December 17, 2024

Jiangmen New Era External Use Drug Co., Ltd
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Co. Ltd.
14th Floor, 1500# Century Avenue
Shanghai, Shanghai 200122
China

Re: K241036
Trade/Device Name: Autoclave Indicator Tape; EO Indicator Tape
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization process indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: November 15, 2024
Received: November 15, 2024

Dear Ivy Wang:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2024.12.17 08:16:57 -05'00'

for: Christopher K. Dugard
Assistant Director
DHT4C: Division of Infection Control 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)*
K241036

Device Name
Autoclave Indicator Tape
EO Indicator Tape

Indications for Use *(Describe)*

Autoclave Indicator Tape 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. After steam sterilization, the chemical indicator lines will show a visual color change from yellow to Black. This is a single use, disposable device(s), and provided non-sterile.
The Autoclave Indicator Tape can be used in the following steam sterilization cycles:
1. Gravity: 121℃, 30 minutes
2. Vacuum assisted (pre-vacuum): 134℃, 4 minutes

EO Indicator Tape is designed for use by a healthcare 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 chemical indicator lines turn from Orange to Green when exposed to EO gas sterilization conditions. This is a single use, disposable device(s), and provided non-sterile.
The EO Indicator Tape can be used in the following EO sterilization cycle:
55℃, 762mg/l EO, 40~80%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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

K241036

Prepared date: 2024-12-10

A. Applicant:

Jiangmen New Era External Use Drug Co., Ltd
Address: No 8 Beiyuan RD., Jianghai Dist., Jiangmen City Guangdong China
Contact: Mr. Yingxuan Mu
Tel: +86 13119640020
Email: myxuan@kenai-tape.com

Submission Correspondent:
Primary contact: Ms. Ivy Wang
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-58817802
Email: haiyu.wang@sungoglobal.com
Secondary contact: Mr. Raymond Luo
14th Floor, 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-68828050
Email: zxfda@sungoglobal.com

B. Device:

Device Name	Model
Autoclave Indicator Tape	19mm x 50m, 25mm x 50m, 18mm x 50m, 24mm x 50m, 12mm x 50m, 12.5mm x 50m, 19mm x 30m, 25mm x 30m, 12mm x 30m, 19mm x 55m, 25mm x 55m, 18mm x 55m, 24mm x 55m, 12mm x 55m, 12.5mm x 55m, 19mm x 45yards, 25mm x 45yards, 12mm x 45yards, 20mm x 45yards
EO Indicator Tape	19mm x 50m, 25mm x 50m, 18mm x 50m, 24mm x 50m, 12mm x 50m, 12.5mm x 50m, 19mm x 30m, 25mm x 30m, 12mm x 30m, 19mm x 55m, 25mm x 55m, 18mm x 55m, 24mm x 55m, 12mm x 55m, 12.5mm x 55m, 19mm x 45yards, 25mm x 45yards, 12mm x 45yards, 20mm x 45yards

Common name: Sterilization Indicator
Classification Name: Physical/Chemical Sterilization Process Indicator
Regulation Number: 880.2800
Product Code: JOJ
Device Class: Class II

C. Predicate device:

510(k) Number	Trade Name	Manufacturer
K210553	Steam-Dot Process Indicator	Propper Manufacturing Company, Inc.
K210866	Steri-Dot® Process Indicator	Propper Manufacturing Company, Inc.

D. Indications for use of the device:

Autoclave Indicator Tape 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. After steam sterilization, the chemical indicator lines will show a visual color change from yellow to Black. This is a single use, disposable device(s), and provided non-sterile.

The Autoclave Indicator Tape can be used in the following steam sterilization cycles:

1. Gravity: 121℃, 30 minutes
2. Vacuum assisted (pre-vacuum):
134℃, 4 minutes

EO Indicator Tape 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 chemical indicator lines turn from orange to Green when exposed to EO gas sterilization conditions. This is a single use, disposable device(s), and provided non-sterile.

