June 12, 2024

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

Re: K240910
Trade/Device Name: EO Chex™ Indicator Tape
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: April 2, 2024
Received: April 4, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2024.06.12 15:51:31 -04'00'

for: Christopher Dugard
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240910

Device Name
EO Chex Indicator Tape

Indications for Use *(Describe)*
The EO Chex Indicator Tape for Ethylene Oxide gas sterilization is designed to secure wrapped packs by a health care provider. EO Chex indicator tape demonstrates that the packs have been exposed to an EO gas sterilization process, and to distinguish between processed and unprocessed packs. The EO process indicator turns from pink to orange-brown when exposed to EO gas sterilization conditions, thus providing an indication of processed items.

The EO Chex indicator tape can be used in the following EO sterilization cycles:

1. 38°C, 736 mg/L EO, 40-80% RH, 4.5 hours exposure
2. 38°C, 759 mg/ L EO, 40-80% RH, 4.5 hours exposure
3. 54°C, 600 mg/ L EO, 40-60% RH, 45 min or longer
4. 55°C, 736 mg/ L EO, 40-80% RH, 1 hour exposure
5. 55°C, 759 mg/ L EO, 40-80% RH, 1 hour exposure

Performance
The performance of the EO Chex indicator tape meets the requirements of ANSI/AAMI/ISO 11140-1:2014 for Type 1 process indicators.

Stated Values

Temperature: 37°C, RH: 60%, Time: 25min, EO: 600mg/L
Temperature: 54°C, RH: 60%, Time: 20min, EO: 600mg/L

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.

K240910
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
Fax: (718) 482-8909
E-mail: as@proppermfg.com

Date Submitted: April 2, 2024

Device information:

Device Trade Name: EO Chex™ Indicator Tape
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 EO Chex™ indicator tape is a single-use, beige color pressure-sensitive adhesive tape with pink stripes that can be used to secure packages for Ethylene Oxide Gas (EO) sterilization.
The pink stripes are process chemical indicators for monitoring of exposure to Ethylene Oxide sterilization. After sterilization exposure the pink stripes turn to orange-brown.

The EO Chex indicator tape is made in rolls ¾ inch and 1 inch wide and 55-60 yards long. Each roll has a core with 3-inch internal diameter that allows for use with any standard tape dispenser.

The indicator responds to the critical parameters of an EO sterilization cycle: exposure time, temperature, relative humidity, and concentration of Ethylene Oxide gas. During EO sterilization process indicator ink chemicals react forming an orange-brown compound. The degree of the reaction depends on the sterilization exposure. When the parameters achieve the required level, the indicator ink chemistry changes color from pink to orange-brown. If the parameters do not achieve the required level, the indicator color remains as any shade of pink.

EO Chex™ Indicator Tape - Indications for Use

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Performance

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

Stated Values:

Temperature: 37ºC, RH: 60%, Time: 25min, EO: 600mg/L
Temperature: 54ºC, RH: 60%, Time: 20min, EO: 600mg/L

Technological Characteristic Comparison Table

Comparison of the subject device (EO Chex™ Indicator Tape, Propper Manufacturing Co., Inc.) to Predicate device EO Gas Sterilization Process Indicator Tapes, SteriTec Products, Inc., K002861.

Parameter	Subject Device	Predicate Device, K002861	Comparison
Product Name	EO Chex Indicator Tape	EO Gas Sterilization Process Indicator Tapes	Similar. Both devices are "EO Indicator Tapes"
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 Cycles	38°C,736 mg/L EO,40-80% RH, 4.5 hrs 38°C,759 mg/L EO,40-80% RH, 4.5 hrs 54°C,600 mg/L EO, 40-60% RH, 45 min or longer 55°C, 736 mg/L EO, 40-80% RH, 1 hr 55°C, 759 mg/L EO, 40-80% RH, 1 hr	54°C(130ºF), 600 mg/l EO, 40-60% RH, 45 min or longer	Similar. EO-Chex indicator tape can be used in several additional cycles.
Device Design	Cured crepe paper printed with indicator ink lines. The tape is manufactured from a creped, printed, saturated paper, with a natural rubber and hydrocarbon resin adhesive on the back.	Cured crepe paper printed with indicator ink lines. The tape is manufactured from a creped, printed, saturated paper with a natural rubber adhesive on the back.	Similar design – substrate paper with adhesive and printed indicator.

Device Purposes	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.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.	Identical.
Back Side of the Tapes	Adhesive	Adhesive	Identical
Initial Color	Pink	Brown	Different
End Point Color	Orange-brown	Green	Different
FDA Indicator	EO Process indicator	EO Process indicator	Identical
ISO Indicator Type	Type 1, process indicator	Type 1, process indicator	Identical
Single Use	Yes	Yes	Identical
Shelf Life	24 months	36 months	Similar
Indications for Use	The EO Chex indicator tape for Ethylene Oxide gas sterilization is designed to secure wrapped packs by a health care provider. EO Chex indicator tape demonstrates that the packs have been exposed to an EO gas sterilization process, and to distinguish between processed and unprocessed packs. The EO process indicator turns from pink to orange-brown when exposed to EO gas sterilization conditions, thus providing an indication of processed items. The EO Chex indicator tape can be used in the following cycles: 1. 38°C, 736 mg/L EO, 40-80% RH, 4.5 hours exposure 2. 38°C, 759 mg/L EO, 40-80% RH, 4.5 hours exposure 3. 54°C, 600 mg/L EO, 40-60% RH, 45 min or longer 4. 55°C, 736 mg/L EO, 40-80% RH, 1 hour exposure 5. 55°C, 759 mg/L EO, 40-80% RH, 1 hour exposure	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. EO Chex indicator tape can be used in several additional cycles.

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
Performance testing in BIER vessel: ANSI/AAMI/ ISO 11140-1:2014 testing for Type 1 Indicator.	To demonstrate conformance of EO Chex indicator tape to the requirements specified in ISO 11140-1:2014 for process indicators.	37ºC, RH 60%, EO 600mg/L, 3 min: no color change or color markedly different compared to orange-brown 37ºC, RH 60%, EO 600mg/L, 25 min: orange-brown 54ºC, RH 60%, EO 600mg/L, 2 min: no color change or color markedly different compared to orange-brown 54ºC, RH 60%, EO 600mg/L, 20 min: orange-brown 60ºC, RH ≥85%, EO - none, 90 min: no change	Passed
Testing in EO cycles with parameters typical for use in healthcare.	To demonstrate that EO Chex indicator tape achieves specified end color in typical cycles.	Color change from pink to orange-brown	Passed
Biocompatibility study and ink transfer test	To demonstrate that the indicator does not create biocompatibility issues for 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 EO Chex indicator tape has acceptable stability after processing when achieved and not achieved end point color ("Pass" and "Fail" conditions). To demonstrate that EO Chex indicator tape meet the performance parameters when tested using real-time shelf-life exposure method.	EO Chex indicator tape processed in Pass and Fail cycles at various time points after production and at the end of shelf-life should demonstrate stable color for 180 days. Met specifications after 24 months of real time 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 EO processing.	Passed

Conclusion

The conclusion drawn from the non-clinical test demonstrates that the EO Chex™ indicator tape is as safe, as effective, and performs as well as or better than the legally marketed predicate device, K002861.