March 13, 2020

3M Health Care
Andrew Wingen
Regulatory Affairs Commercialization Strategy Lead
2510 Conway Avenue, Bldg. 275-5W-06
St. Paul, Minnesota 55144-1000

Re: K193110
Trade/Device Name: 3M Attest Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: QKM
Dated: February 13, 2020
Received: February 14, 2020

Dear Andrew Wingen:

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,

For Sreekanth Gutala, Ph.D.
Acting 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K193110

Device Name

3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator (1348/1348E)

Indications for Use *(Describe)*

Use the 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E for pack control monitoring of the following hydrogen peroxide sterilization sterilizers and cycles: STERRAD® 100S System, STERRAD® NX® System (Standard and Advanced cycles), STERRAD® NX® System with AllClear™ Technology (Standard and Advanced cycles), STERRAD® 100NX® System (Standard, Flex, Express and Duo cycles) STERRAD® 100NX® System with AllClear™ Technology (Standard, Flex, Express and Duo cycles) vaporized hydrogen peroxide sterilizers and STERIS® V-PRO® 1 (Lumen cycle), STERIS ® V-PRO® 1 Plus (Lumen and Non-Lumen cycles) and STERIS ® V-PRO® maX Low Temperature Sterilization System (Lumen, Non-Lumen and Flexible cycles), STERIS® V-PRO® 60 Temperature Sterilization System (Lumen, Non-Lumen and Flexible cycles), and STERIS® V-PRO® maX 2 Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast Non-Lumen cycles).

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.***

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# 510(k) Summary
# for
# 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E

**Sponsor Information:**

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

Contact: Andrew Wingen
Regulatory Affairs Commercialization Strategy Lead
Phone Number: (651) 733-9209
Fax Number: (651) 737-5320

**Date of Summary:** 9 March 2020

## 1. Device Name and Classification:

| | |
|---|---|
| Common or Usual Name: | Chemical Indicator |
| Proprietary Name: | 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E |
| Classification Name: | Indicator, physical/chemical sterilization process |
| Device Classification: | Class II, 21 CFR § 880.2800 |
| Product Code: | QKM |

## 2. Predicate Device:

K183211 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248

## 3. Description of Device:

The 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E is a chemical indicator consisting of a non-cellulose based coated indicator strip sensitive to vaporized hydrogen peroxide, contained in a film laminate.

The 3M™ Attest™ CI 1348/1348E verifies that the stated values for the three critical parameters of exposure time, temperature, and amount of vaporized hydrogen peroxide have been achieved within a package or containment device (i.e. wrapped trays, rigid containers, sterilization pouches, and other types of packs) and/or at a specific location within the load or empty chamber.

Upon exposure to vaporized hydrogen peroxide, the color of the coated indicator strip progressively changes from blue toward pink along the strip. The progression of the blue to pink color change along the strip is visible through a window with marked “REJECT” and “ACCEPT” zones. The extent of the progression depends on exposure time, temperature, and amount of vaporized hydrogen peroxide.

## 4. Indications for Use

Use the 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E for pack control monitoring of the following hydrogen peroxide sterilization sterilizers and cycles: STERRAD® 100S System, STERRAD® NX® System (Standard and Advanced cycles), STERRAD® NX® System with AllClear™ Technology (Standard and Advanced cycles), STERRAD® 100NX® System (Standard, Flex, Express and Duo cycles) STERRAD® 100NX® System with AllClear™ Technology (Standard, Flex, Express and Duo cycles) vaporized hydrogen peroxide sterilizers and

STERIS® V-PRO® 1 (Lumen cycle), STERIS® V-PRO® 1 Plus (Lumen and Non-Lumen cycles) and STERIS® V-PRO® maX Low Temperature Sterilization System (Lumen, Non-Lumen and Flexible cycles), STERIS® V-PRO® 60 Temperature Sterilization System (Lumen, Non-Lumen and Flexible cycles), and STERIS® V-PRO® maX 2 Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast Non-lumen cycles).