The EO Indicator Tape can be used in the following EO sterilization cycle:

55℃, 762mg/l EO, 40~80%RH, 4 hours exposure

E. Device Description:

Autoclave Indicator Tape is a single chemical indicator designed for steam sterilizing monitoring. The diagonal strips are printed along the length of the tape using chemical indicator ink. During the sterilization cycle, the initial yellow color of the indicator ink on the autoclave indicator tape changes to Black. If no color change occurs, it may indicate that the autoclave indicator tape was not exposed to the sterilization process due to equipment malfunctions or procedural errors during the sterilization process. This is a single use, disposable device(s), and provided non-sterile.

EO Indicator Tape is single chemical indicator designed for use in ethylene oxide sterilizing processes. The diagonal strips are printed along the length of the tape using chemical indicator ink. During the sterilization cycle, the initial orange color of the indicator ink on the EO indicator tape changes to green. If no color change occurs, it may indicate that the EO indicator tape was not exposed to the sterilization process due to equipment malfunctions or procedural errors during the sterilization process. This is a single use, disposable device(s), and provided non-sterile.

F. Technological Characteristics Comparison Table

Device	**Subject Device**	**Predicate Device**	**Result**
510K number	K241036	K210553	-

Product name	Autoclave Indicator Tape	Steam-Dot™ Process Indicator	-
Classification	Class II	Class II	Same
Regulation	880.2800	880.2800	Same
Product code	JOJ	JOJ	Same
Indications for use	Autoclave Indicator Tape 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. After steam sterilization, the chemical indicator lines will show a visual color change from yellow to Black. This is a single use, disposable device(s), and provided non-sterile. The Autoclave Indicator Tape can be used in the following steam sterilization cycles: 1. Gravity: 121℃, 30 minutes 2. Vacuum assisted (pre-vacuum): 134℃, 4 minutes	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	Similar The subject device has less steam sterilization cycle than predicate device.
Intended use	sterilization process indicator	sterilization process indicator	Same
Sterilization method	Steam sterilization	Steam sterilization	Same
Type of sterilization cycles	Gravity and pre-vacuum	Gravity and pre-vacuum	Same
Sterilization cycles	Gravity: 121℃, 30 minutes Vacuum assisted (pre-vacuum): 134℃, 4 minutes	121oC-30 min gravity 132oC-3 min pre-vacuum 132oC-4 min pre-vacuum 134oC-3 min pre-vacuum 134oC-4 min pre-vacuum 135oC-3 min pre-vacuum	Similar The subject device has less steam sterilization cycle than predicate device.

Endpoint specification	Change to Black color	Change to Black, dark brown color	Similar
Initial color	Yellow	White	Similar
Device design	Crepe paper printed with indicator ink lines	Paper dots printed with indicator ink	Similar
Back side of indicators	Adhesive	Adhesive	Same
Performance	ISO 11140-1:2014	ANSI/AAMI/ISO 11140-1:2014	Same
ISO Indicator type	Type 1	Type 1	Same
Single use	Yes	Yes	Same
Shelf life	2 years	4 years	Similar

Device	**Subject Device**	**Predicate Device**	**Result**
510K number	K241036	K210866	-
Product name	EO Indicator Tape	Steri-Dot Process Indicator	-
Classification	Class II	Class II	Same
Regulation	880.2800	880.2800	Same
Product code	JOJ	JOJ	Same
Indications for use	EO Indicator Tape 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 chemical indicator lines turn from orange to Green when exposed to EO gas sterilization conditions. This is a single use, disposable device(s), and provided non-sterile. The EO Indicator Tape can be used in the following EO sterilization cycle: 55℃, 762mg/l EO, 40~80%RH, 4	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%	Similar The subject device has less sterilization cycle than predicate device.

