September 23, 2022

3M Company
Yumi Wackerfuss
Senior Regulatory Affairs Associate
2510 Conway Avenue, Bldg. 275-5W-06
St. Paul, Minnesota 55144-1000

Re: K222152
Trade/Device Name: 3M™ Attest™ Hydrogen Peroxide Indicator Tape 1228
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: July 14, 2022
Received: July 20, 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.*

Submission Number *(if known)*

K222152

Device Name

3M™ Attest™ Hydrogen Peroxide Indicator Tape 1228

Indications for Use *(Describe)*

Use the 3M™ Attest™ Hydrogen Peroxide Indicator Tape 1228 to secure packs and as an external pack process indicator to differentiate unprocessed items from items processed in the following sterilizers:
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 tape is suitable for use on non-woven disposable wraps and peel pouches. The chemical indicator stripes turn 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.**

# 510(k) Summary
# for
# 3M™ Attest™ Hydrogen Peroxide Indicator Tape 1228
# K222152

**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 Summary:** July 14th, 2022

## 1. Device Name and Classification:

| | |
|---|---|
| Common or Usual Name | Chemical Indicator |
| Proprietary Name | 3M™ Attest™ Hydrogen Peroxide Chemical Indicator 1228 |
| Classification Name | Indicator, physical/chemical sterilization process |
| Device Classification | Class II, 21 CFR § 880.2800 |
| Product Code | JOJ |

## 2. Predicate Device:

K212081, 3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228

## 3. Description of Device:

The 3M™ Attest™ 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. The chemical indicator stripes turn from blue toward pink after exposure to vaporized hydrogen peroxide. 3M™ Attest™ Hydrogen Peroxide Indicator Tape 1228 is a Type 1 (Category e1) Process Indicator as categorized by ISO 11140-1:2014.

## 4. Indications for Use

Use the 3M™ Attest™ Hydrogen Peroxide Indicator Tape 1228 to secure packs and as an external pack process indicator to differentiate unprocessed items from items processed in the following sterilizers:

| |
|---|
| 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 tape is suitable for use on non-woven disposable wraps and peel pouches. The chemical indicator stripes turn from blue toward pink after exposure to vaporized hydrogen peroxide.

## 5. Summary of Technological Characteristics compared to Predicate Device

| Feature | Submission Device: K222152<br>3M™ Attest™ Hydrogen Peroxide Indicator Tape 1228 | Predicate Device (K212081)<br>3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 | Comparison |
|---|---|---|---|
| Indications for use | Use the 3M™ Attest™ Hydrogen Peroxide Indicator Tape 1228 to secure packs and as an external pack process indicator to differentiate unprocessed items from items processed in the following sterilizers: | 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 following sterilizers: | Similar. Product brand name is changed from Comply™ to Attest™. |
| | STERRAD 100® Sterilization System | STERRAD 100® Sterilization System | |
| | STERRAD 100S® Sterilization System | STERRAD 100S® Sterilization System | |
| | STERRAD NX® Sterilization System (Standard and Advanced cycles) | STERRAD NX® Sterilization System (Standard and Advanced cycles) | |
| | STERRAD 100NX® Sterilization System (Standard, Flex, Express and Duo cycles) | STERRAD 100NX® Sterilization System (Standard, Flex, Express and Duo cycles) | |
| | STERRAD NX® with ALLClear® Technology Sterilization System (Standard and Advanced 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) | 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 Low Temperature Sterilization System (Lumen cycle) | |
| | V-PRO® 1 Plus Low Temperature Sterilization System (Lumen and Non Lumen cycles) | 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® 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® 60 Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles) | |

| Feature | Submission Device: K222152<br>3M™ Attest™ Hydrogen Peroxide Indicator Tape 1228 | Predicate Device (K212081)<br>3M™ Comply™ Hydrogen Peroxide Indicator Tape 1228 | Comparison |
|---|---|---|---|
| | V-PRO® maX 2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast Non Lumen cycles)<br>V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles)<br>STERIZONE® VP4 Sterilizer (Cycle 1)<br>The tape is suitable for use on non-woven disposable wraps and peel pouches. The chemical indicator stripes turn from blue toward pink after exposure to vaporized hydrogen peroxide. | V-PRO® maX 2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast Non Lumen cycles)<br>V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles)<br>STERIZONE® VP4 Sterilizer (Cycle 1)<br>The tape is suitable for use on non-woven disposable wraps and peel pouches. The chemical indicator stripes turn from blue toward pink after exposure to vaporized hydrogen peroxide. | |
| Substrate | Non-cellulosic plastic | Non-cellulosic plastic | Same |
| Type of indicator | Type 1 process indicator | No claim for indicator type | New claim for Type 1 process indicator |
| 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 | Six (6) months | Six (6) months | Same |
| Shelf life | Eighteen (18) months | Eighteen (18) months | Same |

The 3M™ Attest™ 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 (K212081). No changes have been made to the device materials or fundamental technology.

## 6. Nonclinical Comparison to the Predicate Device

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.

There is no change for the subject device from predicate device regarding the type 1 process indicator claim.

**Table 6.1 Summary of Nonclinical Testing**

| Test Name | Purpose | Acceptance Criteria | | Result |
|---|---|---|---|---|
| Absence of hydrogen peroxide (ISO 11140-1:2014 Type 1) | Verify device requires the presence of vaporized hydrogen peroxide to reach endpoint. | 45 Min at 50°C | Device does not reach endpoint color. | Pass |
| Hydrogen peroxide (ISO 11140-1:2014 Type 1) | 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. | |
| Off-set/transference (ISO 11140-1:2014) | 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 nonclinical testing demonstrate that the subject device, the 3M™ Attest™ Hydrogen Peroxide Indicator Tape 1228 is as safe, as effective, and performs as well as or better than the legally marketed predicate device, 3M™ Attest™ Hydrogen Peroxide Indicator Tape 1228 cleared under K212081, Class II (21 CFR 880.2800), product code JOJ.