Stated Values (SV)

Stated values of a critical process variable are values at which the indicator is designed to reach its endpoint as defined by the manufacturer. The critical process variables measured by the 3M™ Attest™ CI 1348/1348E are exposure time, temperature, and concentration of vaporized hydrogen peroxide. The stated critical values for the 3M™ Attest™ CI 1348/1348E are contained in **Table 1**.

**Table 1: Stated Values of 3M™ Attest™ CI 1348/1348E**

| Attribute | Measurement |
|---|---|
| VH2O2 | 5.1 mg/L |
| Exposure Time | 1 minute |
| Temperature | 50 C |

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

### Table 2: Comparison of Submission Device and Predicate Device

| Feature | Submission Device: 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator (K193110) | Predicate Device: 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 (K183211) | Comparison |
|---|---|---|---|
| Device Models | 1348, 1348E | 1248 | Different |
| Device Design | The 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E is a chemical indicator consisting of a non-cellulose based coated indicator strip sensitive to vaporized hydrogen peroxide, contained in a film laminate.<br><br>The 3M™ Attest™ CI 1348/1348E verifies that the three critical parameters of exposure time, temperature, and concentration of vaporized hydrogen peroxide have been achieved within a package or containment device (i.e. wrapped trays, rigid containers, sterilization pouches, and other types of packs) and/or at a specific location within the load or empty chamber.<br><br>Upon exposure to vaporized hydrogen peroxide, the color of the coated indicator strip progressively changes from blue toward pink along the strip. The progression of the blue to pink color change along the strip is visible through a window with marked "REJECT" and "ACCEPT" zones. The extent of the progression depends on exposure time, temperature, and concentration of vaporized hydrogen peroxide. | 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.<br><br>Upon exposure to vaporized hydrogen peroxide, the chemical indicator bar turns from blue toward pink. | Similar |
| Sterilizers in which Color Change Performance was Demonstrated (Blue toward Pink) | STERRAD® 100S<br>STERRAD® NX (Standard and Advanced cycles)<br>STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles)<br>STERRAD® 100NX (Standard, Flex, Express, and Duo cycles)<br>STERRAD® 100NX with ALLClear™ Technology (Standard, Flex, Express, and Duo cycles)<br>STERIS® V-PRO® maX (Lumen, Non-Lumen, and Flexible cycles)<br>STERIS® V-PRO® maX2 (Lumen, Non-Lumen, Flexible, and Fast Non-Lumen cycles)<br>STERIS® V-PRO® 60 (Lumen, Non-Lumen, and Flexible cycles) | STERRAD® 100<br>STERRAD® 100S<br>STERRAD® NX (Standard and Advanced cycles)<br>STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles)<br>STERRAD® 100NX (Standard, Flex, Express, and Duo cycles)<br>STERRAD® 100NX with ALLClear™ Technology (Standard, Flex, | Similar. The Tri-Metric CI is not indicated to be used with the STERRAD® 100 sterilizer. Testing with the STERIS® V-PRO® maX is equivalent to V-PRO® 1 and V-PRO® 1 Plus cycles. |

| | | | |
|---|---|---|---|
| | | 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) AMSCO® V-PRO™ 60 (Lumen, Non Lumen and Flexible cycles) | |
| Indications for use | Use the 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E for pack control monitoring of the following hydrogen peroxide sterilization sterilizers and cycles: STERRAD® 100S System, STERRAD® NX® System (Standard and Advanced cycles), STERRAD® NX® System with AllClear™ Technology (Standard and Advanced cycles), STERRAD® 100NX® System (Standard, Flex, Express and Duo cycles) STERRAD® 100NX® System with AllClear™ Technology (Standard, Flex, Express and Duo cycles) vaporized hydrogen peroxide sterilizers and STERIS® V-PRO® 1 (Lumen cycle), STERIS ® V-PRO® 1 Plus (Lumen and Non-Lumen cycles) and STERIS ® V-PRO® maX Low Temperature Sterilization System (Lumen, Non-Lumen and Flexible cycles), STERIS® V-PRO® 60 Temperature Sterilization System (Lumen, Non-Lumen and Flexible cycles), and STERIS® V-PRO® maX 2 Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast Non-lumen cycles). | 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, STERRAD® 100S, STERRAD® NX (Standard and Advanced cycles), STERRAD® 100NX (Standard, Flex, Express and Duo cycles), STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles), STERRAD® 100NX with ALLClear™ Technology (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, | Similar. Tri-Metric removes STERRAD® 100 and updates brand names associated with the former AMSCO® V-PRO sterilizers. Tri-Metric notes color change in the device description portion of the instructions for use rather than in the indications for use portion of the instructions for use. |

