January 20, 2022

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

Re: K212592
Trade/Device Name: Gas-Chex Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: December 20, 2021
Received: December 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: K212592

Device Name
Gas-Chex Indicator

Indications for Use *(Describe)*
The Gas-Chex Indicator is an integrating indicator designed to respond to all critical parameters over a specified range of Ethylene Oxide sterilization cycles. The Gas-Chex 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:

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. 38°C, 736 mg/l EO, 40-80% RH, 4.5 hours exposure
4. 38°C, 759 mg/l EO, 40-80% RH, 4.5 hours exposure
5. 55°C, 736 mg/l EO, ≥35% RH, 1 hour exposure
6. 55°C, 759 mg/l EO, ≥35% RH, 1 hour exposure
7. 55°C, 600 mg/l EO, 60% RH, 4 hours exposure

The Gas-Chex Indicator for EO sterilization has the following minimum Stated Values determined in a Resistometer:

54℃, 42 min, EO 600 mg/l, RH 60±10%
37℃, 75 min, EO 600 mg/l, RH 60±10%

55°C, 36 min, EO 736 mg/l, RH 50±l0%
37°C, 75 min, EO 736 mg/l, RH 50±l0%

55°C, 35 min, EO 759 mg/l, RH 50±l0%
37°C, 75 min, EO 759 mg/l, RH 50±l0%

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
K212592

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: August 12, 2021

Device information:

Device Trade Name: Gas-Chex® 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)
510k number K212592

Description of the Device

The Gas-Chex® Indicator is a single use chemical integrating indicator designed for Ethylene Oxide (EO) sterilization monitoring. Each indicator consists of reactive EO 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. Gas-Chex® Indicators are sold in boxes of 250 strips.

The indicator responds to all critical parameters of an EO sterilization cycle: exposure time, temperature, relative humidity and amount of Ethylene Oxide gas. During sterilization process the indicator ink chemicals react to EO gas 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 brown-red to green. If the parameters do not achieve the required level, the indicator color will be brown, brown-red, or brown-yellow.

Indications for Use

The Gas-Chex® Indicator is an integrating indicator designed to respond to all critical parameters over a specified range of Ethylene Oxide sterilization cycles. The Gas-Chex® 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:

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. 38°C, 736 mg/l EO, 40-80% RH, 4.5 hours exposure
4. 38°C, 759 mg/l EO, 40-80% RH, 4.5 hours exposure
5. 55°C, 736 mg/l EO, ≥35% RH, 1 hour exposure
6. 55°C, 759 mg/l EO, ≥35% RH, 1 hour exposure
7. 55°C, 600 mg/l EO, 60% RH, 4 hours exposure

The Gas-Chex® Indicator has the following minimum Stated Values determined in a Resistometer:

54ºC, 42 min, EO 600 mg/l, RH 60±10%
37ºC, 75 min, EO 600 mg/l, RH 60±10%

55ºC, 36 min, EO 736 mg/l, RH 50±10%
37ºC, 73 min, EO 736 mg/l, RH 50±10%

55ºC, 35 min, EO 759 mg/l, RH 50±10%
37ºC, 73 min, EO 759 mg/l, RH 50±10%

Performance

The performance of the Gas-Chex® Indicator complies with FDA guidance for industry and FDA Staff: Pre-market notification [510(k)] submissions for chemical indicators, 2003 for integrating indicators.

Technological Characteristics Comparison to Legally Marketed Predicate Device

Comparison of the subject device (Gas-Chex Indicator, Propper Manufacturing Co., Inc) to Predicate device (Integron IT12, k191021, by Terragene S.A.).

	Subject device	Predicate device	Comparison
Product name	Gas-Chex Indicator	Integron IT12 integrator, k191021	
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	37°C,736 mg/l EO, ≥35% RH, 3hrs 37°C,759 mg/l EO, ≥35% RH, 3hrs 38°C,736 mg/l EO, 40-80% RH, 4.5 hrs 38°C,759 mg/l EO, 40-80% RH, 4.5 hrs 55°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, 60% RH, 4 hrs	55°C, 600 mg/l EO, 60% RH, 240min	Identical with additional cycles for Gas-Chex Indicator
Device	Paper strip printed with indicator ink	Paper strip printed with	Identical

