December 7, 2020

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

Re: K203284
Trade/Device Name: 3M Attest Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: QKM
Dated: November 6, 2020
Received: November 9, 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,

Clarence W. Murray, III, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203284

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), STERIS® V-PRO® maX 2 Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast Non-Lumen cycles), and the STERIS® V-PRO® s2 Low Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast 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.

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Special 510(k) Summary
for
3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E
K203284

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) 733-0929
Fax Number: (651) 737-5320

Date of Summary: 4 December 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:

K193110, 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E

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), STERIS® V-PRO® maX 2 Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast Non-Lumen cycles), and the STERIS® V-PRO® s2 Low Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast cycles).

5. Summary of Technological Characteristics compared to Predicate Device

Feature	**Submission Device: 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator**	**Predicate Device: 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator (K193110)**	**Comparison**
Device Models	1348, 1348E	1348, 1348E	Identical
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. The 3M™ Attest™ CI 1348/1348E verifies that the stated values for 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. 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™ 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 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. 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.	Identical
Sterilizers in which Color Change	STERRAD® 100S STERRAD® NX (Standard and Advanced cycles)	STERRAD® 100S STERRAD® NX (Standard and Advanced cycles)	Similar. The submission device adds

Performance was Demonstrated (Blue toward Pink)	STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles) STERRAD® 100NX (Standard, Flex, Express, and Duo cycles) STERRAD® 100NX with ALLClear™ Technology (Standard, Flex, Express, and Duo cycles) STERIS® V-PRO® maX (Lumen, Non-Lumen, and Flexible cycles) STERIS® V-PRO® maX2 (Lumen, Non-Lumen, Flexible, and Fast Non-Lumen cycles) STERIS® V-PRO® 60 (Lumen, Non-Lumen, and Flexible cycles) STERIS® V-PRO® s2 (Lumen, Non-Lumen, Flexible, and Fast cycles)	STERRAD® NX with ALLClear™ Technology (Standard and Advanced cycles) STERRAD® 100NX (Standard, Flex, Express, and Duo cycles) STERRAD® 100NX with ALLClear™ Technology (Standard, Flex, Express, and Duo cycles) STERIS® V-PRO® maX (Lumen, Non-Lumen, and Flexible cycles) STERIS® V-PRO® maX2 (Lumen, Non-Lumen, Flexible, and Fast Non-Lumen cycles) STERIS® V-PRO® 60 (Lumen, Non-Lumen, and Flexible cycles)	the STERIS® V-PRO® s2 sterilizer to the indications for use and testing was conducted to demonstrate color change performance.
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), STERIS® V-PRO® maX 2 Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast Non-lumen cycles), STERIS® V-PRO® s2 Low Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast cycles).	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).	Similar. The submission device adds the STERIS® V-PRO® s2 sterilizer to the indications for use.
Indicator Agent	Proprietary	Proprietary	Identical
Stability of the endpoint reaction	At least one month (4 weeks)	At least one month (4 weeks)	Identical

<table>
<tr><td>Shelf life</td><td>15 months</td><td>6 months</td><td>Similar. 15 month shelf life data has been generated for the submission device using the same protocol used in the predicate submission.</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><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>Identical</td></tr>
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6. Summary of Nonclinical Testing

Provided below are the non-clinical test methodologies performed to demonstrate the Tri-Metric CI met the acceptance criteria of the standard.

Test Method	Purpose	Acceptance Criteria	Results
Health Care Facility Simulated Use Testing on STERIS V-PRO s2 sterilizer	Assess color change of indicator after exposure to representative complete and incomplete cycles for the STERIS V-PRO s2 sterilizer	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 Lumen, Non-Lumen, Flexible, or Fast Cycle in the STERIS V-PRO s2 Low Temperature Sterilization System.	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 Lumen, Non-Lumen, Flexible, or Fast Cycle in the STERIS V-PRO s2 Low Temperature Sterilization System.	All Tri-Metric CIs tested met acceptance criteria.

7. Conclusion

Based on the non-clinical performance data, the submission device 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 predicate of the same name (K193110), Class II (21 CFR 880.2800), product code QKM.