April 15, 2020

3m
Andrew Wingen
Regulatory Affairs Commercialization Strategy Lead
2510 Conway Ave, Bldg 275-5W-06
St. Paul, Minnesota 55144-1000

Re: K200092
Trade/Device Name: 3M™ Attest™ Mini Auto-reader 490M
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: January 15, 2020
Received: January 16, 2020

Dear Andrew Wingen:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Christopher K. Dugard, M.S.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200092

Device Name
3MTM AttestTM Mini Auto-reader 490M

Indications for Use *(Describe)*

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 and 1492V, at 60°C for a final fluorescent result at 24 minutes.

The following Indications for Use are proposed for the 3M™ Attest™ Super Rapid Readout Biological Indicators 1491 and 1492V, as well as the vaporized hydrogen peroxide biological indicator, 3M™ Attest™ Rapid Readout Biological Indicator 1295. The only change to the previously cleared indications for these BIs is the addition of the Mini Auto-reader 490M as being able to be used in conjunction with each of the BIs:

Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1491 in conjunction with the 3M™ Attest™ 490/490H Auto-reader or 3M™ Attest™ Mini Auto-reader 490M to monitor gravity displacement steam sterilization cycles of 3 minutes at 270°F (132°C), 10 minutes at 270°F (132°C), 3 minutes at 275°F (135°C) and 10 minutes at 275°F (135°C). An optional visual pH color change result is observed in 24 hours.

Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V in conjunction with the 3M™ Attest™ 490/490H Auto-reader or 3M™ Attest™ Mini Auto-reader 490M 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). An optional visual pH color change result is observed in 48 hours.

Use 3M™ Attest™ Rapid Readout Biological Indicator 1295 in conjunction with the 3M™ Attest™ 490/490H Auto-reader or 3M™ Attest™ Mini Auto-reader 490M 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® VPRO™ 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). An optional visual pH color change result is observed in 7 days.

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™ Mini Auto-reader 490M
K200092

Sponsor Information:

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

Contact: Andrew Wingen
Regulatory Affairs Commercialization Strategy Lead
Phone Number: (651) 733-9209
Fax Number: (651) 737-5320
Email: acwingen@mmm.com

Date of Summary: 14 January 2020

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Attest™ Mini Auto-reader 490M

1. **Device Name and Classification:**

Common or Usual Name:	Biological Indicator Reader/Incubator
Proprietary Name:	3M™ Attest™ Mini Auto-reader
Classification Name:	Accessory to Biological Sterilization Process Indicator
Device Classification:	Class II, 21 CFR § 880.2800(a)
Product Code:	FRC (Accessory)

2. **Predicate Device:**

K173437 3M™ Attest™ 490/490H Auto-reader / 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V

3. **Description of Device:**

The 3M™ Attest™ Mini Auto-reader 490M is a compact, 4-well incubator for processing the steam biological indicators 3M™ Attest™ Super Rapid Readout Biological Indicators 1491 and 1492V, as well as the vaporized hydrogen peroxide biological indicator, 3M™ Attest™ Rapid Readout Biological Indicator 1295. These biological indicators (BIs) are used to monitor sterilization processing equipment. After a sterilization cycle is complete, the BIs are removed from the sterilizer, cooled as needed, activated, and placed into any available well in the Mini Auto-reader 490M. Incubation starts automatically. UV fluorescence, measured during each interval, is analyzed by measuring fluorescent by-product of enzyme that occurs naturally during biological growth of the spore. The maximum time-to-result is 24 minutes at 60oC. An LED array on the front panel will display the time remaining for each BI, the result (positive or negative), and any error codes that occur. The device includes USB connectivity for in-field firmware updates, downloading data, and communicating to third party instrument tracking systems.

The 3M™ Attest™ Mini Auto-reader 490M is indicated to work as a system with the 1491, 1492V, and 1295 BIs, and is not compatible with other BIs.

4. Indications for Use

The following Indications for Use are proposed for the Mini Auto-reader:

> 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 and 1492V, at 60°C for a final fluorescent result at 24 minutes.

