November 16, 2019

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

Re: K192937
Trade/Device Name: 3M Comply Hydrogen Peroxide Chemical Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: October 17, 2019
Received: October 18, 2019

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,

Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192937

Device Name
3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248

Indications for Use *(Describe)*

Use the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 as an internal pack process indicator to verify exposure to vaporized hydrogen peroxide in the STERRAD® 100, STERRAD® l 00S, STERRAD® NX (Standard and Advanced cycles), STERRAD® l00NX (Standard, Flex , Express and Duo cycles), STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles), STERRAD® l00NX with ALLClear™ Technology (Standard, Flex , Express and Duo cycles), AMSCO® V PRO® 1 (Lumen cycle), AMSCO® V PRO® 1 Plus (Lumen and Non Lumen cycles), AMSCO® V PRO® maX Low Temperature Sterilization System (Lumen , Non Lumen, and Flexible cycles), AMSCO® V-PRO® 60 Low Temperature Sterilization System (Lumen , Non Lumen , Flexible cycles), and AMSCO® V-PRO™ maX 2 Low Temperature Sterilization System (Lumen , Non Lumen, Flexible, and Fast Non Lumen cycles) sterilizers. The chemical indicator bar turns 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.

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510(k) Summary
for
3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248
K192937

Sponsor Information:

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

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

Date of Summary: November 04, 2019

PREMARKET NOTIFICATION [510(k)]
3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248

1. **Device Name and Classification:**

Common or Usual Name:	Chemical Indicator
Proprietary Name:	3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248
Classification Name:	Indicator, physical/chemical sterilization process
Device Classification:	Class II, 21 CFR § 880.2800
Product Code:	JOJ

2. **Predicate Device:**

K183211 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248

3. **Description of Device:**

The 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 consists of a non-cellulosic plastic material onto which a chemical indicator bar is printed. A comparison color match is also printed on the product to aid in color interpretation.

4. **Indications for Use**

Use the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 as an internal pack process indicator to verify exposure to vaporized hydrogen peroxide in the STERRAD® 100, STERRAD® 100S, STERRAD® NX (Standard and Advanced cycles), STERRAD® 100NX (Standard, Flex, Express and Duo cycles), STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles), STERRAD® 100NX with ALLClear™ Technology (Standard, Flex, Express and Duo cycles), AMSCO® V-PRO® 1 (Lumen cycle), AMSCO® V-PRO® 1 Plus (Lumen and Non Lumen cycles), AMSCO® V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles), AMSCO® V-PRO® 60 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible cycles) and AMSCO® V-PRO™ maX 2 Low Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast Non-Lumen cycles) sterilizers. The chemical indicator bar turns from blue toward pink after exposure to vaporized hydrogen peroxide.

