



April 6, 2022

3M Company
Hilary Hovde
Regulatory Affairs Specialist
3M Center
2510 Conway Ave, Building 275-5W-06
Saint Paul, Minnesota 55144

Re: K213809

Trade/Device Name: 3M™ Attest™ Super Rapid Steam Biological Indicator 1592, 3M™ Attest™ Super Rapid Steam Challenge Pack 51582, 3M™ Attest™ Auto-reader 490, 3M™ Attest™ Auto-reader 490H, 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: March 17, 2022

Received: March 18, 2022

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. 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 Clarence Murray, III, Ph.D.
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)
K213809

Device Name

3M™ Attest™ Super Rapid Steam Biological Indicator 1592,
3M™ Attest™ Super Rapid Steam Challenge Pack 51582,
3M™ Attest™ Auto-reader 490, 3M™ Attest™ Auto-reader 490H, 3M™ Attest™ Mini Auto-reader 490M

Indications for Use (Describe)

3M™ Attest™ Super Rapid Steam Biological Indicator 1592:

Use the 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, 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
Gravity Displacement	250°F (121°C)	30 minutes
Dynamic-air-removal (pre-vacuum and SFPP)	250°F (121°C)	15, 20, 30, or 35 minutes
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™ Super Rapid Steam Challenge Pack 51582:

Use the 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, 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
Gravity Displacement	250°F (121°C)	30 minutes
Dynamic-air-removal (pre-vacuum and SFPP)	250°F (121°C)	30 minutes
Dynamic-air-removal (pre-vacuum and SFPP)	270°F (132°C)	4 minutes
Dynamic-air-removal (pre-vacuum and SFPP)	273°F (134°C)	4 minutes
Dynamic-air-removal (pre-vacuum and SFPP)	275°F (135°C)	3 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 indications for use for Attest™ Biological Indicators are provided in the product's Instructions for Use.

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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3M™ Attest™ Super Rapid Steam Biological Indicator 1592

3M™ Attest™ Super Rapid Steam Challenge Pack 51582

3M™ Attest™ Auto-readers 490 and 490H

3M™ Attest™ Mini Auto-reader 490M



**510(k) Summary for
3M™ Attest™ Super Rapid Steam Biological Indicator 1592,
3M™ Attest™ Super Rapid Steam Challenge Pack 51582,
3M™ Attest™ Auto-reader 490,
3M™ Attest™ Auto-reader 490H,
3M™ Attest™ Mini Auto-reader 490M**

3M Company
3M Health Care
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Contact: Hilary B. Hovde
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Submission Date: April 5, 2022

3M™ Attest™ Super Rapid Steam Biological Indicator 1592

3M™ Attest™ Super Rapid Steam Challenge Pack 51582

3M™ Attest™ Auto-readers 490 and 490H

3M™ Attest™ Mini Auto-reader 490M

Device Name and Classification:

Trade Name: 3M™ Attest™ Super Rapid Steam Biological Indicator 1592
 3M™ Attest™ Super Rapid Steam Challenge Pack 51582
 3M™ Attest™ Auto-reader 490
 3M™ Attest™ Auto-reader 490H
 3M™ Attest™ Mini-Auto-reader 490M

Common/Usual Name: Biological Indicator (BI)

Device Classification: Class II

Classification Name: Indicator, Biological Sterilization Process
 [21 CFR § 880.2800(a), FRC]

Predicate Device:

3M™ Attest™ Super Rapid Steam Biological Indicator 1592, 3M™ Attest™ Super Rapid Steam Challenge Pack 51582, 3M™ Attest™ Auto-reader 490, and 3M™ Attest™ Auto-reader 490H, K192550

Reference Device: 3M™ Attest™ Mini Auto-reader 490M, K200092

Indications for Use – 1592 Biological Indicator

Use the 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, 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
Gravity Displacement	250°F (121°C)	30 minutes
Dynamic-air-removal (pre-vacuum and SFPP)	250°F (121°C)	15, 20, 30, or 35 minutes
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™ Super Rapid Steam Biological Indicator 1592

3M™ Attest™ Super Rapid Steam Challenge Pack 51582

3M™ Attest™ Auto-readers 490 and 490H

3M™ Attest™ Mini Auto-reader 490M

Indications for Use – 51582 Challenge Pack

Use the 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, 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
Gravity Displacement	250°F (121°C)	30 minutes
Dynamic-air-removal (pre-vacuum and SFPP)	250°F (121°C)	30 minutes
Dynamic-air-removal (pre-vacuum and SFPP)	270°F (132°C)	4 minutes
Dynamic-air-removal (pre-vacuum and SFPP)	273°F (134°C)	4 minutes
Dynamic-air-removal (pre-vacuum and SFPP)	275°F (135°C)	3 minutes

Indications for Use – 490 Auto-reader

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.

Indications for Use – 490H Auto-reader

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.

Indications for Use – 490M 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, 1492V and 1592, 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.

3M™ Attest™ Super Rapid Steam Biological Indicator 1592**3M™ Attest™ Super Rapid Steam Challenge Pack 51582****3M™ Attest™ Auto-readers 490 and 490H****3M™ Attest™ Mini Auto-reader 490M**

Description of Device

The 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 is a self-contained biological indicator (BI) specifically designed for rapid and reliable qualification testing and routine monitoring of 250°F (121°C) dynamic-air-removal and gravity displacement steam sterilization processes and of dynamic-air-removal steam sterilization processes at 270°F (132°C), 273°F (134°C), and 275°F (135°C) in healthcare facilities. The 1592 BI is used in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, or a 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater, or a 3M™ Attest™ Mini Auto-reader 490M.