The following Indications for Use are proposed for the 3M™ Attest™ Super Rapid Readout Biological Indicators 1491 and 1492V, as well as the vaporized hydrogen peroxide biological indicator, 3M™ Attest™ Rapid Readout Biological Indicator 1295. The only change to the previously cleared indications for these BIs is the addition of the Mini Auto-reader 490M as being able to be used in conjunction with each of the BIs:

> Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1491 in conjunction with the 3M™ Attest™ 490/490H Auto-reader or 3M™ Attest™ Mini Auto-reader 490M to monitor gravity displacement steam sterilization cycles of 3 minutes at 270°F (132°C), 10 minutes at 270°F (132°C), 3 minutes at 275°F (135°C) and 10 minutes at 275°F (135°C). An optional visual pH color change result is observed in 24 hours.
>
> Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V in conjunction with the 3M™ Attest™ 490/490H Auto-reader or 3M™ Attest™ Mini Auto-reader 490M 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). An optional visual pH color change result is observed in 48 hours.
>
> Use 3M™ Attest™ Rapid Readout Biological Indicator 1295 in conjunction with the 3M™ Attest™ 490/490H Auto-reader or 3M™ Attest™ Mini Auto-reader 490M 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® VPRO™ 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). An optional visual pH color change result is observed in 7 days.

5. Technical Characteristic Comparison Table

Device Identity	Proposed Device: 3M™ Attest™ Mini Auto-reader / 3M™ Attest™ Super Rapid Readout Biological Indicators 1491 and 1492V, 3M™ Attest™ Rapid Readout Biological Indicator 1295	Predicate: 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V / 3M™ Attest™ 490/490H Auto-reader (K173437)	Reference: 3M™ Attest™ Super Rapid Readout Biological Indicator 1491 / 3M™ Attest™ 490/490H Auto-reader (K173584)	Reference: 3M™ Attest™ Rapid Readout Biological Indicator 1295 / 3M™ Attest™ 490H Auto-reader (K173435)	Comments
Intended Use	The 3M™ Attest™ Mini Auto-reader is designed to incubate and automatically read the 3M™ Attest™ Super Rapid Readout Biological Indicators 1491 and 1492V, as well as 3M™ Attest™ Rapid Readout Biological Indicator 1295, at 60°C for a final fluorescent result at 24 minutes.	The 3M™ Attest™ 490/490H 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™ 490/490H Auto-reader is designed to incubate and automatically read the 3M™ Attest™ Super Rapid Readout Biological Indicator 1491 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.	Identical
Indications for Use	The 3M™ Attest™ Mini Auto-reader	Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V in conjunction with both the 3M™	Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1491 in conjunction	Use the 3M™ Attest™ Rapid Readout Biological Indicator 1295 in conjunction with the 3M™ Attest™ Auto reader 490H as a standard method of	Similar

	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 and 1492V, at 60°C for a final fluorescent result at 24 minutes. The indications for use for Attest™ Biological Indicators are provided in the product's Instructions for Use.	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)	with the 3M™ Attest™ 490/490H Auto-reader to monitor gravity displacement steam sterilization cycles of 3 minutes at 270°F (132°C), 10 minutes at 270°F (132°C), 3 minutes at 275°F (135°C) and 10 minutes at 275°F (135°C)	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)	

Method of Fluorescence Detection	UV LED, photo diode with embedded optical filters	UV LED, optical filters, with sensing by photo diode	UV LED, optical filters, with sensing by photo diode	UV LED, optical filters, with sensing by photo diode	Similar
Number of Incubation Wells	4 incubation wells/reader	10 incubation wells/reader	10 incubation wells/reader	10 incubation wells/reader	Different
Incubation Temperature	60 ± 2º C	60 ± 2º C	60 ± 2º C	60 ± 2º C	Identical
Readout Time	24 minute final fluorescent result Optional visual pH color change result as follows: 1492V: 48 hours 1491: 24 hours 1295: 7 days	24 minute final fluorescent result Optional visual pH color change result in 48 hours	24 minute final fluorescent result Optional visual pH color change result in 24 hours	24 minute final fluorescent result Optional visual pH color change result in 7 days	Identical
Chemical Indicator	1491, 1492V - Turns from pink to light brown or darker upon steam exposure 1295 - Turns from blue towards pink upon	1492V - Turns from pink to light brown or darker upon steam exposure	1491 - Turns from pink to light brown or darker upon steam exposure	1295 - Turns from blue towards pink upon vaporized hydrogen peroxide exposure	Identical

