September 12, 2024

3M Company
Michelle M. Larsen
Advanced Regulatory Affairs Specialist
3M Center
2510 Conway Ave., Building 275-5W-06
St. Paul, Minnesota 55144

Re: K241710
Trade/Device Name: 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V; 3M™ Attest™ Auto-reader 490; 3M™ Attest™ Auto-reader 490H; 3M™ Attest™ Mini Auto-reader 490M
Regulation Number: 21 CFR 880.2800(a)
Regulation Name: Biological Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: June 13, 2024
Received: June 14, 2024

Dear Michelle Larsen:

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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2024.09.12 15:23:32 -04'00'

for: Christopher K. Dugard
Assistant Director
DHT4C: Division of Infection Control 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)*
K241710

Device Name
3M™ Attest™ Super Rapid Readout Biological Indicator 1492V;
3M™ Attest™ Auto-reader 490;
3M™ Attest™ Auto-reader 490H;
3M™ Attest™ Mini Auto-reader 490M

Indications for Use *(Describe)*

3M™ Attest™ Super Rapid Readout Biological Indicator 1492V:
Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V in conjunction with the 3M™ Attest™ Auto-reader 490, the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater, or the 3M™ Attest™ Mini Auto-reader 490M to qualify or monitor the following steam sterilization cycles:

Cycle Type	Exposure Temperature	Exposure Time
Dynamic-air-removal (pre-vacuum and SFPP)	270°F (132°C)	3, 3.5, 4, 5.5, or 6 minutes
Dynamic-air-removal (pre-vacuum and SFPP)	273°F (134°C)	3 or 4 minutes
Dynamic-air-removal (pre-vacuum and SFPP)	275°F (135°C)	3, 3.5 or 10 minutes

3M™ Attest™ Auto-reader 490:
The 3M™Attest™ Auto-reader 490 is designed to incubate and automatically read 3M™ Attest™ Rapid Readout Biological Indicators 1295 and 3M™ Attest™ Super Rapid Readout Biological Indicators, catalog numbers 1491, 1492V, and 1592 at 60°C for a final fluorescent result at 24 minutes.

3M™ Attest™ Auto-reader 490H:
The 3M™ Attest™ Auto-reader 490H is designed to incubate and automatically read 3M™ Attest™ Rapid Readout Biological Indicators 1295, 3M™ Attest™ Super Rapid Readout Biological Indicators, catalog numbers 1491 and 1492V, and 3M™ Attest Super Rapid Steam Biological Indicators 1592 at 60°C for a final fluorescent result at 24 minutes.

3M™ Attest™ Mini Auto-reader 490M:
The 3M™ Attest™ Mini Auto-reader 490M is designed to incubate and automatically read 3M™ Attest™ Rapid Readout Biological Indicators 1295 and 3M™ Attest™ Super Rapid Readout Biological Indicators, catalog numbers 1491, 1492V and 1592, at 60°C for a final fluorescent result at 24 minutes.

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."

510(k) Summary (K241710)
for
3M™ Attest™ Super Rapid Readout Biological Indicator 1492V,
3M™ Attest™ Auto-reader 490,
3M™ Attest™ Auto-reader 490H,
3M™ Attest™ Mini Auto-reader 490M

Sponsor Information:

3M Company
3M Center
2510 Conway Ave., Bldg. 275-5W-06
St. Paul, MN 55144-1000, USA

Contact: Michelle M. Larsen, Advanced Regulatory Affairs Specialist
Phone Number: (651) 467-3991
Fax Number: (651) 737-5320
Email: mmlarsen@solventum.com

Date of Summary: 04, September 2024

1. **Device Name and Classification:**

   Common or Usual Name: Sterilization Biological Indicator

   Proprietary Name: 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V,

	3M™ Attest™ Auto-reader 490, 3M™ Attest™ Auto-reader 490H, 3M™ Attest™ Mini Auto-reader 490M
Classification Name:	Indicator, Biological Sterilization Process
Device Classification:	Class II, 21 CFR 880.2800(a)
Product Code:	FRC

2. Predicate Device:

Primary Predicate: 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V, 3M™ Attest™ Auto-reader 490, 3M™ Attest™ Auto-reader 490H, K173437

3. Description of Device:

The 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V is a self-contained biological indicator (BI) specifically designed to be used with the 3M™ Attest™ Auto-reader 490, the 3M™ Attest™ Auto-reader 490H (having software version 4.0.0 or greater), or the 3M™ Attest™ Mini Auto-reader 490M to qualify or monitor dynamic-air-removal steam sterilization cycles at 132°C, 134°C and 135°C.

