December 5, 2022

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

Re: K222137
Trade/Device Name: OK Plus Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ,
Dated: October 24, 2022
Received: October 27, 2022

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,

Christopher K. Dugard -S

for Clarence W. Murray, III, Ph.D.
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)*
K222137

Device Name
OK Plus Indicator

Indications for Use *(Describe)*
The OK Plus indicator is a chemical indicator designed for monitoring the efficacy of steam sterilization process. The indicator responds to all critical sterilization parameters. The OK Plus indicator changes color from off-white to black to indicate that the conditions of the cycle have been met. The indicator is intended to be placed in each pack, pouch, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles:

*Gravity: 121 C/250 F - 30 minutes

*Vacuum assisted (prevacuum): 132 C/270 F - 4 minutes
*Vacuum assisted (prevacuum): 132 C/270 F - 10 minutes
*Vacuum assisted (prevacuum): 134 C/273 F - 3.5 minutes
*Vacuum assisted (prevacuum): 134 C/273 F - 4 minutes
*Vacuum assisted (prevacuum): 135 C/275 F - 3 minutes

The OK Plus indicator has the following Stated Values determined in Resistometer:

* 121 C/250 F - 15 minutes
* 132 C/270 F - 4 minutes
* 134 C/273 F - 3 minutes
* 135 C/275 F - 2.9 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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K222137 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

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Date Submitted: July 15, 2022

Device information:

Device Trade Name: OK Plus™ 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 OK Plus indicator is a single use chemical indicator designed for steam sterilization monitoring. Each indicator consists of reactive steam indicator ink printed on a 4" x 9/16" substrate paper strip. It can be also printed on other substrate sizes, for example 8" x 9/16" paper. OK Plus indicators are sold in boxes of 250 strips.

The indicator responds to all 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 off-white to black. If the parameters do not achieve the required level, the indicator color will be light brown or brown.

Indications for Use

The OK Plus indicator is a chemical indicator designed for monitoring the efficacy of steam sterilization process. The indicator responds to all critical sterilization parameters. The OK Plus indicator changes color from off-white to black to indicate that the conditions of the cycle have been met. The indicator is intended to be placed in each pack, pouch, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles:

*Gravity: 121º C/250º F - 30 minutes
*Vacuum assisted (prevacuum): 132º C/270º F - 4 minutes
*Vacuum assisted (prevacuum): 132º C/270º F - 10 minutes
*Vacuum assisted (prevacuum): 134º C/273º F - 3.5 minutes
*Vacuum assisted (prevacuum): 134º C/273º F - 4 minutes
*Vacuum assisted (prevacuum): 135º C/275º F - 3 minutes

The OK Plus indicator has the following Stated Values determined in Resistometer:

* 121º C/250º F - 15 minutes
* 132º C/270º F - 4 minutes
* 134º C/273º F - 3 minutes
* 135º C/275º F - 2.9 minutes

Performance

The performance of the OK Plus indicator was verified using half-cycle criterion.

The indicator also meets several requirements of ANSI/AAMI/ISO 11140-1:2014 for chemical indicators and the requirements of FDA Guidance for Industry and FDA Staff: Pre-market Notification [510(k)] Submissions for Chemical Indicators, 2003.
It includes conformance with general requirements on the design, verification of sensitivity to steam - dry heat testing, ink transfer, shelf life and stability, as well as ink color change in large chamber hospital type and small chamber table-top sterilizers.

Comparison to Legally Marketed Predicate Device

Comparison of the subject device (OK Plus indicator, Propper Manufacturing Co., Inc) to Predicate device (Chemdye CD29 indicator, k191021, Terragene S.A.).

	Subject device	Predicate device	Comparison
Product name	OK Plus indicator	Chemdye CD29 indicator, k191021	
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
Types of	Gravity and pre-vacuum.	Gravity and Dynamic air	Identical

