilizers operating at 121°C for 30 minutes or pre-vacuum sterilizers operating at 132°C for 4 minutes and 135°C for 3 minutes. The indicator stripes turn dark brown/black when exposed to steam sterilization conditions, thus providing an indication of processed items.	Similar Steam-Dot Process Indicator can be used in additional cycles: 132°C-3 min pre-vacuum, 134°C-3 min pre-vacuum 134°C-4 min pre-vacuum. The predicate device is a process indicator tape that changes color in the presence of the sterilant at Gravity: 121°C for 30 minutes and Pre-Vacuum: 132°C for 4 minutes and 135°C for 3 minutes.

Summary of Non-Clinical Testing

Test	Purpose	Acceptance Criteria	Result
ANSI/AAMI/ ISO 11140-1:2014 testing for Type 1 indicator.	To demonstrate conformance of Steam-Dot indicator to the requirements specified in ISO 11140-1:2014 for process indicators.	121^{o}C-10 min: dark brown or black color 121^{o}C-2 min: no color change or color markedly different compared to dark brown or black 134^{o}C-2 min: dark brown or black color 134^{o}C-0.3 min: no color change or color markedly different compared to dark brown or black 140^{o}C-30 min Dry heat: no color change	Passed
FDA Guidance for industry for chemical indicators. Steam process indicator performance test.	To demonstrate conformance of Steam-Dot indicator to the requirements specified in the FDA Guidance for industry for process indicators.	121^{o}C-10 min: dark brown or black color 121^{o}C-2 min: no color change or color markedly different compared to dark brown or black 132-135^{o}C-2 min: dark brown or black color 132-135^{o}C-20sec: no color change or color markedly different compared to dark brown or black 140^{o}C-30 min Dry heat: no color change	Passed
Testing in hospital type sterilizers in gravity and pre-vacuum 510k cleared cycles.	To demonstrate that Steam-Dot Process indicator achieves specified end color in typical cycles in hospital sterilizers.	Color change from white to dark brown or black	Passed
Biocompatibility study and ink transfer test	To demonstrate that the indicator does not create biocompatibility issues to health care professionals and patients.	Individual components should not create biocompatibility issues. Testing according to ISO 11140-1:2014. Requirement: 6.2.2. No ink transfer should be observed on unprocessed and steam processed indicators.	Passed
End point stability and shelf- life study	To confirm that Steam-Dot process indicator has acceptable stability after processing when achieved and not achieved end point color (“Pass” and “Fail” conditions). To demonstrate that Steam-Dot indicator meets the performance parameters when tested using real-time shelf-life exposure method.	Steam-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 110 days. Meet specifications after real-time 48 months shelf-life exposure.	Passed

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 steam processing.	Passed

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the Steam-Dot process indicator is as safe, as effective, and performs as well as or better than the legally marketed device k140940.