The 1492V BI is a single-use device composed of a plastic vial containing a spore carrier and media ampoule, enclosed with a color-coded cap. On each 1492V BI cap is a chemical process indicator that changes color from pink to light brown or darker when exposed to steam. The detection of fluorescence upon incubation of the 1492V BI in the 490 Auto-reader, the 490H Auto-reader (software version 4.0.0 or greater), or the 490M Mini Auto-reader indicates a sterilization failure.

4. Indications for Use

3M™ Attest™ Super Rapid Readout Biological Indicator 1492V:
Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V in conjunction with the 3M™ Attest™ Auto-reader 490, the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater, or the 3M™ Attest™ Mini Auto-reader 490M to qualify or monitor the following steam sterilization cycles:

Cycle Type	Exposure Temperature	Exposure Time
Dynamic-air-removal (pre-vacuum and SFPP)	270°F (132°C)	3, 3.5, 4, 5.5, or 6 minutes

Cycle Type	Exposure Temperature	Exposure Time
Dynamic-air-removal (pre-vacuum and SFPP)	273°F (134°C)	3 or 4 minutes
Dynamic-air-removal (pre-vacuum and SFPP)	275°F (135°C)	3, 3.5 or 10 minutes

3M™ Attest™ Auto-reader 490:
The 3M™Attest™ Auto-reader 490 is designed to incubate and automatically read 3M™ Attest™ Rapid Readout Biological Indicators 1295 and 3M™ Attest™ Super Rapid Readout Biological Indicators, catalog numbers 1491, 1492V, and 1592 at 60°C for a final fluorescent result at 24 minutes.

3M™ Attest™ Auto-reader 490H:
The 3M™ Attest™ Auto-reader 490H is designed to incubate and automatically read 3M™ Attest™ Rapid Readout Biological Indicators 1295, 3M™ Attest™ Super Rapid Readout Biological Indicators, catalog numbers 1491 and 1492V, and 3M™ Attest Super Rapid Steam Biological Indicators 1592 at 60°C for a final fluorescent result at 24 minutes.

3M™ Attest™ Mini Auto-reader 490M:
The 3M™ Attest™ Mini Auto-reader 490M is designed to incubate and automatically read 3M™ Attest™ Rapid Readout Biological Indicators 1295 and 3M™ Attest™ Super Rapid Readout Biological Indicators, catalog numbers 1491, 1492V and 1592, at 60°C for a final fluorescent result at 24 minutes.

The submission device, the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V, has the same intended use as the predicate device. Both the submission device and the predicate device are Single Use biological sterilization indicators that are intended to be used in healthcare facilities to accompany products being sterilized and to monitor adequacy of the sterilization process. The 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V was cleared per K173437 for use with the 3M™ Attest™ Auto-reader 490, and the 3M™ Attest™ Auto-reader 490H and the 3M™ Attest™ Mini Auto-reader 490M was subsequently cleared for use with the 1492V BI per K200092. As a result, the Indications for Use for the currently marketed 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V have been updated to include the 490M Mini Auto-reader. Both the predicate and submission BIs are indicated for use in dynamic-air-removal steam sterilization cycles. The submission device covers additional exposure temperatures and times for dynamic-air-removal steam sterilization cycles compared to the predicate device. The differences in Indications for Use do not alter the fundamental Intended Use of these products as sterilization process monitors.