design		indicator ink	
Initial color	Brown-red	Purple	Similar
End point color	Green	Green	Identical
Indicator category	Integrating indicator	ISO Integrator	Similar. Both indicators are designed to respond to all critical parameters over a specified range.
Single use	Yes	Yes	Identical
Shelf life	36 months	36 months	Identical
Indications for use	The Gas-Chex Indicator is designed to respond to all critical parameters over a specified range of Ethylene Oxide sterilization cycles. The Gas-Chex 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: 37°C,736 mg/l EO, ≥35% RH, 3hrs 37°C,759 mg/l EO, ≥35% RH, 3hrs 38°C,736 mg/l EO, 40-80% RH, 4.5 hrs 38°C,759 mg/l EO, 40-80% RH, 4.5 hrs 55°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, 60% RH, 4 hrs The Gas-Chex Indicator for EO sterilization has the following minimum Stated Values determined in a Resistometer: 54ºC, 42 min, EO 600 mg/l, RH 60±10% 37ºC, 75 min, EO 600 mg/l, RH 60±10% 55ºC, 36 min, EO 736 mg/l, RH 50±10% 37ºC, 73 min, EO 736 mg/l, RH 50±10% 55ºC, 35 min, EO 759 mg/l, RH 50±10% 37ºC, 73 min, EO 759 mg/l, RH 50±10%	The integrator Terragene Integron® IT12 is designed to chemically react over time with the critical parameters of ethylene oxide sterilization cycle within a specified tolerance. The integrating indicator strip is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles: 55°C for 240 minutes, 600 mg/l, RH 60 %. SV 37°C/75 min, SV 54°C/30 min, SV 55ºC/28 min.	Similar. Gas-Chex indicator can be used in several additional cycles. Stated value at 37ºC is identical. Gas-Chex indicator has longer stated value time in BIER vessel at 54ºC which is within typical performance range and conforms to the requirement not to achieve end point before biological indicator spore death.

Propper BI-OK® EO Gas Biological Test Pack, K972747, was used as a reference device for stability and shelf-life review because this reference device includes EO sterilization record card – a paper sheet printed with EO indicator ink very similar to the ink of Gas-Chex Indicator.
Terragene ChemDye CD16 EO Multivariable process indicator, k191021, was used as a reference device for color change comparison.

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 EO BIER vessel	Demonstrate conformance of Gas-Chex Indicator with the FDA guidance for industry and FDA Staff: Pre-market notification [510(k)] submissions for chemical indicators, 2003 for integrating indicators.	Color changes: 54ºC, 42 min, EO 600 mg/l, RH 60%: green 49ºC, 33.6min, EO 510 mg/l, RH 60%: brown, brown-red, brown-yellow 37ºC, 75 min, EO 600 mg/l, RH 60%: green 32ºC, 60 min, EO 510 mg/l, RH 60%: brown, brown-red, brown-yellow 55ºC, 36 min, EO 736 mg/l, RH 50%: green 50ºC, 28.8min, EO 625mg/l, RH 50%: brown, brown-red, brown-yellow 37ºC, 73 min, EO 736 mg/l, RH 50%: green 32ºC, 58.4min, EO 625mg/l, RH 50%: brown, brown-red, brown-yellow 55ºC, 35 min, EO 759 mg/l, RH 50%: green 50ºC, 28 min, EO 645 mg/l, RH 50%: brown, brown-red, brown-yellow 37ºC, 73 min, EO 759 mg/l, RH 50%: green 32ºC, 58.4min, EO 645mg/l, RH 50%: brown, brown-red, brown-yellow	Passed
Testing in "No EO Gas" cycles	Confirm that Gas-Chex indicator does not change color in absence of Ethylene Oxide gas	When tested in cycle with temperature 60ºC±2ºC, RH≥85%, time 90 min±1min, the indicator should not achieve end point color.	Passed
Testing against biological indicator	Establish correlation between performance of Gas-Chex indicator and EO Biological indicator	The integrator does not achieve end-point color before the biological indicator is inactivated and demonstrates parallel performance to the biological indicator.	Passed
Single parameter variation testing	Confirm that Gas-Chex indicator is sensitive to critical sterilization parameters.	Variation of one parameter while other ones are maintained steady. Gas-Chex Indicator should not reach specified end-point green color.	Passed
Testing in cycles with parameters typical for healthcare	Demonstrate Gas-Chex indicator achieves specified end color in typical cycles.	Color change from brown-red to green.	Passed

Biocompatibility 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 EO processed samples.	Passed
End-point stability and shelf- life study	Confirm that Gas-Chex indicator has acceptable stability after processing when achieved and not achieved end point color ("Pass" and "Fail" conditions). Demonstrate that Gas-Chex indicator maintains its performance when tested using real-time shelf-life exposure method.	Gas-Chex 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 3 months. Meet specifications after real-time 36 months shelf-life exposure.	Passed

Conclusion

The conclusion drawn from the nonclinical test demonstrate that the Gas-Chex Indicator is as safe, as effective, and performs as well as or better that the legally marketed predicate device, K191021.