March 3, 2021

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

Re: K210277
Trade/Device Name: 3M Attest Rapid Readout Biological Indicator, 1295
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: January 28, 2021
Received: February 1, 2021

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 and Part 809); 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, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210277

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)

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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"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."

510(k) Summary
for
3M™ Attest™ Rapid Readout Biological Indicator 1295

Sponsor Information:

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

Contact: Mary Fretland
Regulatory Affairs Specialist
Phone Number: (651) 737-2296

Date of Summary: January 28, 2021

510(k) References: K210277

PREMARKET NOTIFICATION [510(k)]
3M™ Attest™ Rapid Readout Biological Indicator 1295

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

2. **Predicate Device:**

K200996 3M™ Attest™ Rapid Readout Biological Indicator 1295

3. **Description of Device:**

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.

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)

Technological Characteristic Comparison Table

Feature	Submission Device: 3M™ Attest™ Rapid Readout Biological Indicator 1295	Predicate Device (K200996): 3M™ Attest™ Rapid Readout Biological Indicator 1295	Comparison
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,	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: AMSCO® V-PRO® 1 Low Temperature Sterilization System (Lumen cycle), AMSCO® V-PRO® 1 Plus Low Temperature Sterilization System (Lumen and Non Lumen cycles), AMSCO® V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles), AMSCO® V-PRO® 60 Low Temperature Sterilization System (Lumen, Non Lumen and Flexible cycles), STERIS® V-PRO® maX 2 Low Temperature Sterilization System (Fast Non Lumen, Lumen, Non Lumen, and Flexible cycles) and in STERRAD® 100S, STERRAD® NX (Standard and Advanced cycles), STERRAD® 100NX (Standard, Flex, Express and Duo cycles) systems, STERRAD® NX with AllClear™ Technology (Standard and Advanced cycles) and STERRAD® 100NX with AllClear™ Technology (Standard, Flex, Express and Duo cycles).	Addition of the V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles)

Feature	Submission Device: 3M™ Attest™ Rapid Readout Biological Indicator 1295	Predicate Device (K200996): 3M™ Attest™ Rapid Readout Biological Indicator 1295	Comparison
	Flexible, and Fast Non Lumen cycles) V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles)		
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
Incubation temperature	60 ± 2°C	60 ± 2°C	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

5. Nonclinical Comparison to the Predicate Device

The 3M™ Attest™ Rapid Readout Biological Indicator 1295 is identical to the previously cleared device of the same model number (the predicate) which is sold under the same tradename and cleared via K200996.

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*, 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** for testing completed in V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles)

Table 5.1 Summary of Nonclinical Testing

Test Name	Purpose	Acceptance Criteria	Result
Full Cycle Performance	Verify performance in each of the full cycles in the V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles).	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 V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles).	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 V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles).	Color change from blue toward pink.	Pass

6. Conclusion

Based on the non-clinical performance data, the 3M™ Attest™ Rapid Readout Biological Indicator 1295 is as safe, as effective, and performs as well or better than the legally marketed predicate, the 3M™ Attest™ Rapid Readout Biological Indicator 1295 cleared under K200996, Class II (21 CFR 880.2800), product code FRC.