	hours exposure	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	
Intended use	sterilization process indicator	sterilization process indicator	Same
Sterilization method	Ethylene Oxide gas sterilization	Ethylene Oxide gas sterilization	Same
Sterilization cycles	55℃, 762mg/l EO, 40~80%RH, 4 hours exposure	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	Similar. The subject device has less sterilization cycle than predicate device.
Endpoint specification	Change to Green color	Change to green color	Similar
Initial color	Orange	Purple-red	Similar
Device design	Crepe paper printed with indicator ink lines.	Paper dots printed with adhesive backing printed with indicator ink	Similar
Back side of indicators	Adhesive	Adhesive	Same
ISO Indicator type	Type 1	Type 1	Same
Single use	Yes	Yes	Same

Shelf life	18 months	42 months	Similar

G. 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.

Autoclave Indicator Tape

Test	Purpose	Acceptance Criteria	Result
Steam process indicator performance test according to ISO 11140-1:2014 testing for Type 1 indicator and FDA guidance	To demonstrate conformance of Autoclave indicator tape to the requirements specified in ISO 11140-1:2014 and FDA guidance for industry and FDA staff, "Premarket Notification [510(k)] Submissions for Chemical Indicators".	121°C for 10 minutes: black 121°C for 2 minutes: no color change or color markedly different compared to black 134°C for 2 minutes: black 134°C for 0.3 minutes: no color change or color markedly different compared to black 140°C for 30 minutes Dry heat: no color change	PASS
Hospital steam sterilizer testing	To demonstrate that Autoclave indicator tape achieves specified end color in typical cycles in hospital sterilizers.	Color change from yellow to black	PASS
Biocompatibility 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. Testing according to ISO 10993-5, ISO 10993-10 and ISO 1099-23. The subject device is non-toxic, non-irritant or non-sensitizing.	PASS
End point stability and shelf-life study	Determine the length of time that an exposed Autoclave Indicator Tape retains its	9 month	PASS

	postexposure signal color. To demonstrate that Autoclave Indicator Tape meets the performance parameters when tested using real-time shelf-life exposure method.	Meet specifications after real-time 24 months shelf-life exposure.	
Offset/ transference	Demonstrate the Autoclave indicator tape do not bleed or offset to substrate which it's applied according to ISO 11140-1: 2014.	The Autoclave indicator tapes shall not offset or bleed, penetrate the substrate to which it is applied, or materials in which it is in contact before, during or after the steam sterilization cycles for which it is designed.	PASS
Adhesion test	To evaluate if the peel adhesion of the autoclave indicator tape.	≥3.8 N/19mm	PASS

EO Indicator Tape

Test	Purpose	Acceptance Criteria	Result
ISO 11140-1:2014 testing for Type 1 indicator	To demonstrate conformance of EO indicator tape to the requirements specified in ISO 11140-1:2014 for process indicators and the FDA guidance for industry and FDA staff, "Premarket Notification [510(k)] Submissions for Chemical Indicators".	54℃, RH 60%, EO 600mg/l, 2 min: no color change or color markedly different compared to green 54℃, RH 60%, EO 600mg/l, 20 min: green color 60℃, RH ⩾85%, EO - none, 90 min: no change	PASS
Hospital EO sterilizer testing	To demonstrate that EO indicator tape achieves specified end color in typical cycles in hospital sterilizers.	Color change from orange to green.	PASS
Biocompatibility 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 EO processed indicators.	PASS

		Testing according to ISO 10993-5, ISO 10993-10 and ISO 1099-23. The subject device is non-toxic, non-irritant or non-sensitizing.	
End point stability and shelf-life study	Determine the length of time that an exposed EO Indicator Tape retains its postexposure signal color. To demonstrate that Autoclave Indicator Tape meets the performance parameters when tested using real-time shelf-life exposure method.	9 month Meet specifications after real-time 18 months shelf-life exposure.	PASS
Offset/ transference	Demonstrate the EO indicator tape do not bleed or offset to substrate which it's applied according to ISO 11140-1: 2014.	The EO indicator tapes shall not offset or bleed, penetrate the substrate to which it is applied, or materials in which it is in contact before, during or after the EO sterilization cycles for which it is designed.	PASS
Adhesion test	To evaluate if the peel adhesion of the EO indicator tape.	≥3.8 N/19mm	PASS

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K210553 and K210866.