



Food and Drug Administration  
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October 1, 2015

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

Re: K150694  
Trade/Device Name: 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228  
Regulation Number: 21 CFR 880.2800  
Regulation Name: Sterilization process indicator  
Regulatory Class: II  
Product Code: JOJ  
Dated: August 19, 2015  
Received: August 21, 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 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 yours,

*Tejashri Purohit-Sheth, M.D.*

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Enclosure

## Indications for Use

510(k) Number (if known)

K150694

Device Name

3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228

Indications for Use (Describe)

Use the 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 to secure packs and as an external pack process indicator to differentiate unprocessed items from items processed in the STERRAD® 100, 100S, NX® (Standard and Advanced cycles) and 100NX® (Standard, Flex, Express and Duo cycles) sterilization processes. The tape is suitable for use on non-woven disposable wraps and peel pouches. The chemical indicator stripes turn 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:

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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 28, 2015

### Device Name and Classification:

Common or Usual Name:	Chemical Indicator
Proprietary Name:	3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228
Classification Name:	Indicator, physical/chemical sterilization process (21 CFR § 880.2800)
Device Classification:	Class II
Product Code:	JOJ

### Predicate Device:

- 3M™ Comply™ 1228 Gas Plasma Indicator Tape (K020589)

### Description of Device:

The 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 consists of a non-cellulosic plastic backing material with a pressure-sensitive adhesive on one side and chemical indicator stripes on the other side.

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

The 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 is similar in design to the previously cleared device of the same model number (the predicate) which is sold under the tradename 3M™ Comply™ 1228 Gas Plasma Indicator Tape (K020589). After the original clearance, but prior to product launch and commercialization in 2002, the adhesive was changed to improve adhesion. The change was managed according to 3M quality system design controls. 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 Indicator Tape 1228 to secure packs and as an external pack process indicator to differentiate unprocessed items from items processed in the STERRAD® 100, 100S, NX® (Standard and Advanced cycles) and 100NX® (Standard, Flex, Express and Duo cycles) sterilization processes. The tape is suitable for use on non-woven disposable wraps and peel pouches. The chemical indicator stripes turn from blue to pink after exposure to vaporized hydrogen peroxide.

## Comparison to Predicate Device

Feature	Submission Device: 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228	Predicate Device (K020589): 3M™ Comply™ 1228 Gas Plasma Indicator Tape
Indications for use	Use the 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 to secure packs and as an external pack process indicator to differentiate unprocessed items from items processed in the STERRAD® 100, 100S, NX® (Standard and Advanced cycles) and 100NX® (Standard, Flex, Express and Duo cycles) sterilization processes. The tape is suitable for use on non-woven disposable wraps and peel pouches. The chemical indicator stripes turn from blue to pink after exposure to vaporized hydrogen peroxide.	The 3M™ Comply™ 1228 Gas Plasma Indicator Tape is indicated for use to secure packs as an external pack indicator to differentiate processed from unprocessed items when exposed to vapor hydrogen peroxide in the STERRAD® sterilization processes (100, 100S, 50). The Comply 1228 is suitable for use on non-woven disposable wraps and peel pouches. The diagonal stripes of chemical indicator ink turn from blue to pink after exposure to vapor hydrogen peroxide in these sterilization processes.
Sterilizers and Cycles	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 Indicator Tape 1228 samples turned from blue to pink when exposed to the STERRAD® 100 Sterilization cycle and the minimum time required for all indicator tape samples to indicate a “pass” in relation to the color match was found. Demonstrated per original submission K020589.	
Cycle Conditions for Color Change in STERRAD® 100S	Testing verified that the 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 samples turned from blue to pink when exposed to the STERRAD® 100S Sterilization cycle and the minimum time required for all indicator tape samples to indicate a “pass” in relation to the color match was found. Demonstrated per original submission K020589.	
Cycle Conditions for Color Change in STERRAD® 50	Not Applicable.	Testing verified that the 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 samples turned from blue to pink when exposed to the STERRAD® 50 Sterilization cycle and the minimum time required for all indicator tape samples to indicate a “pass” in relation to the color match was found. Demonstrated per original submission K020589.
Cycle Conditions for Color Change in STERRAD® NX®	Testing verified that the 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 samples turned from blue to pink and the minimum time required for all indicator tape samples 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 Indicator Tape 1228 samples turned from blue to pink and the minimum time required for all indicator tape samples 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	Twelve (12) months	
Shelf life	Eighteen (18) months	Identical

## **Biocompatibility**

The components of the indicator ink used on the 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 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 exposure to medical instruments with the ink, nor to the patient.

## **Effectiveness**

The effectiveness of the 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 is demonstrated by the following tests:

**Performance in a Health Care Facility Cycle** – Samples from six different lots were verified to meet the requirements for detectable color change and post-sterilization adhesion 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 a 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 twelve months post-exposure in a Hydrogen Peroxide Health Care Facility Cycle.

## **Conclusion**

Testing was conducted to confirm performance of the 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 with the STERRAD® NX® and 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 Indicator Tape 1228 is substantially equivalent to the predicate device. There are no new questions of safety or effectiveness.