September 5, 2021

3M Company
Mary Fretland
Regulatory Affairs Specialist
3M Center, Building 275-5W-06
St. Paul, Minnesota 55144

Re: K212081
Trade/Device Name: 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: August 6, 2021
Received: August 9, 2021

Dear Mary Fretland:

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
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)*

K212081

Device Name
3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228

Indications for Use *(Describe)*

Use the 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 to secure packs and as an external pack process indicator to differentiate unprocessed items from items processed in the following sterilizers:

STERRAD 100® Sterilization System
STERRAD 100S® Sterilization System
STERRAD NX® Sterilization System (Standard and Advanced cycles)
STERRAD 100NX® Sterilization System (Standard, Flex, Express and Duo cycles)
STERRAD NX® with ALLClear® Technology Sterilization System (Standard and Advanced cycles)
STERRAD 100NX® with ALLClear® Technology Sterilization System (Standard, Flex, Express and Duo cycles)
V-PRO® 1 Low Temperature Sterilization System (Lumen cycle)
V-PRO® 1 Plus Low Temperature Sterilization System (Lumen and Non Lumen cycles)
V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles)
V-PRO® 60 Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles)
V-PRO® maX 2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast Non Lumen cycles)
V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles)
STERIZONE® VP4 Sterilizer (Cycle 1)

The tape is suitable for use on non-woven disposable wraps and peel pouches. The chemical indicator stripes turn from blue toward pink after exposure to vaporized hydrogen peroxide.

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 for
3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228

K212081

Sponsor Information:

3M Company
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact: Mary Fretland
Regulatory Affairs Specialist
Phone Number: (651) 737-2296
Fax Number: (651) 737-5320

Date of Summary: August 02, 2021

1. Device Name and Classification:

Common or Usual Name:	Chemical Indicator
Proprietary Name:	3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228
Classification Name:	Indicator, physical/chemical sterilization process
Device Classification:	Class II, 21 CFR § 880.2800
Product Code:	JOJ

2. Predicate Device:

K203285 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228

3. Description of Device:

The 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 consists of a non-cellulosic plastic backing material with a pressure-sensitive adhesive on one side and chemical indicator stripes on the other side. The chemical indicator stripes turn from blue toward pink after exposure to vaporized hydrogen peroxide.

4. Indications for Use

Use the 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 to secure packs and as an external pack process indicator to differentiate unprocessed items from items processed in the following sterilizers:

STERRAD 100® Sterilization System
STERRAD 100S® Sterilization System
STERRAD NX® Sterilization System (Standard and Advanced cycles)
STERRAD 100NX® Sterilization System (Standard, Flex, Express and Duo cycles)
STERRAD NX® with ALLClear® Technology Sterilization System (Standard and Advanced cycles)
STERRAD 100NX® with ALLClear® Technology Sterilization System (Standard, Flex, Express and Duo cycles)
V-PRO® 1 Low Temperature Sterilization System (Lumen cycle)
V-PRO® 1 Plus Low Temperature Sterilization System (Lumen and Non Lumen cycles)
V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles)
V-PRO® 60 Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles)
V-PRO® maX 2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast Non Lumen cycles)
V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles)
STERIZONE® VP4 Sterilizer (Cycle 1)

The tape is suitable for use on non-woven disposable wraps and peel pouches. The chemical indicator stripes turn from blue toward pink after exposure to vaporized hydrogen peroxide.

5. Technological Characteristic Comparison Table

Feature	Submission Device: 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228	Predicate Device (K203285): 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228	Comparison
Indications for Use	Use the 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 to secure packs and as an external pack process indicator to differentiate unprocessed items from items processed in the following sterilizers:	Use the 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 to secure packs and as an external pack process indicator to differentiate unprocessed items from items processed in the following sterilizers:	Similar. The submission device adds the STERIZONE® VP4 Sterilizer (Cycle 1) to the Indications for Use.
	STERRAD 100® Sterilization System	STERRAD 100® Sterilization System	
	STERRAD 100S® Sterilization System	STERRAD 100S® Sterilization System	
	STERRAD NX® Sterilization System (Standard and Advanced cycles)	STERRAD NX® Sterilization System (Standard and Advanced cycles)	
	STERRAD 100NX® Sterilization System (Standard, Flex, Express and Duo cycles)	STERRAD 100NX® Sterilization System (Standard, Flex, Express and Duo cycles)	
	STERRAD NX® with ALLClear® Technology Sterilization System (Standard and Advanced cycles)	STERRAD NX® with ALLClear® Technology Sterilization System (Standard and Advanced cycles)	
	STERRAD 100NX® with ALLClear® Technology Sterilization System (Standard, Flex, Express and Duo cycles)	STERRAD 100NX® with ALLClear® Technology Sterilization System (Standard, Flex, Express and Duo cycles)	
	V-PRO® 1 Low Temperature Sterilization System (Lumen cycle)	V-PRO® 1 Low Temperature Sterilization System (Lumen cycle)	
	V-PRO® 1 Plus Low Temperature Sterilization System (Lumen and Non Lumen cycles)	V-PRO® 1 Plus Low Temperature Sterilization System (Lumen and Non Lumen cycles)	
	V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles)	V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles)	
	V-PRO® 60 Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles)	V-PRO® 60 Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles)	
	V-PRO® maX 2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast Non Lumen cycles)	V-PRO® maX 2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast Non Lumen cycles)	
	V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles)	V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles)	

Feature	Submission Device: 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228	Predicate Device (K203285): 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228	Comparison
	STERIZONE® VP4 Sterilizer (Cycle 1) The tape is suitable for use on non-woven disposable wraps and peel pouches. The chemical indicator stripes turn from blue toward pink after exposure to vaporized hydrogen peroxide.	The tape is suitable for use on non-woven disposable wraps and peel pouches. The chemical indicator stripes turn from blue toward pink after exposure to vaporized hydrogen peroxide.	
Substrate	Non-cellulosic plastic	Identical	
Biocompatibility	The exposure to health care professionals is minimal and well below any identified toxic thresholds for the compounds.	Identical	
Color Change	Blue toward pink	Identical	
Detection	Hydrogen Peroxide	Identical	
Stability of the endpoint reaction	Six (6) months	Twelve (12) months	Alignment of claim with similar 3M products.
Shelf life	Eighteen (18) months	Identical	

The 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 is the same design as the previously cleared device of the same model number (the predicate) which is sold under the tradename 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 (K203285). No changes have been made to the device materials or fundamental technology.

6. Summary of Non-clinical Testing

To demonstrate performance in the newly claimed sterilizer and cycles, nonclinical testing was performed in accordance with the *FDA Guidance for Industry and Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators*, issued December 19, 2003. Reference **Table 6.1** for testing completed in the STERIZONE® VP4 Sterilizer (Cycle 1).

Table 6.1 Summary of Nonclinical Testing

Test	Purpose	Acceptance Criteria	Result
Color Change in Health Care Facility Cycle	To demonstrate the color change of the device when used in the STERIZONE® VP4 Sterilizer (Cycle 1)	Color change from blue toward pink	Pass
Minimum Exposure Parameters	To determine the minimum time required for the color change of the device when used in the STERIZONE® VP4 Sterilizer (Cycle 1)	Determination of the minimum time for color to change from blue toward pink	Pass

7. Conclusion

Based on the non-clinical performance data, the 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 is as safe, as effective, and performs as well as or better than the legally marketed predicate device, 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 cleared under K203285, Class II (21 CFR 880.2800), product code JOJ.