5. Comparison of Technological Characteristics with the Predicate Device

The submission device, 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V, is the same design as the previously cleared device of the same model number (the predicate K173437). Both the subject device and the predicate device utilize the same spores to accomplish their intended use as biological sterilization indicators. There have been no changes to the device's materials, technology, engineering or performance specifications since this clearance. The predicate device is indicated for qualifying and monitoring dynamic-air removal steam sterilization cycles at 132°C and 135°C. The submission device is indicated for qualifying and monitoring dynamic-air removal steam sterilization cycles at 132°C and 135°C plus steam sterilization cycles at 134°C. The Resistance Characteristics (D-Value, Survival/Kill Window) of the submission device have been updated to include the monitoring of steam sterilization cycles at 273°F (134°C). The 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V was cleared for use with the 3M™ Attest™ Auto-reader 490, and the 3M™ Attest™ Auto-reader 490H, per K173437. The 3M™ Attest™ Mini Auto-reader 490M was cleared for use with the 1492V BI per K200092. There are no changes to the 3M™ Attest™ Auto-readers 490 and 490H, nor to the 490M Mini-Auto-reader. The accessories (Auto-readers) are the same for both the submission and predicate device and the readout time or the time to a result is the same for both the submission and predicate device.

The differences in technological characteristics between the submission and predicate device are summarized in the Device Technological Characteristics Comparison Table (**Table 1**).

Table 1: Device Technological Characteristics Comparison Table

Feature	Submission Device: (K241710) 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K173437) 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V and 3M™ Attest™ Auto-reader 490 and 490H	Comparison
Intended Use	Single Use sterilization process indicator	Single Use sterilization process indicator	Identical
Indications for use	Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V in conjunction	Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V in conjunction	Both the predicate and submission BIs are indicated for use in dynamic-air-

Feature	Submission Device: (K241710) 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K173437) 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V and 3M™ Attest™ Auto-reader 490 and 490H	Comparison
	with the 3M™ Attest™ Auto-reader 490, the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater, or the 3M™ Attest™ Mini Auto-reader 490M to qualify or monitor the following steam sterilization cycles: • Dynamic-air-removal (pre-vacuum and SFPP), 3, 3.5, 4, 5.5 or 6 minutes at 270°F (132°C) • Dynamic-air-removal (pre-vacuum and SFPP), 3 or 4 minutes at 273°F (134°C) • Dynamic-air-removal (pre-vacuum and SFPP), 3, 3.5 or 10 minutes at 275°F (135°C)	with both the 3M™ Attest™ Auto-reader 490 or the Attest™ Auto-reader 490H having software version 4.0.0 or greater to qualify or monitor dynamic-air-removal steam sterilization cycles of: • 3 or 4 minutes at 270°F (132°C) • 3 minutes at 275°F (135°C)	removal steam sterilization cycles. The intent of this submission is to expand the indications for use to include additional exposure temperatures and times compared to the predicate device. Both the predicate and submission BIs are intended to be used in conjunction with the 3M™ Attest™ Auto-reader 490, the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater to qualify or monitor dynamic-air removal steam sterilization cycles. The 1492V was cleared for use with the 3M™ Attest™ Mini Auto-reader 490M per K200092.
Organism	*Geobacillus stearothermophilus* traceable to ATCC™ 7953	*Geobacillus stearothermophilus* traceable to ATCC™ 7953	Identical

Feature	Submission Device: (K241710) 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K173437) 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V and 3M™ Attest™ Auto-reader 490 and 490H	Comparison
Viable spore population	$\geq 1 \times 10^6$	$\geq 1 \times 10^6$	Identical
Mechanism of Action	When the enzyme that is naturally occurring in the spore is in its active state, it is detected by measuring the fluorescence produced by the enzymatic hydrolysis of a non-fluorescent substrate. The resultant fluorescent by-product is detected by the Auto-reader. The presence of fluorescence upon incubation in the Auto-reader indicates a sterilization process failure. There is an optional visual pH color change which indicates a steam sterilization process failure.	When the enzyme that is naturally occurring in the spore is in its active state, it is detected by measuring the fluorescence produced by the enzymatic hydrolysis of a non-fluorescent substrate. The resultant fluorescent by-product is detected by the Auto-reader. The presence of fluorescence upon incubation in the Auto-reader indicates a sterilization process failure. There is an optional visual pH color change which indicates a steam sterilization process failure.	Identical
Resistance characteristics • D-value • Survival/Kill Window	D-value ≥ 10 seconds at 132°C D-value ≥ 8 seconds at 134°C D-value ≥ 8 seconds at 135°C Survival Time = Calculated survival time* or 1 minute at 132°C and 40 seconds at 134°C and 135°C, whichever is longer	D-value ≥ 10 seconds at 132°C D-value ≥ 8 seconds at 135°C Survival Time = Calculated survival time* or 1 minute at 132°C and 40 seconds at 135°C, whichever is longer Kill Time = Calculated kill time* at 132°C and at 135°C	The predicate device is indicated for qualifying and monitoring dynamic-air removal steam sterilization cycles at 132°C and 135°C. The submission device is indicated for qualifying and monitoring dynamic-air removal steam sterilization cycles at 132°C and 135°C

