June 27, 2024

3M Company
Heidi Wallis
Regulatory Affairs Senior Associate
3M Center
2510 Conway Avenue, Building 275-5W-06
St. Paul, Minnesota 55144-1000

Re: K240717
Trade/Device Name: 3M™ Attest™ Rapid Readout Biological Indicator 1295 and 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: FRC, QKM
Dated: May 14, 2024
Received: May 29, 2024

Dear Heidi Wallis:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Christopher K. Dugard -S

Christopher K. Dugard, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240717

Device Name
3M ™ Attest ™ Rapid Readout Biological Indicator 1295

Indications for Use *(Describe)*
Use the 3M ™ Attest ™ Rapid Readout Biological Indicator 1295 in conjunction with the 3M ™ Attest ™ Auto-reader 490H or 490 Auto-reader having software version 4.0.0 or greater or 490M Auto-reader as a standard method of routine monitoring of vaporized hydrogen peroxide sterilization processes in the following systems:
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)
SteroScope® Sterilization System

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240717

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® 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)
SteroScope® Sterilization System

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)

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510(k) Summary
for
3M™ Attest™ Rapid Readout Biological Indicator 1295 and 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E

Sponsor Information:

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

Contact: Heidi Wallis
Regulatory Affairs Senior Associate

Date of Summary: June 24, 2024

510(k) Reference: K240717

PREMARKET NOTIFICATION [510(k)]
3M™ Attest™ Rapid Readout Biological Indicator 1295 and
3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E

1. Device Name and Classification:

Common or Usual Name:	Biological Indicator
Proprietary Name:	3M™ Attest™ Rapid Readout Biological Indicator 1295
Classification Name:	Indicator, biological sterilization process
Device Classification:	Class II, 21 CFR § 880.2800(a)
Product Code:	FRC

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:

K211705, 3M™ Attest™ Rapid Readout Biological Indicator 1295

K212022, 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E

3. Description of Device:

3M™ Attest™ Rapid Readout Biological Indicator 1295:
The 3M™ Attest™ Rapid Readout Biological Indicator 1295 is a self-contained biological indicator specifically designed for rapid and reliable routine monitoring of vaporized hydrogen peroxide sterilization processes when used in conjunction with the 3M™ Attest™ Auto-reader 490H or the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater or a 3M™ Attest™ Mini Auto-reader 490M. The 1295 BI is a single-use device composed of a plastic sleeve containing a spore carrier and media ampoule, enclosed with a color-coded cap. A chemical process indicator printed with stripes which change from blue toward pink upon exposure to vaporized hydrogen peroxide is located on the top of the cap. The detection of fluorescence upon incubation of the 1295 BI in one of the designated Attest™ Auto-readers indicates a sterilization failure.

3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E:
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. There has been no change to the product construction compared to the predicate submission, K212022.

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.

4. Indications for Use

Use the 3M™ Attest™ Rapid Readout Biological Indicator 1295 in conjunction with the 3M™ Attest™ Auto-reader 490H or 490 Auto-reader having software version 4.0.0 or greater or 490M Auto-reader as a standard method of routine monitoring of vaporized hydrogen peroxide sterilization processes in the following systems:

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)
SteroScope® Sterilization System

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 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)
SteroScope® Sterilization System

Technological Characteristic Comparison Table

Feature	Submission Device: 3M™ Attest™ Rapid Readout Biological Indicator	Predicate Device (K211705): 3M™ Attest™ Rapid Readout Biological Indicator	Comparison
Device Models	1295	1295	Identical
Indications for use	Use the 3M™ Attest™ Rapid Readout Biological Indicator 1295 in conjunction with the 3M™ Attest™ Auto-reader 490H or 490 Auto-reader having software version 4.0.0 or greater or 490M Auto-reader as a standard method of routine monitoring of vaporized hydrogen peroxide sterilization processes in the following systems: STERRAD 100S® Sterilization System	Use the 3M™ Attest™ Rapid Readout Biological Indicator 1295 in conjunction with the 3M™ Attest™ Auto-reader 490H or 490 Auto-reader having software version 4.0.0 or greater or 490M Auto-reader as a standard method of routine monitoring of vaporized hydrogen peroxide sterilization processes in the following systems: STERRAD 100S® Sterilization System	Addition of SteroScope® Sterilization System

PREMARKET NOTIFICATION [510(k)]
3M™ Attest™ Rapid Readout Biological Indicator 1295 and
3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E

