



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 29, 2015

3M Health Care,
Ms. Hilary B. Hovde
Regulatory Affairs
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144

Re: K150622
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: August 24, 2015
Received: August 27, 2015

Dear Ms. Hovde,

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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)
K150622

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) 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.

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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Premarket Notification [510(k)] Summary



Sponsor Information:

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

Contact Person: Hilary B. Hovde
Regulatory Affairs
Phone Number: (651) 736-0364
FAX Number: (651) 737-5320

Date of Summary: September 29, 2015

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™ 1248 Gas Plasma Chemical Indicator (K013228)

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™ 1248 Gas Plasma Chemical Indicator (K013228). 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 STERRAD® NX® and STERRAD® 100NX® 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) 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.

Comparison to Predicate Device

Feature	Submission Device: 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248	Predicate Device (K013228): 3M™ Comply™ 1248 Gas Plasma Chemical Indicator
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) 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.	The 3M™ Comply™ 1248 Gas Plasma Chemical Indicator is indicated for use as an internal pack process indicator to verify exposure to vapor hydrogen peroxide in the STERRAD® 100, STERRAD® 100S, and STERRAD® 50 Sterilization processes.
Sterilizers	STERRAD® 100 STERRAD® 100S STERRAD® NX® (Standard and Advanced cycles) STERRAD® 100NX® (Standard, Flex, Express, and Duo cycles)	STERRAD® 100 STERRAD® 100S STERRAD® 50
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 original 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 original submission K013228.	
Cycle Conditions for Color Change in STERRAD® 50	Not Applicable.	Testing verified that the 3M™ Comply™ Hydrogen Peroxide Chemical Indicators 1248 turned from blue to pink when exposed to the STERRAD® 50 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 0.25 and 2 minutes. Demonstrated per original submission K013228.
Cycle Conditions for Color Change in STERRAD® NX®	Testing verified that the 3M™ Comply™ Hydrogen Peroxide Chemical Indicators 1248 turned from blue to pink and the minimum time required for all indicators to indicate a “pass” in relation to the color specification was found when exposed to the following STERRAD® NX® Sterilization Cycles: Standard Advanced	
Cycle Conditions for Color Change in STERRAD® 100NX®	Testing verified that the 3M™ Comply™ Hydrogen Peroxide Chemical Indicators 1248 turned from blue to pink and the minimum time required for all indicators to indicate a “pass” in relation to the color specification was found when exposed to the following STERRAD® 100NX® Sterilization Cycles: Standard Flex Express Duo	
Stability of the endpoint reaction	At least one month (4 weeks)	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.

Effectiveness

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 STERRAD® NX® (Standard and Advanced cycles) and the STERRAD® 100NX® (Standard, Flex, Express, and Duo cycles) sterilizers.

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 STERRAD® NX® (Standard and Advanced cycles) and the STERRAD® 100NX® (Standard, Flex, Express, and Duo cycles) sterilizers.

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

Conclusion

The composition, physical properties, specifications and technological characteristics of the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 remain the same as the predicate device.

Testing was conducted to confirm performance of the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 in the STERRAD® NX® and the STERRAD® 100NX® per FDA's *Premarket Notification [510(k)] Submissions for Chemical Indicators; Guidance for Industry and FDA Staff*, December 19, 2003.

The 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 is substantially equivalent to the predicate device. There are no new questions of safety or effectiveness.