5. Technological Characteristic Comparison Table

Feature	Submission Device (K192937): 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248	Predicate Device (K183211): 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248	Comparison
Indications for use	Use the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 as an internal pack process indicator to verify exposure to vaporized hydrogen peroxide in the STERRAD® 100, STERRAD® 100S, STERRAD® NX (Standard and Advanced cycles), STERRAD® 100NX (Standard, Flex, Express and Duo cycles), STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles), STERRAD® 100NX with ALLClear™ Technology (Standard, Flex, Express and Duo cycles), AMSCO® V-PRO® 1 (Lumen cycle), AMSCO® V-PRO® 1 Plus (Lumen and Non Lumen cycles), AMSCO® V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles), AMSCO® V-PRO® 60 Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles) and AMSCO® V-PRO™ maX 2 Low Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast Non-Lumen cycles) sterilizers. The chemical indicator bar turns from blue toward pink after exposure to vaporized hydrogen peroxide.	Use the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 as an internal pack process indicator to verify exposure to vaporized hydrogen peroxide in the STERRAD® 100, STERRAD® 100S, STERRAD® NX (Standard and Advanced cycles), STERRAD® 100NX (Standard, Flex, Express and Duo cycles), STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles), STERRAD® 100NX with ALLClear™ Technology (Standard, Flex, Express and Duo cycles), AMSCO® V-PRO® 1 (Lumen cycle), AMSCO® V-PRO® 1 Plus (Lumen and Non Lumen cycles), AMSCO® V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles) and AMSCO® V-PRO® 60 Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles) sterilizers. The chemical indicator bar turns from blue toward pink after exposure to vaporized hydrogen peroxide.	Similar
Sterilizers and Sterilization Cycles	STERRAD® 100 STERRAD® 100S STERRAD® NX (Standard and Advanced cycles) STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles) STERRAD® 100NX (Standard, Flex, Express, and Duo cycles) STERRAD® 100NX with ALLClear™ Technology (Standard, Flex, Express, and Duo cycles) AMSCO® V-PRO™ 1 (Lumen cycle) AMSCO® V-PRO™ 1 Plus (Lumen and Non Lumen cycles) AMSCO® V-PRO™ maX Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles)	STERRAD® 100 STERRAD® 100S STERRAD® NX (Standard and Advanced cycles) STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles) STERRAD® 100NX (Standard, Flex, Express, and Duo cycles) STERRAD® 100NX with ALLClear™ Technology (Standard, Flex, Express, and Duo cycles) AMSCO® V-PRO™ 1 (Lumen cycle) AMSCO® V-PRO™ 1 Plus (Lumen and Non Lumen cycles) AMSCO® V-PRO™ maX Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles)	Similar

Feature	Submission Device (K192937): 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248	Predicate Device (K183211): 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248	Comparison
	AMSCO® V-PRO™ 60 (Lumen, Non Lumen and Flexible cycles) AMSCO® V-PRO™ maX 2 Low Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast Non-Lumen cycles)	AMSCO® V-PRO™ 60 (Lumen, Non Lumen and Flexible cycles)	
Substrate	Polyethylene	Polyethylene	Identical
Biocompatibility	The exposure to health care professionals is minimal and well below any identified toxic thresholds for the compounds.	The exposure to health care professionals is minimal and well below any identified toxic thresholds for the compounds.	Identical
Color Change	Blue toward pink	Blue toward pink	Identical
Detection	Hydrogen Peroxide	Hydrogen Peroxide	Identical
Stability of the endpoint reaction	At least one month (4 weeks)	At least one month (4 weeks)	Identical
Shelf life	Two (2) years	Two (2) years	Identical

The 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 is identical to the previously cleared device of the same model number (the predicate) which is sold under the tradename 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 (K183211). As no change has been made to the device materials, performance specifications, or fundamental technology, the biocompatibility and nonclinical testing provided in K183211 was referenced in this submission to support performance of the device in the claimed sterilizers.

6. Summary of Nonclinical Testing

To demonstrate performance in the newly claimed sterilizers 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 AMSCO® V-PRO™ maX 2 Low Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast Non-Lumen cycles) sterilizer.

Table 6.1 Summary of Nonclinical Testing

Test Method / Name	Purpose	Acceptance Criteria	Result
Color Change in Health Care Facility Cycle	To demonstrate the color change of the device when used in the AMSCO® V-PRO™ maX 2 Low Temperature Sterilization System	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 AMSCO®	Determination of the minimum time for color to change from blue toward pink	Pass

Test Method / Name	Purpose	Acceptance Criteria	Result
	V-PRO™ maX 2 Low Temperature Sterilization System		
End Point Color Stability	To demonstrate the post-sterilization color stability of the device after use in the AMSCO® V-PRO™ maX 2 Low Temperature Sterilization System	No significant color change after exposure to fluorescent light for a minimum of 1 month (4 weeks).	Pass

7. Conclusion

Based on the non-clinical testing performance data, the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 is as safe, as effective, and performs as well as or better than the legally marketed predicate device, the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 cleared under K183211, Class II (21 CFR 880.2800), product code JOJ.