



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

August 14, 2017

3M Company  
Nadia Battah  
Regulatory Affairs Associate  
3M Health Center  
3M Center, Building 275-5W-06  
St Paul, Minnesota 55144-1000

Re: K170321

Trade/Device Name: 3M Comply Hydrogen Peroxide Chemical Indicator 1248

Regulation Number: 21 CFR 880.2800

Regulation Name: Sterilization Process Indicator

Regulatory Class: II

Product Code: JOJ

Dated: July 12, 2017

Received: July 13, 2017

Dear Nadia Battah:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

**Michael J. Ryan -S**

for Lori Wiggins  
Acting Director  
Division of Anesthesiology,  
General Hospital, Respiratory,  
Infection Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K170321

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, 100S, NX® (Standard and Advanced cycles), 100NX® (Standard, Flex, Express and Duo cycles), AMSCO® V-PRO™ 1 (Lumen cycle), AMSCO® V-PRO™ 1 Plus (Lumen and Non Lumen cycles), and AMSCO® V-PRO™ maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles) sterilizers. The chemical indicator bar turns from blue to 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."*

## Premarket Notification [510(k)] Summary

### Sponsor Information:

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

Contact Person: Nadia Battah  
Regulatory Affairs Associate  
Phone Number: (651) 733-0929  
FAX Number: (651) 737-5320

**Date of Summary:** July 31, 2017

### 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 (21 CFR §880.2800)
Device Classification:	Class II
Product Code:	JOJ

### Predicate Device:

3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 (K150622)

### 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.

## **Nonclinical Comparison to the Predicate Device**

The 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 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 Chemical Indicator 1248 (K150622). There has been no change to the device's materials, performance specifications, or fundamental scientific technology. The intent of this submission is to expand the indications for use to include use in the AMSCO® V-PRO™ 1 (Lumen cycle), AMSCO® V-PRO™ 1 Plus (Lumen and Non Lumen cycles), and AMSCO® V-PRO™ maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles) sterilizers.

## **Summary of Clinical Testing**

No clinical data was included in this premarket application submission.

## **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, 100S, NX® (Standard and Advanced cycles), 100NX® (Standard, Flex, Express and Duo cycles), AMSCO® V-PRO™ 1 (Lumen cycle), AMSCO® V-PRO™ 1 Plus (Lumen and Non Lumen cycles), and AMSCO® V-PRO™ maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles) sterilizers. The chemical indicator bar turns from blue to pink after exposure to vaporized hydrogen peroxide.

## Comparison to Predicate Device

Feature	Submission Device: 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248	Predicate Device (K150622): 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, 100S, NX® (Standard and Advanced cycles), 100NX® (Standard, Flex, Express and Duo cycles), AMSCO® V-PRO™ 1 (Lumen cycle), AMSCO® V-PRO™ 1 Plus (Lumen and Non Lumen cycles), and AMSCO® V-PRO™ maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles) sterilizers. The chemical indicator bar turns from blue to 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, 100S, NX® (Standard and Advanced cycles) and 100NX® (Standard, Flex, Express and Duo cycles) sterilization processes. The chemical indicator bar turns from blue to pink after exposure to vaporized hydrogen peroxide.
Sterilizers	STERRAD® 100 STERRAD® 100S STERRAD® NX (Standard and Advanced cycles) STERRAD® 100NX (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® 100NX (Standard, Flex, Express, and Duo cycles)
Indicator Agent	Alkali blue 6B dye	Identical
Cycle Conditions for Color Change in STERRAD® 100	Testing verified that the 3M™ Comply™ Hydrogen Peroxide Chemical Indicators 1248 turned from blue to pink when exposed to the STERRAD® 100 Sterilization cycle and the minimum time required for all indicators to indicate a “pass” in relation to the color match was found to be between 10 and 15 minutes. Demonstrated per submission K013228.	
Cycle Conditions for Color Change in STERRAD® 100S	Testing verified that the 3M™ Comply™ Hydrogen Peroxide Chemical Indicators 1248 turned from blue to pink when exposed to the STERRAD® 100S Sterilization cycle and the minimum time required for all indicators to indicate a “pass” in relation to the color match was found to be between 4 and 8 minutes. Demonstrated per submission K013228.	
Cycle Conditions for Color Change in STERRAD® NX (Standard and Advanced cycles)	Testing verified that the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 turns from blue to pink to indicate a “pass” in relation to the device color match printed on the indicator when exposed to complete Standard and Advanced cycles in the STERRAD® NX® sterilizer. The minimum time required for all samples to indicate a “pass” in these cycles is listed below:  Standard cycle: Between 5.25 minutes and 7 minutes Advanced cycle: Between 11.25 minutes and 15 minutes  Demonstrated per submission K150622.	
Cycle Conditions for Color Change in STERRAD® 100NX (Standard, Flex Express and Duo cycles)	Testing verified that the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 turns from blue to pink to indicate a “pass” in relation to the device color match printed on the indicator when exposed to complete Standard, Flex, Express, and Duo cycles in the STERRAD® 100NX® sterilizer. The minimum time required for all samples to indicate a “pass” in these cycles is listed below:  Standard cycle: Between 12.75 minutes and 17 minutes	

	Flex cycle: Between 12.75 minutes and 17 minutes Express cycle: Between 4.5 and 6 minutes Duo cycle. Between 10 seconds and 8 minutes	
	Demonstrated per submission K150622.	
Cycle Conditions for Color Change in AMSCO® V-PRO™ 1 (Lumen cycle), AMSCO® V-PRO™ 1 Plus (Lumen and Non Lumen cycles), and AMSCO® V-PRO™ maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles) sterilizers	Testing verified that the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 turns from blue to pink to indicate a “pass” in relation to the color match when exposed to a complete Lumen, Non Lumen or Flexible cycle in an AMSCO® V-PRO™ maX Low Temperature Sterilization System. The minimum time required for all samples to indicate a “pass” in these cycles is listed below:  Lumen cycle: Between 7 seconds and 8 minutes Non Lumen cycle: Between 6 minutes and 9 minutes. Flexible cycle: Between 9 minutes and 12 minutes.	
Stability of the endpoint reaction	At least four (4) weeks (28 days)	Identical
Shelf life	Two (2) years	Identical

### Biocompatibility

The components of the indicator ink used on the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 are all of low general toxicity. The exposure to the health care professional is minimal and well below any identified toxic thresholds for the compounds. There is no anticipated direct exposure to the patient. Indirect exposure to the patient via potential exposure to medical instruments with the indicator ink is minimal and well below any identified toxic thresholds for the compounds.

### Summary of Nonclinical Testing

The effectiveness of the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 is demonstrated by the following tests:

**Color Change in Health Care Facility Cycle** – Samples from six different lots were verified to meet the requirements for detectable color change in the AMSCO® V-PRO™ maX Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles) sterilizer.

**Minimum Exposure Parameters to Affect the Change of the Indicator in Health Care Facility Cycle** – Samples from six different lots were evaluated to determine the minimum time required for the color change of the indicator when used in the AMSCO® V-PRO™ maX Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles).

**End Point Color Stability** – Samples from six different lots were verified to be stable to storage under typical office lighting conditions for at least one month (4 weeks) post-exposure in a Hydrogen Peroxide Health Care Facility Cycle.

## **Conclusion**

The 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 is as safe, as effective, and performs as well as the predicate, K150622, 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248.