



Food and Drug Administration
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July 27, 2017

3M Company
Nadia Battah
Regulatory Affairs Associate
3m Center, Building 275-5w-06
St. Paul, Minnesota 55144

Re: K170563

Trade/Device Name: 3M Comply Hydrogen Peroxide Indicator Tape
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: July 10, 2017
Received: July 10, 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,

Tara A. Ryan -S

for

Lori Wiggins, MPT,CLT

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)

K170563

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 and 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 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
K170563**



Sponsor Information:

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

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

Date of Summary: July 26, 2017

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™ Hydrogen Peroxide Indicator Tape 1228 (K150694)

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 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 Indicator Tape 1228 (K150694). 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 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 and 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 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 1228 | Predicate Device (K150694): 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 |
|---|---|---|
| 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 and 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 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. | 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 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 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 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 submission K020589. | |
| Cycle Conditions for Color Change in STERRAD® NX (Standard and Advanced cycles) | 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 Demonstrated per submission K150694. | |
| Cycle Conditions for Color Change in STERRAD® 100NX (Standard, Flex Express and Duo cycles) | 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 Demonstrated per submission K150694. | |
| 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 Indicator Tape 1228 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 AMSCO® V-PRO™ maX Low Temperature Sterilization System Cycles: Lumen Non Lumen Flexible | |
| Stability of the endpoint reaction | Twelve (12) months | Identical |
| 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 direct exposure to medical instruments with the ink, nor the patient.

Summary of Non-Clinical Testing

The non-clinical testing of the 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 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 twelve months post-exposure in a Hydrogen Peroxide Health Care Facility Cycle.

Conclusion

The 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 is substantially equivalent to the predicate device.