	vaporized hydrogen peroxide exposure				
Visual Indicator of Adequate Sterilization Cycle	(-) on dot matrix LED display	(-) on LCD display	(-) on LCD display	(-) on LCD display	Similar
Visual Indicator of Possible Sterilization Cycle Failure	(+) on dot matrix LED display	(+) on LCD display	(+) on LCD display	(+) on LCD display	Similar
Alarm Function	Audible Alarm	Audible Alarm	Audible Alarm	Audible Alarm	Identical
Voltage Range	100-240 Volts AC	100-240 Volts AC	100-240 Volts AC	100-240 Volts AC	Identical
Calibration	No calibration – fluorescent baseline measured independently for each BI placed in a well	No calibration – fluorescent baseline measured independently for each BI placed in a well	No calibration – fluorescent baseline measured independently for each BI placed in a well	No calibration – fluorescent baseline measured independently for each BI placed in a well	Identical
System Operation	Software monitors incubation duration Software performs reading of BI Software allows results to be stored	Software monitors incubation duration	Software monitors incubation duration	Software monitors incubation duration	Similar

	electronically in the reader				
Software Application	Software allows user to view status remotely via USB connection and PC application	Software allows user to view status remotely via ethernet	Software allows user to view status remotely via ethernet	Software allows user to view status remotely via ethernet	Similar
Cloud Server Connection	Enabled via the USB connection to the PC. Facilitates software application and firmware updates.	Not present	Not present	Not present	Different
BI Insertion Detection	Detected by white LED and detector	Detected by photo-interrupter sensor	Detected by photo-interrupter sensor	Detected by photo-interrupter sensor	Similar
Product Safety	IEC 61010-1, IEC 61010-2-010	IEC 61010-1, IEC 61010-2-010	IEC 61010-1, IEC 61010-2-010	IEC 61010-1, IEC 61010-2-010	Identical
EMC Compliance	Title 47 CFR 15, Subclass B, for Class A type devices IEC 61326-1	Title 47 CFR 15, Subclass B, for Class A type devices IEC 61326-1	Title 47 CFR 15, Subclass B, for Class A type devices IEC 61326-1	Title 47 CFR 15, Subclass B, for Class A type devices IEC 61326-1	Identical
Preventative Maintenance	Area outside of wells can be cleaned. Full instructions in user manual.	Area outside of wells can be cleaned. Full instructions in user manual.	Area outside of wells can be cleaned. Full instructions in user manual.	Area outside of wells can be cleaned. Full instructions in user manual.	Identical
Biological Indicator Compatibility	1491, 1492V, 1295	1492V	1491	1295	Identical

6. Nonclinical Comparison to the Predicate Device

The 3M™ Attest™ Mini Auto-reader 490M, like the predicate 3M™ Attest™ 490/490H Auto-reader, is designed to automatically read the 3M™ Attest™ Super Rapid Readout Biological Indicators 1491 and 1492V, as well as 3M™ Attest™ Rapid Readout Biological Indicator 1295, at 60°C for a final fluorescent result at 24 minutes. The hardware and firmware utilized by the Attest™ Mini Auto-reader 490M is similar to the predicate Attest™ 490/490H Auto-reader.

The 3M™ Attest™ Mini Auto-reader 490M has additional software functionality and cloud services functionality via the PC App, 3M™ Attest™ Connect, compared to the predicate 490/490H Auto-reader.

The functional areas of comparison of the submission and predicate auto-readers comprised of temperature testing, analytical sensitivity using standard curves of reference dye solutions, signal-to-noise measurements of fluorescent standards during incubation, and analysis of the fluorescence background measurements of both readers. Comparative BI performance was comprised of testing the 1491, 1492V, and 1295 BIs in both auto-readers under positive control conditions, lethal sterilizer conditions (kill cycle), sub-lethal sterilizer conditions (survive cycle), and reduced incubation time.

The Mini Auto-reader 490M was also tested for safety by Underwriters Laboratory and complies 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.*
- IEC 62471 (2008); *Photobiological safety of lamps and lamp systems*

The Mini Auto-reader 490M was tested for electromagnetic compatibility and complies to:

- *Class A digital device - pursuant to Part 15 of the FCC rules,* and
- IEC 61326-1 (2013); *Electrical equipment for measurement, control and laboratory use – EMC requirements*.

7. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the 3M™ Attest™ Mini Auto-reader 490M is as safe, as effective, and performs at least as well as or better than the predicate, the 3M™ Attest™ Auto-reader 490/490H cleared under K173437, Class II (21 CFR 880.2800), product code FRC.