<table>
<tr><td></td><td></td><td>and Flexible cycles) and AMSCO® V-PRO® 60 Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles) sterilizers. The chemical indicator bar turns from blue toward pink after exposure to vaporized hydrogen peroxide.</td><td></td></tr>
<tr><td>Indicator Agent</td><td>Proprietary</td><td>Proprietary</td><td>Identical</td></tr>
<tr><td>Stability of the endpoint reaction</td><td>At least one month (4 weeks)</td><td>At least one month (4 weeks)</td><td>Identical</td></tr>
<tr><td>Shelf life</td><td>6 months</td><td>Two (2) years</td><td>Similar</td></tr>
<tr><td>Endpoint Specifications (Minimum Stated Values)</td><td><table><tr><th>VH2O2 Concentration</th><th>Exposure Time</th><th>Temperature</th></tr><tr><td>5.1 mg/L</td><td>1 minute</td><td>50 degrees C</td></tr></table></td><td>Not applicable. The CI turns from blue toward pink after exposure to vaporized hydrogen peroxide.</td><td>Different. The predicate is sensitive to VH2O2 exposure only, while the submission device is sensitive to VH2O2 concentration, exposure time, and temperature.</td></tr>
</table>

## 6. Nonclinical Comparison to the Predicate Device

The 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E has similar design, fundamental technology, and performance specification to the predicate device sold under the tradename 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248 (K183211). The key difference between the Tri-Metric CI 1348/1348E and the Hydrogen Peroxide CI 1248 is that Tri-Metric is sensitive to three critical process variables (sterilant exposure duration, concentration, and temperature), while the predicate is sensitive to sterilant exposure.

Given differences in device construction and performance specifications between the predicate and new device, nonclinical testing was performed in accordance with the *FDA Guidance for Industry and Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators*, issued December 19, 2003.

**Table 3: Summary of Nonclinical Testing**

| Test | Result |
|---|---|
| **Health Care Facility Simulated Use Testing**: Color change of the indicator was assessed after exposure to representative complete and incomplete cycles for the STERRAD® 100S, STERRAD® NX® (Standard and Advanced cycles), STERRAD® NX® with AllClear™ (Standard and Advanced cycles), STERRAD® 100NX® (Standard, Flex, Express and Duo cycles) STERRAD® 100NX® System with AllClear™ (Standard, Flex, Express and Duo cycles), STERIS ® V-PRO® maX (Lumen, Non-Lumen and Flexible cycles), STERIS® V-PRO® maX 2 (Lumen, Non-Lumen, Flexible, and Fast Non-lumen cycles), and STERIS® V-PRO® 60 (Lumen, Non-Lumen, Flexible and Fast Non-Lumen cycles) sterilizers. | Pass |
| **Worst Case Sterilant Exposure Testing**: Testing was conducted using overexposure conditions in a commercial sterilizer to ensure color change in overexposure conditions was similar to color change observed for in-pack monitoring of the same cycle. | Pass |
| **Endpoint Color Stability**: Following VH2O2 processing, chemical indicator samples were placed in a shelf life study to confirm the chemical indicator samples conserved their color change reading over time. | Pass |
| **Shelf Life Testing**: 6 months of shelf life testing assessing endpoint and non-endpoint conditions was conducted. | Pass |

## 7. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E is as safe, as effective, and performs as well as or better than the legally marketed predicate device, the 3M™ Comply™ Hydrogen Peroxide Chemical Indicator 1248, cleared under K183211.