



December 11, 2020

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

Re: K200996

Trade/Device Name: 3M™ Attest™ Rapid Readout Biological Indicator  
Regulation Number: 21 CFR 880.2800  
Regulation Name: Sterilization Process Indicator  
Regulatory Class: Class II  
Product Code: FRC  
Dated: November 13, 2020  
Received: November 16, 2020

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](mailto: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

## Indications for Use

510(k) Number (if known)

K200996

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: 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).

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™ Rapid Readout Biological Indicator 1295**  
**K200996**

**Sponsor Information:**

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

Contact: Mary Fretland  
Senior Regulatory Affairs Associate  
Phone Number: (651) 737-2296  
Fax Number: (651) 737-5320

**Date of Summary:** December 09, 2020

**510(k) Reference:** K200996

**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:**

K173435 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: 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).

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

**5. Technological Characteristic Comparison Table**

Feature	Submission Device: 3M™ Attest™ Rapid Readout Biological Indicator 1295	Predicate Device (K173435): 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: 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).	Use the 3M™ Attest™ Rapid Readout Biological Indicator 1295 in conjunction with the 3M™ Attest™ Auto reader 490H 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) 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 490 and 490M Auto-readers  and  Addition of the STERIS® V-PRO® maX 2 Low Temperature Sterilization System (Fast Non Lumen, Lumen, Non Lumen, and Flexible cycles) sterilizer
Organism	<i>Geobacillus stearothermophilus</i> traceable to ATCC™ 7953	<i>Geobacillus stearothermophilus</i> traceable to ATCC™ 7953	Identical
Viable spore population	≥1x10 <sup>6</sup>	≥1x10 <sup>6</sup>	Identical
Resistance characteristics • D-value • Survival/Kill Window	(Tested at 10 mg/L vaporized hydrogen peroxide) D <sub>10 mg/L</sub> ≥ 1 second Survival Time ≥ 5 seconds Kill Time = 7 minutes	(Tested at 10 mg/L vaporized hydrogen peroxide) D <sub>10 mg/L</sub> ≥ 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

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

<b>Feature</b>	<b>Submission Device: 3M™ Attest™ Rapid Readout Biological Indicator 1295</b>	<b>Predicate Device (K173435): 3M™ Attest™ Rapid Readout Biological Indicator 1295</b>	<b>Comparison</b>
Chemical indicator	H <sub>2</sub> O <sub>2</sub> sensitive ink; changes from blue towards pink	H <sub>2</sub> O <sub>2</sub> sensitive ink; changes from blue towards pink	Identical
Shelf life	Two (2) years	Two (2) years	Identical

**6. 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 K173435.

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 6.1** for testing completed in AMSCO® V-PRO™ maX 2 Low Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast Non-Lumen cycles).

**Table 6.1 Summary of Nonclinical Testing**

<b>Test Name</b>	<b>Purpose</b>	<b>Acceptance Criteria</b>	<b>Result</b>
Full Cycle Performance	Verify performance in each of the full cycles in the AMSCO® V-PRO™ maX 2 Low Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast Non-Lumen cycles) sterilizer.	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 AMSCO® V-PRO™ maX 2 Low Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast Non-Lumen 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 AMSCO® V-PRO™ maX 2 Low Temperature Sterilization System (Lumen, Non-Lumen, Flexible, and Fast Non-Lumen cycles).	Color change from blue toward pink.	Pass

- Addition of 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater per K173437 and K173584.
- Addition of 3M™ Attest™ Mini Auto-reader 490M per K200092.

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

**7. 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 as or better than the legally marketed predicate, the 3M™ Attest™ Rapid Readout Biological Indicator 1295 cleared under K173435, Class II (21 CFR 880.2800), product code FRC.