sterilization cycles		removal (pre-vacuum)	
Sterilization cycles	121ºC-30 min gravity 132ºC-4 min pre-vacuum 132ºC-10 min pre-vacuum 134ºC-3.5 min pre-vacuum 134ºC-4 min pre-vacuum 135ºC-3 min pre-vacuum	121ºC-30 min gravity 132ºC-15 min gravity 132ºC-25 min gravity 135ºC-10 min gravity 132ºC-4 min pre-vacuum 135ºC-3 min pre-vacuum	Similar.
End-point specification	121ºC-15 min 132ºC-4min 134ºC-3min 135ºC-2.9 min	121ºC-15 min 134ºC-3.5 min	Similar
Device design	Paper strip printed with indicator ink	Paper strip printed with indicator ink	Identical
Operational principle	Color change chemistry	Color change chemistry	Identical
Initial color	Off-white	Light yellow	Similar
End point color	Black	Black	Identical
Indicator type	Internal indicator	Internal Indicator	Identical
Single use	Yes	Yes	Identical
Shelf life	4 years	5 years	Similar
Indications for use	The OK Plus indicator is a chemical indicator designed for monitoring the efficacy of steam sterilization process. The indicator responds to all critical sterilization parameters. The OK Plus indicator changes color from off-white to black to indicate that the conditions of the cycle have been met. The indicator is intended to be placed in each pack, pouch, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles: 121ºC-30 min gravity 132ºC-4 min pre-vacuum 132ºC-10 min pre-vacuum 134ºC-3.5 min pre-vacuum 134ºC-4 min pre-vacuum 135ºC-3 min pre-vacuum	Terragene Chemdye® CD29 is a chemical process indicator intended for monitoring the efficacy of steam sterilization processes. The chemical indicator changes from yellow to dark brown/black to indicate that the conditions of the cycle have been met. 121ºC-30 min gravity 132ºC-15 min gravity 132ºC-25 min gravity 135ºC-10 min gravity 121ºC-30 min gravity 132ºC-4 min pre-vacuum 135ºC-3 min pre-vacuum	Similar. The difference is in the sterilization cycles

	The OK Plus indicator has the following Stated Values determined in Resistometer: 121°C/250°F - 15 min 132°C/270°F - 4 min 134°C/273°F - 3 min 135°C/275°F -2.9 min		

Summary of non-clinical testing

Provided below is the summary of 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
Performance testing in Steam BIER vessel	Demonstrate conformance of OK Plus Indicator with the half-cycle requirements. The indicator should demonstrate end-point color when bacteria/spores are deactivated.	Color changes - end-point colors: 121°C - 15 min 00 s - black 132°C - 4 min 00 s - black 134°C - 3 min 00 s - black 135°C - 2 min 54 s - black	Passed
Testing in Dry Heat oven	Confirm that OK Plus indicator does not change color in absence of Stam.	When tested in cycles at 140°C+/-2°C and time 30+/1 min as per ANSI/AAMI/ISO 11140-1:2014 the OK Plus indicator should not achieve end color. Also, OK Plus indicator should not demonstrate color change to the end point in 180°C - 60 min dry heat typical cycle which it sufficient to kill biological indicator spores.	Passed
Testing against biological indicator	Establish correlation between performance of OK Plus indicator and Steam Biological indicator	The OK Plus indicator should not achieve end-point color before the biological indicator is inactivated.	Passed
Single parameter variation testing	Confirm that OK Plus indicator is sensitive to critical sterilization parameters.	Variation of one parameter while other ones are maintained steady. OK Plus indicator should not reach specified end-point black color.	Passed
Testing in cycles with parameters typical for healthcare	Demonstrate OK Plus indicator achieves specified end color in typical cycles in hospital-size and table-top sterilizers.	Color change from off-white to black.	Passed

Bio-compatibility study and ink transfer test	Demonstrate that the indicator does not create biocompatibility issues to health care professionals and patients.	Evaluation of individual components for biocompatibility and review of biocompatibility of indicators with similar formulation with history on the market. Testing according to ISO 11140-1:2014. Requirement: 6.2.2. No ink transfer should be observed on unprocessed and Steam processed samples.	Passed
End-point stability and shelf- life study	Confirm that OK Plus indicator has acceptable stability after processing when achieved and not achieved end point color ("Pass" and "Fail" conditions). Demonstrate that OK Plus indicator maintains its performance when tested using real-time shelf-life exposure method.	OK Plus 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 at least 6 months. Meet specifications after real-time 48 months shelf-life exposure.	Passed

Conclusion

The OK Plus indicator for steam sterilization is substantially equivalent to the predicate device. OK Plus indicator is as safe, as effective, and performs as well as or better than the legally marketed device k191021.