April 20, 2022

3M Company
Mary Fretland
Regulatory Affairs Specialist
3M Center, Building 275-5W-06
St. Paul, Minnesota 55144

Re: K212022
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: March 24, 2022
Received: March 25, 2022

Dear Mary Fretland:

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.

510(k) Number *(if known)*
K212022

Device Name
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 sterilizers and cycles:

- 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)

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.

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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: Mary Fretland
Regulatory Affairs Specialist
Phone Number: (651) 461-2734

Date of Summary: 19 April 2022

510(k): K212022

PREMARKET NOTIFICATION [510(k)]
3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E

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

1. **Predicate Device:**

K203284, 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E

2. **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 to 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.

3. **Indications for Use**

Use the 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E for pack control monitoring of the following sterilizers and cycles:

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)

4. Summary of Technological Characteristics compared to Predicate Device

<table>
<tr><th>Feature</th><th>Submission Device: 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator</th><th>Predicate Device: 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator (K203284)</th><th>Comparison</th></tr>
<tr><td>Device Models</td><td>1348, 1348E</td><td>1348, 1348E</td><td>Identical</td></tr>
<tr><td>Indications for Use</td><td>Use the 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E for pack control monitoring of the following sterilizers and cycles:

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)</td><td>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® 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</td><td>Similar. The submission device adds the STERIZONE® VP4 Sterilizer (Cycle 1) to the indications for use and removes the “hydrogen peroxide sterilization” as a descriptor for the list of sterilizers. The list now includes both hydrogen peroxide and a dual sterilant (hydrogen peroxide/ozone) sterilizer.</td></tr>
</table>

	V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles) STERIZONE® VP4 Sterilizer (Cycle 1)	Lumen, Flexible, and Fast Non Lumen cycles) V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles)	
Indicator Agent	Proprietary	Proprietary	Identical
Stability of the endpoint reaction	At least six months	At least six months	Identical
Shelf life	15 months	15 months	Identical
Endpoint Specifications (Minimum Stated Values)	**VH2O2 Concentration**: 5.1 mg/L; **Exposure Time**: 1 minute; **Temperature**: 50 degrees C	**VH2O2 Concentration**: 5.1 mg/L; **Exposure Time**: 1 minute; **Temperature**: 50 degrees C	Identical

5. Nonclinical Comparison to the Predicate Device

The submission device, 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E, has identical design, fundamental technology, and performance specifications to the predicate device under the same name. The key difference between the submission device and the predicate device is that the submission device adds an indication for pack control monitoring of the exposure time, temperature, and amount of vaporized hydrogen peroxide of the dual sterilant vaporized hydrogen peroxide/ozone STERIZONE® VP4 Sterilizer (Cycle 1), last cleared under K203284.

Given the addition of this indication for the STERIZONE® VP4 Sterilizer, 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. Testing was conducted via simulated use testing of the STERIZONE® VP4 Sterilizer in a health care facility and all tests conducted passed.

Summary of Nonclinical Testing

Test Name	Purpose	Acceptance Criteria	Result
Health Care Facility Simulated Use Testing on STERIONE VP4 Sterilizer (Cycle 1)	Assess color change of indicator after exposure to representative complete and incomplete cycles for the STERIONE VP4 Sterilizer (Cycle 1)	The 3M™ Tri-Metric CI turns from blue toward pink in the ACCEPT region of the indicator window to indicate a "PASS" (reaches endpoint) when exposed to a complete cycle in the STERIONE VP4 Sterilizer (Cycle 1).	All Tri-Metric CIs tested met acceptance criteria.
		The 3M™ Tri-Metric CI turns from blue toward pink only within the REJECT region of the indicator window to indicate a "FAIL" (does not reach endpoint) when exposed to an incomplete cycle in the STERIONE VP4 Sterilizer (Cycle 1).	All Tri-Metric CIs tested met acceptance criteria.

6. Conclusion

The conclusions drawn from the non-clinical performance data demonstrate that the submission device, 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348^{E}, is as safe, as effective, and performs as well or better than the legally marketed predicate of the same name (K203284), Class II (21 CFR 880.2800), product code QKM.