DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 19, 2018

3M Health Care
Ms. Hilary B. Hovde
Regulatory Affairs Associate
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Re: K173437

Trade/Device Name: 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V
3M™ Attest™ Auto-reader 490
3M™ Attest™ Auto-reader 490H
Regulation Number: 21 CFR 880.2800
Regulation Name: Biological Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: February 12, 2018
Received: February 14, 2018

Dear Hilary B. Hovde:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173437

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

Indications for Use *(Describe)*
Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V in conjunction 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 minutes at 270°F (132°C)
- 4 minutes at 270°F (132°C)
- 3 minutes at 275°F (135°C)

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 Readout Biological Indicator 1492V, 3M™ Attest™ Auto-reader 490, and 3M™ Attest™ Auto-reader 490H

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

Contact: Hilary B. Hovde
Regulatory Affairs Associate
Phone Number: (651) 736-0364
FAX Number: (651) 737-5320

Submission Date: March 16, 2018

K173437

Device Name and Classification:

Common or Usual Name:	Biological Indicator
Proprietary Name:	3M™ Attest™ Super Rapid Readout Biological Indicator 1492V 3M™ Attest™ Auto-reader 490 3M™ Attest™ Auto-reader 490H
Classification Name:	Indicator, Biological Sterilization Process (21 CFR § 880.2800(a))
Device Classification:	Class II
Product Code:	FRC

Predicate Device:

- 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V and 3M™ Attest™ Auto-reader 490, K121484

Reference Device:

- 3M™ Attest™ Auto-reader 490H, K171003
  (490 Auto-reader will be shown to be identical to the 490H Auto-reader)

Indications for Use

Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V in conjunction 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 minutes at 270°F (132°C)
- 4 minutes at 270°F (132°C)
- 3 minutes at 275°F (135°C)

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 or the 3M™ Attest™ Auto-reader 490H (software version 4.0.0 or greater) to qualify or routinely challenge dynamic-air-removal steam sterilization cycles at 132°C and 135°C.

The 1492V BI is a single-use device composed of a polycarbonate sleeve containing a spore carrier and media ampoule, enclosed with a 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 or the 490H Auto-reader (software version 4.0.0 or greater) indicates a sterilization failure.

Nonclinical Comparison to the Predicate Device

This submission is addressing an expansion to the indications for use to include qualifying or monitoring dynamic-air-removal steam sterilization cycles of 3 minutes at 270°F (132°C), a software change to the 3M™ Attest™ Auto-reader 490 to reduce the final fluorescent readout for the 1492V BI from 1 hour to 24 minutes, and to change the incubation temperature from 56°C to 60°C. The Model 490 Auto-reader is now identical to the Model 490H Auto-reader (software version 4.0.0 or greater) as it incubates at the same temperature and uses the same software. The 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V is the same design as the previously cleared device of the same model number. The device has the same materials and fundamental scientific technology.

Summary of Nonclinical Testing

Testing was conducted on the biological indicator following the FDA guidance and the standards below:

- *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*
- ISO 11138-3:2017 *Sterilization of health care products – Biological indicators, Part 3: Biological indicators for moist heat sterilization processes*
- ANSI/AAMI/ISO 18472:2006 (R)2015 *Sterilization of Health Care Products – Biological and Chemical Indicators: Test Equipment*
- United States Pharmacopeia, Chapter <1035> Biological Indicators for Sterilization and Chapter <55> Biological Indicators – Resistance Performance Tests

The effectiveness of the 3M™ Super Attest™ Rapid Readout Biological Indicator 1492V in conjunction with the 3M™ Attest™ Auto-reader 490 with a final fluorescent readout of 24 minutes and an incubation temperature of 60°C (i.e., identical to the Model 490H Auto-reader having software version 4.0.0 or greater) is demonstrated in the following tests:

Test	Results
Positive Control	Passed
Survival Time = Calculated survival time* or 1 minute at 132°C and 40 seconds at 135°C, whichever is longer	Passed 132°C ≥ 2.07 minutes 135°C ≥ 1.82 minutes
Kill Time = Calculated kill time* at 132°C and at 135°C * ISO 11138-1:2017, Annex E	Passed 132°C ≤ 5.07 minutes 135°C ≤ 4.45 minutes
Reduced Incubation Time 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 • Optional visual pH color change result in 48 hours	Passed
D-Value Greater than or equal to 10 seconds at 132°C Greater than or equal to 8 seconds at 135°C	Passed $D_{132°C} \geq 24$ seconds $D_{135°C} \geq 21$ seconds
Population (Total Viable Spore Count) Greater than or equal to 10^6 spores	Passed
Component Inhibition Studies Components have no impact on the recovery of 10-100 organisms	Passed
Hold Time Assessment D-value does not change when activated 7 days post sterilization	Passed
Simulated Use Verification of performance in claimed cycles	Passed
Auto-reader Maintenance of Incubation Temperature Maintain 60 ± 2°C over a period of 7 days	Passed

The results of these evaluations showed that the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V, when used with the 3M™ Attest™ Auto-reader 490 or Attest™ Auto-reader 490H having software version 4.0.0 or greater, complies with ISO 11138-1:2017 and ISO 11138-3:2017, the USP requirements for biological indicators, as well as the FDA's Guidance for Biological Indicators.

The Attest™ Auto-readers were tested for safety by Underwriters Laboratory to verify compliance to:

- IEC 61010-1 (2010) 3rd Edition; *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements,* and
- IEC 61010-2-010 (2014) 3rd Edition; *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials*

Summary of Clinical Testing

No clinical data was included in this premarket application submission.

