June 27, 2024

3M Company
Samantha Miller
Regulatory Affairs Associate
3M Center
2510 Conway Avenue, Building 275-5W-06
St. Paul, Minnesota 55144

Re: K241542
Trade/Device Name: 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD (1295PCD)
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: May 30, 2024
Received: May 31, 2024

Dear Samantha Miller:

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.

Submission Number *(if known)*

K241542

Device Name

3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD (1295PCD)

Indications for Use *(Describe)*

3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack (1295PCD):
Use the 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater or a 3M™ Attest™ Mini Auto-reader 490M or a 3M™ Attest™ Auto-reader 490H as a standard method of routine monitoring and performance qualification of vaporized hydrogen peroxide sterilization processes in the follow 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)
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.

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510(k) Summary
for
3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD

Sponsor Information:

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

Contact: Samantha Miller
Regulatory Affairs Associate

Date of Summary: May 30, 2024

510(k) Reference: K241542

1. **Device Name and Classification:**

Common or Usual Name:	Sterilization Biological Indicator
Proprietary Name:	3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD
Classification Name:	Indicator, biological sterilization process
Device Classification:	Class II, 21 CFR § 880.2800(a)
Product Code:	FRC

2. **Predicate Device:**

K233814, 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD

3. **Description of Device:**

The 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD is designed as a standard method of rapid and reliable routine monitoring and performance qualification of vaporized hydrogen peroxide sterilization processes.

The 1295PCD Challenge Pack consists of a clear plastic shell, with two individual channels allowing for air removal and sterilant penetration. Those two individual channels connect to a cavity containing the monitoring products and all are covered by a foil lid. The 1295PCD is a single-use device.

Each 1295PCD Challenge Pack contains a 3M™ Attest™ Rapid Readout Biological Indicator (BI) 1295 (pink cap) and a 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator (CI) 1348. The 1348 CI verifies that the stated values for the three critical parameters of exposure time, temperature, and concentration of vaporized hydrogen peroxide have been achieved and offers an ACCEPT or REJECT reading. The 1295 BI is specifically designed for rapid and reliable routine monitoring of vaporized hydrogen peroxide sterilization processes when used in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater or a 3M™ Attest™ Mini Auto-reader 490M or a 3M™ Attest™ Auto-reader 490H. The presence of fluorescence within the specified incubation time for the 1295 BI in the 490, 490M, or the 490H Auto-reader indicates a sterilization process failure. A printed chemical process indicator is present on the cap of the 1295 BI and is visible through the clear plastic shell of the challenge pack. The process indicator turns color upon exposure to vaporized hydrogen peroxide and is used by the customer to verify that the challenge pack was exposed to vaporized hydrogen peroxide.

4. Indications for Use

Use the 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater or a 3M™ Attest™ Mini Auto-reader 490M or a 3M™ Attest™ Auto-reader 490H as a standard method of routine monitoring and performance qualification of vaporized hydrogen peroxide sterilization processes in the follow 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)
SteroScope® Sterilization System

5. Technological Characteristic Comparison Table

Feature	Submission Device: 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD	Predicate Device (K233814): 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD	Comparison
Device Models	1295PCD	1295PCD	Identical
Intended Use	Single Use sterilization process indicator	Single Use sterilization process indicator	Identical
Indications for use	Use the 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater or a 3M™ Attest™ Mini Auto-reader 490M or a 3M™ Attest™ Auto-reader 490H as a standard method of routine monitoring and performance qualification of vaporized hydrogen peroxide sterilization processes in the follow 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)	Use the 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater or a 3M™ Attest™ Mini Auto-reader 490M or a 3M™ Attest™ Auto-reader 490H as a standard method of routine monitoring and performance qualification of vaporized hydrogen peroxide sterilization processes in the follow 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)	Addition of SteroScope® Sterilization System

Feature	Submission Device: 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD	Predicate Device (K233814): 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD	Comparison
	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) SteroScope® Sterilization System	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)	
Biological Indicator	3M™ Attest™ Rapid Readout Biological Indicator 1295 with ≥ 1 x106 *Geobacillus stearothermophilus* spores	3M™ Attest™ Rapid Readout Biological Indicator 1295 with ≥ 1 x106 *Geobacillus stearothermophilus* spores	Identical
Chemical Indicator	3M™ Attest™ Vaporized Hydrogen Peroxide Tri- Metric Chemical Indicator 1348.	3M™ Attest™ Vaporized Hydrogen Peroxide Tri- Metric Chemical Indicator 1348.	Identical
General Design / Construction	Clear plastic tray with channels to the cavity containing the indicators, acting as a challenge to limit air removal and VH2O2 penetration, sealed with a foil lid.	Clear plastic tray with channels to the cavity containing the indicators, acting as a challenge to limit air removal and VH2O2 penetration, sealed with a foil lid.	Identical
Process Indicator	Process indicator present on 1295 BI cap is visible through PCD and turns color from blue towards pink upon vaporized hydrogen peroxide exposure.	Process indicator present on 1295 BI cap is visible through PCD and turns color from blue towards pink upon vaporized hydrogen peroxide exposure.	Identical

6. Nonclinical Comparison to the Predicate Device

The 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD is identical to the 3M-owned predicate device (K233814) with respect to design, materials, performance specifications and fundamental technology. 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.

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 6.1** for testing completed in SteroScope® Sterilization System.

Table 6.1 Summary of Tri-Metric Chemical Indicator Nonclinical Testing

Test Name	Purpose	Acceptance Criteria	Result
Full Cycle Performance	Verify performance in the full normal cycle of a loaded SteroScope® Sterilization System.	Chemical Indicator will change color in the ACCEPT region of the indicator window to a b* value equal to or greater than -18 (PASS)	Pass
		Biological Indicator will result in 100% florescence NEGATIVE response	Pass
Incomplete Cycle Performance	Verify performance in an incomplete normal cycle of a loaded SteroScope® Sterilization System.	Chemical Indicator will change color in the ACCEPT region of the indicator window to a b* value less than -20 (FAIL)	Pass
		Biological Indicator will result in 100% florescence POSITIVE response	Pass

7. Conclusion

Based on the non-clinical performance data, the 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD is as safe, as effective, and performs as well as the legally marketed predicate, the 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD cleared under K233814, Class II (21 CFR 880.2800), product code FRC.