Feature	Submission Device: (K241710) 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K173437) 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V and 3M™ Attest™ Auto-reader 490 and 490H	Comparison
	Kill Time = Calculated kill time* at 132°C, 134°C and at 135°C		plus steam sterilization cycles at 134°C.
Carrier material	Polypropylene	Polypropylene	Identical
Media Ampoule	Crushable glass ampoule containing a liquid growth media.	Crushable glass ampoule containing a liquid growth media.	Identical
Incubation temperature	60 ± 2°C	60 ± 2°C	Identical
Readout time	24 minute final fluorescent result in both the 490 and 490H Auto-readers having software version 4.0.0 or greater or in a 490M Auto-reader. 1 hour final fluorescent result in 490 Auto-readers having software versions less than 4.0.0. Optional visual pH color change result in 48 hours for 490, 490H or 490M Auto-readers.	24 minute final fluorescent result in both the 490 and 490H Auto-readers having software version 4.0.0 or greater. 1 hour final fluorescent result in 490 Auto-readers having software versions less than 4.0.0. Optional visual pH color change result in 48 hours for 490 or 490H Auto-readers.	Both the predicate and submission BIs are intended to be used in conjunction with the 3M™ Attest™ Auto-reader 490, the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater to qualify or monitor dynamic-air removal steam sterilization cycles. The 1492V was cleared for use with the 3M™ Attest™ Mini Auto-reader 490M per K200092.
Chemical indicator	Turns from pink to light brown or darker upon steam exposure	Turns from pink to light brown or darker upon steam exposure	Identical
General Design/Construction	Plastic vial containing a spore carrier and media ampoule, enclosed with a color-coded cap with chemical process	Plastic vial containing a spore carrier and media ampoule, enclosed with a color-coded cap with chemical process	Identical

Feature	Submission Device: (K241710) 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K173437) 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V and 3M™ Attest™ Auto-reader 490 and 490H	Comparison
	indicator located on top of cap.	indicator located on top of cap.	
Shelf-life	21 months	21 months	Identical
Accessories (Auto-readers)	3M™ Attest™ Auto-reader 490 or the 3M™ Attest™ Auto-reader 490H or the 3M™ Attest™ Mini Auto-reader 490M	3M™ Attest™ Auto-reader 490 or the 3M™ Attest™ Auto-reader 490H	Both the predicate and submission BIs are intended to be used in conjunction with the 3M™ Attest™ Auto-reader 490, the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater to qualify or monitor dynamic-air removal steam sterilization cycles. The 1492V was cleared for use with the 3M™ Attest™ Mini Auto-reader 490M per K200092.

***** per ISO 11138-1:2017, Annex E

6. Nonclinical Comparison to the Predicate Device

The differences between the submission and predicate device have been evaluated through performance tests for the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V.

Three lots of 3M™ Attest™ Super Rapid Readout Biological Indicators 1492V were tested for Positive Control, D-Value, Survival, and Kill for 134°C (273°F) cycles. Testing was completed per the *Guidance for Industry and FDA Staff, Biological Indicator Premarket Notification [510(k)] Submissions*, October 4, 2007, ISO 11138-1:2017 Sterilization of Health Care Products—Biological Indicators—Part 1: General Requirements, and ISO 11138-3:2017 *Sterilization of health care products – Biological indicators - Part 3: Biological indicators for moist heat sterilization processes.*

Three lots of 3M™ Attest™ Super Rapid Readout Biological Indicators 1492V were tested for Reduced Incubation Time for 134°C (273°F) cycles. Testing was completed per the *Guidance for Industry and FDA Staff, Biological Indicator Premarket Notification [510(k)] Submissions*, October 4, 2007, ISO 11138-1:2017 Sterilization of Health Care Products—Biological Indicators—Part 1: General Requirements, and ISO 11138-8:2021 *Sterilization of health care products – Biological indicators - Part 8: Method for validation of a reduced incubation time for a biological indicator.*

