December 11, 2020

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

Re: K203458
Trade/Device Name: 3M Comply Hydrogen Peroxide Chemical Indicator 1248
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: November 20, 2020
Received: November 24, 2020

Dear Yumi Wackerfuss:

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, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203458

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 hyrdogen peroxide in the following sterilizers and cycles.

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)

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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K203458 510(k) Summary
for
3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248

Sponsor Information:

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

Contact: Yumi Wackerfuss
Senior Regulatory Affairs Associate
Phone Number: (651) 736-5286
Fax Number: (651) 737-5320

Date of Summary: November 20, 2020

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

1. Device Name and Classification:

Common Name:	Chemical Indicators
Proprietary Name	3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248
Classification Name:	Physical/chemical sterilization process indicators
Device Classification:	Class II, 21 CFR 880.2800(b)
Product Code:	JOJ

2. Predicate Device:

K192937, 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248

3. Description of Device:

The 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 consists of a noncellulosic 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

Proposed indication for use for this submission is:

Use the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 as an internal pack process indicator to verify exposure to vaporized hydrogen peroxide in the following sterilizers and cycles:

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)

The chemical indicator bar turns from blue toward pink after exposure to vaporized hydrogen peroxide.

5. Technological Characteristic Comparison

The 3M™ Comply ™ Hydrogen Peroxide Chemical Indicator 1248 is the same design as the previously cleared device of same model number (predicate device: K192937). No change has been made to the device materials, performance specifications, or fundamental technology.

Table 6.1: Technological Characteristic Comparison Table

Items	Predicate Device (K192937)	Proposed device (this submission)
	3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248	**3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248**
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 following sterilizers and cycles: STERRAD® 100 Sterilization System STERRAD® 100SSterilization 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)

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

Items	Predicate Device (K192937) 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248	Proposed device (this submission) 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248
		The chemical indicator bar turns from blue toward pink after exposure to vaporized hydrogen peroxide.
Sterilizers and Sterilization Cycles	(1) STERRAD® 100 (2) STERRAD® 100S (3) STERRAD® NX (Standard and Advanced cycles) (4) STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles) (5) STERRAD® 100NX (Standard, Flex, Express, and Duo cycles) (6) STERRAD® 100NX with ALLClear™ Technology (Standard, Flex, Express, and Duo cycles) (7) AMSCO® V-PRO™ 1 (Lumen cycle) (8) AMSCO® V-PRO™ 1 Plus (Lumen and NonLumen cycles) (9) AMSCO® V-PRO™ maX Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles) (10) AMSCO® V-PRO™ 60 (Lumen, Non Lumen and Flexible cycles) (11) AMSCO® V-PRO™ maX 2 Low Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast Non-Lumen cycles)	(1) STERRAD® 100 (2) STERRAD® 100S (3) STERRAD® NX (Standard and Advanced cycles) (4) STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles) (5) STERRAD® 100NX (Standard, Flex, Express, and Duo cycles) (6) STERRAD® 100NX with ALLClear™ Technology (Standard, Flex, Express, and Duo cycles) (7) V-PRO™ 1 (Lumen cycle) (8) V-PRO™ 1 Plus (Lumen and NonLumen cycles) (9) V-PRO™ maX Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles) (10) V-PRO™ 60 (Lumen, Non Lumen and Flexible cycles) (11) V-PRO™ maX 2 Low Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast Non-Lumen cycles) (12) V-PRO™ s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles)
Substrate	Polyethylene	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	At least one month (4 weeks)	Identical
Shelf life	Two (2) years	Identical

6. Nonclinical Comparison to the Predicate Device

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 (K192937). As no change has been made to the device materials, performance specifications, or fundamental technology, the biocompatibility and nonclinical testing provided in K192937 was referenced in this submission to support performance of the device in the claimed sterilizers.

To demonstrate performance in the newly claimed sterilizers and cycles for the V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast 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 6.2** for testing completed in V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles) sterilizer and the tests were resulted passed.

Table 6.2 Summary of Nonclinical Testing

Test Method/Name	Result
Color Change in Health Care Facility Cycle	Pass
Minimum Exposure Parameters to Affect the Change of the Indicator in Health Care Facility Cycle	Pass
End Point Color Stability	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 K192937, Class II (21 CFR 880.2800), product code JOJ.