Comparison to Predicate and Reference Devices

Feature	Submission Device: 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V and 3M™ Attest™ Auto-reader 490 and 490H	Predicate Device (K121484): 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V and 3M™ Attest™ Auto-reader 490	Reference Device (K171003): 3M™ Attest™ Auto-reader 490H
Indications for use	Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V in conjunction 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 minutes at 270°F (132°C) • 4 minutes at 270°F (132°C) • 3 minutes at 275°F (135°C)	Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V in conjunction with the 3M™ Attest™ Auto-reader 490 to qualify or monitor dynamic-air-removal (pre-vacuum) steam sterilization cycles of 4 minutes at 270°F (132°C) and 3 minutes at 275°F (135°C). The 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V provides a final fluorescent result in 1 hour. An optional visual pH color change result is observed in 48 hours.	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 Amsco® V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles), and in STERRAD® 100S, STERRAD® NX® (Standard and Advanced cycles) and STERRAD® 100NX® (Standard, Flex, Express and Duo cycles) systems. * Reference Device is 3M™ Attest™ Auto-reader 490H Only.
Organism	*Geobacillus stearothermophilus* traceable to ATCC™ 7953	Identical	N/A- Reference Device is 3M™ Attest™ Auto-reader 490H Only
Viable spore population	$\geq 1 \times 10^6$	Identical	N/A- Reference Device is 3M™ Attest™ Auto-reader 490H Only
Resistance characteristics • D-value • Survival/Kill Window	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	Identical	N/A- Reference Device is 3M™ Attest™ Auto-reader 490H Only

Feature	Submission Device: 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V and 3M™ Attest™ Auto-reader 490 and 490H	Predicate Device (K121484): 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V and 3M™ Attest™ Auto-reader 490	Reference Device (K171003): 3M™ Attest™ Auto-reader 490H
	Kill Time = Calculated kill time* at 132°C and at 135°C		
Carrier material	polypropylene	Identical	N/A- Reference Device is 3M™ Attest™ Auto-reader 490H Only
Incubation temperature	60 ± 2°C	56 ± 2°C	60 ± 2°C
Readout time	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	1 hour final fluorescent result in 490 Auto-readers. Identical	24 minute fluorescence result of 3M™ Attest™ 1295 BI read in the 3M™ Attest™ Auto-reader 490H.
Chemical indicator	Turns from pink to light brown or darker upon steam exposure	Identical	N/A- Reference Device is 3M™ Attest™ Auto-reader 490H Only
Shelf-life	21 months	Identical	N/A- Reference Device is 3M™ Attest™ Auto-reader 490H Only

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

3M™ Attest™ Auto-reader Comparison to Predicate and Reference Auto-readers

Design Function or Characteristic	Submission Device: 3M™ Attest™ Auto-reader 490	Reference Device: (K171003) 3M™ Attest™ Auto-reader 490H	Predicate Device (K121484): 3M™ Attest™ Auto-reader 490
Statement of Intended Use	The 3M™ Attest™ 490 Auto-reader is designed to incubate and automatically read the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V at 60°C for a final fluorescent result at 24 minutes.	The 3M™ Attest™ 490H Auto-reader is designed to incubate and automatically read the 3M™ Attest™ Rapid Readout Biological Indicator 1295 at 60°C for a final fluorescent result at 24 minutes.	The 3M™ Attest™ 490 Auto-reader is designed to incubate and automatically read the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V at 56°C for a final fluorescent result at 1 hour.
Incubation temperature	60 ± 2°C	Identical to Submission Device	56 ± 2°C
Rapid Readout Capability	Yes	Identical	Identical
Basis of Rapid Readout	Fluorescence of biological medium	Identical	Identical
Use with Biological Indicators	3M™ Attest™ Super Rapid Readout Biological Indicator 1492V.	3M™ Attest™ Rapid Readout Biological Indicator 1295.	Identical to Submission Device
Method of Fluorescence Detection	UV LED, optical filters, with sensing by photo diode	Identical	Identical
Identification of (+) Result	Fluorescence measurement and 24 minute readout algorithm	Fluorescence measurement and 24 minute readout algorithm	Fluorescence measurement and 1 hour readout algorithm
Visual Indicator of Adequate Sterilization Cycle	(-) on LCD Display	Identical	Identical
Visual Indicator of Possible Sterilization Cycle Failure	(+) on LCD Display	Identical	Identical
Audible Indicator of Possible Sterilization Cycle Failure	Audible Alarm	Identical	Identical
Number of Incubation Wells	10 incubation wells/reader	Identical	Identical
Voltage Range	100-240 Volts AC (12 Volt DC conversion for internal circuitry)	Identical	Identical
Calibration	No calibration. Fluorescent baseline measured independently for each BI placed in well.	Identical	Identical

Design Function or Characteristic	Submission Device: 3M™ Attest™ Auto-reader 490	Reference Device: (K171003) 3M™ Attest™ Auto-reader 490H	Predicate Device (K121484): 3M™ Attest™ Auto-reader 490
System Operation	Software monitors incubation duration	Identical	Identical
	Software performs reading of BI	Identical	Identical
	Software allows user to view status remotely via Ethernet	Identical	Identical
	Software allows 100 most recent results to be stored electronically in the reader	Identical	Identical
Product Safety	UL/IEC 61010-1	Identical	Identical
EMC Compliance	FCC Part 15, Subpart B, Class A	Identical	Identical
Preventative Maintenance	None	Identical	Identical

Conclusion

Based on the intended use, technological characteristics, performance data, and non-clinical tests performed, the subject device is substantially equivalent to, and is as safe and as effective as the legally marketed predicate devices, the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V and the 3M™ Attest™ Auto-reader 490 cleared under K121484, Class II (21 CFR 880.2800), product code FRC.