One lot of 3M™ Attest™ Super Rapid Readout Biological Indicators 1492V was tested for a holding time assessment for 134°C (273°F) cycles. Testing was completed per the *Guidance for Industry and FDA Staff, Biological Indicator Premarket Notification [510(k)] Submissions*, October 4, 2007, ISO 11138-1:2017 Sterilization of Health Care Products—Biological Indicators—Part 1: General Requirements, and ISO 11138-3:2017 *Sterilization of health care products – Biological indicators - Part 3: Biological indicators for moist heat sterilization processes*.

Four lots of 3M™ Attest™ Super Rapid Readout Biological Indicators 1492V were evaluated for simulated use testing in the claimed cycles. Testing was completed per the *Guidance for Industry and FDA Staff, Biological Indicator Premarket Notification [510(k)] Submissions*, October 4, 2007.

Performance of the 1492V Biological Indicator (BI) was verified through the following tests:

Test Performed	Device Description	Applicable Standards	Purpose	Acceptance Criteria	Results
Positive Control Test	1492V BI	FDA Guidance[1], ISO 11138-1:2017 and ISO 11138-3:2017	To evaluate performance of BI without steam exposure	All BIs must be fluorescent positive at 24 minutes and visual pH color change positive (yellow) at 48 hours	Acceptance criteria met

Test Performed	Device Description	Applicable Standards	Purpose	Acceptance Criteria	Results
D-value for 134°C (273°F) cycles	1492V BI	FDA Guidance[1], ISO 11138-1:2017 and ISO 11138-3:2017	To evaluate the resistance characteristics of the BI	D-value must be ≥ 8 seconds	Acceptance criteria met
Survival for 134C° (273°F) cycles	1492V BI	FDA Guidance[1], ISO 11138-1:2017 and ISO 11138-3:2017		Meets the requirements for Calculated survival time* or 40 seconds, whichever is longer. * ISO 11138-1:2017	Acceptance criteria met
Kill for 134C° (273°F) cycles	1492V BI	FDA Guidance[1], ISO 11138-1:2017 and ISO 11138-3:2017		Meets the requirements for Calculated kill time* * ISO 11138-1:2017	Acceptance criteria met
Reduced Incubation Time for 134°C (273°F) cycles	1492V BI	FDA Guidance[1], ISO 11138-1:2017 and ISO 11138-8:2021	To validate the reduction in incubation time from 7 days (visual color change) to 24 minutes (fluorescent readout) and 48 hours (visual pH color change)	Meets FDA's requirements for Reduced Incubation Time with > 97% alignment with the conventional incubation time of 7 days for the following readout times: • Fluorescent result in 24 minutes • Visual pH color change result in 48 hours	Acceptance criteria met
Holding Time Assessment for 134°C (273°F) cycles	1492V BI	FDA Guidance[1], ISO 11138-1:2017 and ISO 11138-3:2017	To evaluate the effect of the labeled holding time on the D-value	D-value must be within +/- 20% of the initial D-value calculated per ISO 11138-1:2017	Acceptance criteria met
Attest 1492V Simulated Use	1492V BI	FDA Guidance[1]	Verification of performance in claimed cycles	BI performs as intended in claimed cycles	Acceptance criteria met

1 FDA *Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions*, October 4, 2007

7. Clinical Comparison to the Predicate Device

Clinical testing was not required or completed for the submission device.

8. Conclusion

Based on the intended use, technological characteristics, and non-clinical performance data, the submission device, the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V, the 3M™ Attest™ Auto-reader 490, the 3M™ Attest™ Auto-reader 490H, and the 3M™ Attest™ Mini Auto-reader 490M with expanded Indications for Use to cover additional exposure temperatures and times for dynamic-air-removal steam sterilization cycles, is as safe, as effective and performs as well as or better than the legally marketed predicate device, the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V, the 3M™ Attest™ Auto-reader 490, the 3M™ Attest™ Auto-reader 490H (cleared under K173437).