January 22, 2018

3M Company
Hilary Hovde
Regulatory Affairs Associate
3M Center, Building 275-5W-06
St. Paul, Minnesota 55144

Re: K173584
Trade/Device Name: 3M Attest Super Rapid Readout Biological Indicator, 3M Attest Auto-reader 490, 3M Attest Auto-reader 490H
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: November 16, 2017
Received: November 20, 2017

Dear Hilary 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173584

Device Name
3M™ Attest™ Super Rapid Readout Biological Indicator 1491 and 3M™ Attest™ Auto-reader 490 and 490H

Indications for Use *(Describe)*
Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1491 in conjunction with the 3M™ Attest™ Autoreader 490 or 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater to monitor the cycles below.

Sterilization Type	Temperature	Time
	270°F (132°C)	3 minutes
Gravity Displacement	270°F (132°C)	10 minutes
Steam Sterilization Cycle	275°F (135°C)	3 minutes
	275°F (135°C)	10 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.

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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 K173584
3M™ Attest™ Super Rapid Readout Biological Indicator 1491, 3M™ Attest™ Auto-reader 490, and 3M™ Attest™ Auto-reader 490H (software version 4.0.0 or greater)

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: November 16, 2017

Device Name and Classification:

Common or Usual Name: Biological Indicator

Proprietary Name:	3M™ Attest™ Super Rapid Readout Biological Indicator 1491 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 1491 and 3M™ Attest™ Auto-reader 490, K103277

Reference Device:

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

Description of Device:

The 3M™ Attest™ Super Rapid Readout Biological Indicator 1491 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 routinely monitor gravity displacement steam sterilization cycles at 132°C and 135°C.

The 1491 BI is a single-use device composed of a polycarbonate sleeve containing a spore carrier and media ampoule, enclosed with a cap. On each 1491 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 a processed 1491 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 a software change to the 3M™ Attest™ Auto-reader 490 to reduce the final fluorescent readout for the 1491 BI from 30 minutes to 24 minutes, and to change the incubation temperature from 56°C to 60°C making the 490 Auto-reader identical to the 490H Auto-reader (software version 4.0.0 or greater). The 3M™ Attest™ Super Rapid Readout Biological Indicator 1491 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 *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™ Attest™ Super Rapid Readout Biological Indicator 1491 in conjunction with the 3M™ Attest™ Auto-reader 490 with a final fluorescent readout of 24 minutes and an incubation temperature of 60°C 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; Kill Time = Calculated kill time* at 132°C and at 135°C * ISO 11138-1:2017, Annex E	Passed
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 24 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
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
Holding Time Assessment D-value does not change when activated 7 days post sterilization	Passed
Auto-reader Maintenance of Incubation Temperature Maintain 60 ± 2°C over a period of 24 hours	Passed

The results of these evaluations showed that the 3M™ Super Attest™ Rapid Readout Biological Indicator 1491, 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 3M™ Attest™ Auto-readers 490 and 490H 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*

In addition the 3M™ Attest™ Auto-readers 490 and 490H have been tested by a certified Testing Laboratory to verify electromagnetic compatibility per:

- USA Title 47, Code of Federal Regulations for:
  - Radiated Emissions (FCC Part 15, Subpart B, Class A)
  - Conducted Emissions (FCC Part 15, Subpart B, Class A), and
- IEC 61326-1:2012 *Electrical Equipment for Measurement, Control, and Laboratory Use – EMC Requirements*

Summary of Clinical Testing

No clinical data was included in this premarket application submission.

Indications for Use

Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1491 in conjunction with the 3M™ Attest™ Auto-reader 490 or 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater to monitor the cycles below.

Sterilization Type	Temperature	Time
Gravity Displacement Steam Sterilization Cycle	270°F (132°C)	3 minutes
	270°F (132°C)	10 minutes
	275°F (135°C)	3 minutes
	275°F (135°C)	10 minutes

Comparison to Predicate Device

<table>
<tr><th>Feature</th><th>Submission Device:
3M™ Attest™
Super Rapid Readout
Biological Indicator 1491 and
3M™ Attest™ Auto-reader 490</th><th>Predicate Device (K103277):
3M™ Attest™
Super Rapid Readout
Biological Indicator 1491 and
3M™ Attest™ Auto-reader 490</th></tr>
<tr><td>Indications for use</td><td>Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1491 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 monitor the cycles below.
<table>
<tr><th>Sterilization Type</th><th>Temperature</th><th>Time</th></tr>
<tr><td rowspan="4">Gravity Displacement Steam Sterilization Cycle</td><td>270°F (132°C)</td><td>3 minutes</td></tr>
<tr><td>270°F (132°C)</td><td>10 minutes</td></tr>
<tr><td>275°F (135°C)</td><td>3 minutes</td></tr>
<tr><td>275°F (135°C)</td><td>10 minutes</td></tr>
</table></td><td>Use the 3M™ Attest™ 1491 Super Rapid Readout Biological Indicator in conjunction with the 3M™ Attest™ 490 Auto-reader to monitor the cycles below.
<table>
<tr><th>Sterilization Type</th><th>Temperature</th><th>Time</th></tr>
<tr><td rowspan="4">Gravity Displacement Immediate Use Steam Sterilization Cycle (Flash)</td><td>270°F (132°C)</td><td>3 minutes</td></tr>
<tr><td>270°F (132°C)</td><td>10 minutes</td></tr>
<tr><td>275°F (135°C)</td><td>3 minutes</td></tr>
<tr><td>275°F (135°C)</td><td>10 minutes</td></tr>
</table>
The 3M™ Attest™ 1491 Super Rapid Readout Biological Indicator provides a final fluorescent result in 30 minutes. An optional visual pH color change result is observed in 24 hours.</td></tr>
<tr><td>Organism</td><td>Geobacillus stearothermophilus traceable to ATCC™ 7953</td><td>Identical</td></tr>
<tr><td>Viable spore population</td><td>≥ 1 x 10^6</td><td>Identical</td></tr>
<tr><td>Resistance characteristics
• D-value

• Survival/Kill Window</td><td>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</td><td>Identical</td></tr>
<tr><td>Carrier material</td><td>Polypropylene</td><td>Identical</td></tr>
<tr><td>Incubation temperature</td><td>60 ± 2°C</td><td>56 ± 2°C</td></tr>
<tr><td>Readout time</td><td>24 minute final fluorescent result in both the 490 and 490H Auto-readers having software versions 4.0.0 or greater.
30 minute final fluorescent result in 490 Auto-readers having software versions less than 4.0.0.

Optional visual pH color change result in 24 hours</td><td>30 minute final fluorescent result in 490 Auto-readers.

Identical</td></tr>
<tr><td>Chemical indicator</td><td>Turns from pink to light brown or darker upon steam exposure</td><td>Identical</td></tr>
<tr><td>Shelf-life</td><td>12 months</td><td>Identical</td></tr>
</table>

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

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the 3M™ Attest™ Super Rapid Readout Biological Indicator 1491, the 3M™ Attest™ Auto-reader 490, and the 3M™ Attest™ Auto-reader 490H is as safe, as effective, and performs as well as or better than the 3M™ Attest™ Super Rapid Readout Biological Indicator 1491 and 3M™ Attest™ Auto-reader 490 (K103277).