Feature	Submission Device: 3M™ Attest™ Rapid Readout Biological Indicator	Predicate Device (K211705): 3M™ Attest™ Rapid Readout Biological Indicator	Comparison
	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) SteroScope® 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)	
Organism	*Geobacillus stearothermophilus* traceable to ATCC™ 7953	*Geobacillus stearothermophilus* traceable to ATCC™ 7953	Identical
Viable spore population	$\geq 1x10^6$	$\geq 1x10^6$	Identical
Resistance characteristics • D-value • Survival/Kill Window	(Tested at 10 mg/L vaporized hydrogen peroxide) $D_{10\ mg/L} \geq 1$ second Survival Time ≥ 5 seconds Kill Time = 7 minutes	(Tested at 10 mg/L vaporized hydrogen peroxide) $D_{10\ mg/L} \geq 1$ second Survival Time ≥ 5 seconds Kill Time = 7 minutes	Identical
Carrier material	Polyethylene terephthalate	Polyethylene terephthalate	Identical

PREMARKET NOTIFICATION [510(k)]
3M™ Attest™ Rapid Readout Biological Indicator 1295 and
3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E

Feature	Submission Device: 3M™ Attest™ Rapid Readout Biological Indicator	Predicate Device (K211705): 3M™ Attest™ Rapid Readout Biological Indicator	Comparison
Incubation temperature	60 ± 2ºC	60 ± 2ºC	Identical
Readout time	24 minute fluorescence result read	24 minute fluorescence result read	Identical
Chemical indicator	H_2O_2 sensitive ink; changes from blue towards pink	H_2O_2 sensitive ink; changes from blue towards pink	Identical
Shelf life	Two (2) years	Two (2) years	Identical

Feature	Submission Device: 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator	Predicate Device: 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator (K212022)	Comparison
Device Models	1348, 1348E	1348, 1348E	Identical
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® 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)	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)	Addition of SteroScope® Sterilization System

<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 (K212022)</th><th>Comparison</th></tr>
<tr><td></td><td>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)
SteroScope® Sterilization System</td><td>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)</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 six months</td><td>At least six months</td><td>Identical</td></tr>
<tr><td>Shelf life</td><td>24 months</td><td>15 months</td><td>Similar, shelf-life extended to 24 months</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>
</table>

5. Nonclinical Comparison to the Predicate Device

The 3M™ Attest™ Rapid Readout Biological Indicator 1295 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 SteroScope® Sterilization System (last cleared under K211705)

To demonstrate performance in the newly claimed sterilizer and cycles, nonclinical testing was performed in accordance with the *FDA Guidance for Industry and FDA Staff: Biological Indicator (BI) Premarket Notification [510(k)] Submissions*, issued October 04, 2007, and ANSI/AAMI/ISO 11138-1:2017 Sterilization of health care products- Biological Indicators- Part 1: General requirements (FDA Recognition Number 14-502).

Reference **Table 5.1** and **5.2** for testing completed in SteroScope® Sterilization System.

Table 5.1 Summary of Biological Indicator Nonclinical Testing

Test Name	Purpose	Acceptance Criteria	Result
Full Cycle Performance	Verify performance in each of the full cycles in the SteroScope® Sterilization System.	All biological indicators display a negative fluorescent and negative growth response.	Pass
Fractional Cycle Performance	Verify performance in fractional cycles for each of the cycles within the SteroScope® Sterilization System.	All biological indicators display a negative fluorescent and negative growth response.	Pass
Chemical Indicator (CI) Color Change	Demonstrate the color change of the CI when exposed to the SteroScope® Sterilization System.	Color change from blue toward pink.	Pass

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 SteroScope® Sterilization System (last cleared under K212022).

Given the addition of this indication for the SteroScope® Sterilization System, 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 SteroScope® Sterilization System.in a health care facility and all tests conducted passed.

Table 5.1 Summary of Tri-Metric Chemical Indicator Nonclinical Testing

Test Name	Purpose	Acceptance Criteria	Result
Complete (Full) Cycle Performance	Verify performance in the complete (full) cycle of a	Visual assessment of the chemical indicator yields an ACCEPT result with ≥ 95% accuracy	Pass, 100% accuracy

	loaded SteroScope® Sterilization System.	At least 80% of the population of indicators tested has a measured color change value corresponding to an ACCEPT result.	Pass, >99.9% population
Fractional Cycle Performance	Verify performance in an incomplete cycle of a loaded SteroScope® Sterilization System.	Visual assessment of the chemical indicator yields a REJECT result with ≥ 95% accuracy	Pass, 100% accuracy
		At least 80% of the population of indicators tested has a measured color change value corresponding to a REJECT result.	Pass, >99.9% population

6. Conclusion

Based on the non-clinical performance data, the 3M™ Attest™ Rapid Readout Biological Indicator 1295 and 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E is as safe, as effective, and performs as well as the legally marketed predicate, the 3M™ Attest™ Rapid Readout Biological Indicator 1295 cleared under K211705, Class II (21 CFR 880.2800), product code FRC and 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E cleared under K212022, Class II (21 CFR 880.2800), product code QKM.