November 1, 2022

3M Company
Yumi Wackerfuss
Senior Regulatory Affairs Associate
3M Center, Bldg. 275-5W-06
St. Paul, Minnesota 55144-1000

Re: K222508
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: August 17, 2022
Received: August 18, 2022

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, 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)*
K222508

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 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)
STERIZONE® VP4 Sterilizer (Cycle 1)

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.

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

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510(k) Summary
for
3M™ Comply™ Hydrogen Peroxide
Chemical Indicator 1248
K222508

Sponsor Information:

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

Contact: Yumi Wackerfuss
Senior Regulatory Affairs Associate
Phone Number: (651) 733-3556
Fax Number: (651) 737-5320

Date of Preparation: Oct 20th, 2022

PREMARKET NOTIFICATION [510(k)]
3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248
510(k) Summary - K222508

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:

K203458, 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248

3. Description of Device:

The 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 has an indicator ink bar printed on a white plastic strip. The chemical indicator bar turns from blue toward pink after exposure to vaporized hydrogen peroxide. 3M™ Comply™ Hydrogen Peroxide Indicator 1248 is a Type 1 (Category e1) Process Indicator as categorized by ISO 11140-1:2014.

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 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)
STERIZONE® VP4 Sterilizer (Cycle 1)

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

5. Technological Characteristic Comparison Table

Feature	Submission Device (K222508): 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248	Predicate Device (K203458): 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 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)	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)	Similar. The submission device adds the STERIZONE® VP4 Sterilizer (Cycle 1) to the Indications for Use.

PREMARKET NOTIFICATION [510(k)]
3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248
510(k) Summary - K222508

Feature	Submission Device (K222508): 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248	Predicate Device (K203458): 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248	Comparison
	V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles) STERIZONE® VP4 Sterilizer (Cycle 1) The chemical indicator bar turns from blue toward pink after exposure to vaporized hydrogen peroxide.	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.	
Substrate	Polyethylene	Polyethylene	Same
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.	Same
Color Change	Blue toward pink	Blue toward pink	Same
Detection	Hydrogen Peroxide	Hydrogen Peroxide	Same
Stability of the endpoint reaction	At least one month (4 weeks)	At least one month (4 weeks)	Same
Shelf life	Two (2) years	Two (2) years	Same
Indicator Type	Type 1 Process Indicator	Not claimed	New claim for Type 1 process indicator

The 3M™ Comply ™ Hydrogen Peroxide Chemical Indicator 1248 is the same design as the previously cleared device of same model number (predicate device: K203458) which is sold under the same tradename 3M™ Comply™ Hydrogen Peroxide Indicator 1248. No change has been made to the device materials, performance specifications, or fundamental technology.

6. Summary of Non-clinical Testing

3M conducted nonclinical testing to support the product performance in accordance with :

- *FDA Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators,* issued December 19, 2003
- *ISO 11140-1:2014 Sterilization of healthcare products—Chemical Indicators—Part 1: General requirements for Type 1 (e1) Process Indicators*.

Reference **Table 6.1** for summary of nonclinical testing.

Reference **Table 6.1** for testing completed in the used for STERIZONE® VP4 Sterilizer (Cycle 1) and Type 1 Process Indicator claim.

Table 6.1 Summary of Nonclinical Testing

Test	Purpose	Acceptance Criteria		Result
STERIZONE® VP4 Sterilizer (Cycle 1) Color Development	To demonstrate the color change of the device and determine the minimum exposure time for end point color change when used in the STERIZONE® VP4 Sterilizer (Cycle 1)	Complete Cycle: Color change from blue toward pink		Pass
		7 second exposure: Color change is not as pink (bluer) than color reference match.		
		Determination of the minimum time for color to change from blue toward pink.		
STERIZONE® VP4 Sterilizer (Cycle 1) End Point Color (Post-Sterilization) Light Stability	To demonstrate the end point color change stability of the device following exposure to STERIZONE® VP4 Sterilizer (Cycle 1)	No significant change in the endpoint color after exposure to light during storage.		Pass
ISO 11140-1:2014 Type 1 Absence of hydrogen peroxide	Verify device requires the presence of vaporized hydrogen peroxide to reach endpoint.	45 Min at 50°C	Device does not reach endpoint color.	Pass
ISO 11140-1:2014 Type 1 Hydrogen peroxide	Confirm device meets the Type 1 process indicator for vaporized hydrogen peroxide requirements.	7 Sec at 50°C and gas concentration of 2.3 mg/l	Device does not reach endpoint color.	Pass
		6 Min at 50°C and gas concentration of 2.3 mg/l	Device reaches endpoint color.	
ISO 11140-1:2014 Off-set/transference	Confirm device meets the Type 1 process indicator requirements.	After exposure to 6 Min at 50°C and gas concentration of 2.3 mg/l	Ink does not transfer to another surface.	Pass

7. Conclusion

The conclusions drawn from the non-clinical testing demonstrate that the subject device, 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, 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 cleared under K203458, Class II (21 CFR 880.2800), product code JOJ.