The 1592 BI is a single-use device composed of a plastic sleeve containing a spore carrier and media ampoule, enclosed with a cap. On each 1592 BI cap is a chemical process indicator that changes color from pink to light brown or darker when exposed to steam. The presence of fluorescence within the specified incubation time of the 1592 BI in the 490 Auto-reader, 490H Auto-reader, or the 490M Mini Auto-reader indicates a steam sterilization process failure.

The 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 is specifically designed to qualify and monitor dynamic-air-removal (pre-vacuum and SFPP) and gravity displacement steam sterilization processes at 250°F (121°C) and dynamic-air-removal steam sterilization processes at 270°F (132°C), 273°F (134°C), and 275°F (135°C) in healthcare facilities.

The 51582 Challenge Pack consists of multiple layers of medical index cards, some of which are die-cut to contain the monitoring products. The stacked cards are wrapped with sterilization wrap and secured with a label. The Challenge Packs are identical in design to the predicate device. Each 51582 Challenge Pack contains a 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 and a 3M™ Attest™ Steam Chemical Integrator (Type 5 (Category i5) Integrating Indicator as categorized by ISO 11140-1:2014). The 3M™ Attest™ Chemical Integrator offers an immediate ACCEPT or REJECT reading. Each Challenge Pack has a process indicator on the outside of the device that changes from yellow to brown or darker when exposed to steam. 3M™ Attest™ 1592 BI controls are provided with the Challenge Packs.

The 1592 BI is specifically designed for rapid and reliable monitoring of the steam sterilization processes when used in conjunction with a 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, a 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater, or a 3M™ Attest™ Mini Auto-reader 490M. The presence of fluorescence within the specified incubation time of the 1592 BI in the 490, 490H, or the 490M Auto-reader indicates a steam sterilization process failure.

Comparison of Technological Characteristics with the Predicate and Reference Devices

The 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 and the 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 are part of a biological indicator system with the 3M™

3M™ Attest™ Super Rapid Steam Biological Indicator 1592

3M™ Attest™ Super Rapid Steam Challenge Pack 51582

3M™ Attest™ Auto-readers 490 and 490H

3M™ Attest™ Mini Auto-reader 490M

Attest™ Auto-reader 490, 3M™ Attest™ Auto-reader 490H, or 3M™ Attest™ Mini Auto-reader 490M. This 510(k) is to expand the indications for use of the 1592 BI and the 51582 Challenge Pack to qualify and monitor additional steam sterilization cycles and to extend the use of the 490M Mini Auto-reader to include the 1592 BI and the 1592 BI contained within the 51582 Challenge Pack. Safety and efficacy were demonstrated through performance testing.

Technical Characteristics Comparison Table – Biological Indicator

Feature	Submission Device: 3M™ Attest™ Super Rapid Steam Biological Indicator 1592, 3M™ Attest™ Auto-reader 490 and 490H, and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device (K192550): 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 and 3M™ Attest™ Auto-reader 490 and 490H	Comparison
Indications for use	Use the 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, 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: <ul style="list-style-type: none"> • Gravity Displacement, 250°F (121°C), 30 minutes • Dynamic-air-removal (pre-vacuum and SFPP), 250°F (121°C), 15, 20, 30, or 35 minutes • 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 	Use the 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater or the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater to qualify or monitor the following sterilization cycles: <ul style="list-style-type: none"> • Gravity Displacement, 250°F (121°C), 30 minutes • Dynamic-air-removal (pre-vacuum and SFPP), 250°F (121°C), 15, 20, 30, or 35 minutes 	Both the predicate and the submission BIs are indicated for use in gravity displacement and dynamic air-removal (pre-vacuum and SFPP) sterilization cycles at 250°F (121°C). The intent of this submission is to expand the indications for use to include dynamic air-removal (pre-vacuum and SFPP) sterilization cycles at 270°F (132°C), 273°F (134°C), and 275°F (135°C). Both the submission and predicate BIs are intended to be used in conjunction with the 3M™ Attest™ Auto-reader 490 or the 3M™ Attest™ Auto-reader 490H. The intent of this submission is to expand the indications for use to include the use of the reference device, the 3M™

3M™ Attest™ Super Rapid Steam Biological Indicator 1592

3M™ Attest™ Super Rapid Steam Challenge Pack 51582

3M™ Attest™ Auto-readers 490 and 490H

3M™ Attest™ Mini Auto-reader 490M

Feature	Submission Device: 3M™ Attest™ Super Rapid Steam Biological Indicator 1592, 3M™ Attest™ Auto-reader 490 and 490H, and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device (K192550): 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 and 3M™ Attest™ Auto-reader 490 and 490H	Comparison
	(pre-vacuum and SFPP), 275°F (135°C), 3, 3.5, or 10 minutes		Attest™ Mini Auto-reader 490M (cleared per K200092).
Indicator Organism	<i>Geobacillus stearothermophilus</i> traceable to ATCC™ 7953	<i>Geobacillus stearothermophilus</i> traceable to ATCC™ 7953	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.	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.	Identical
Auto-reader	3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, 3M™ Attest™ Auto-reader, or 490H having software version 4.0.0 or greater, or 3M™ Attest™ Mini Auto-reader 490M	3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater or 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater	Both the submission and predicate BIs are intended to be used in conjunction with the 3M™ Attest™ Auto-reader 490 or the 3M™ Attest™ Auto-reader 490H. The intent of this submission is to expand the indications for use to include the use of the reference device, the 3M™ Attest™ Mini Auto-reader 490M (cleared per K200092). The 3M™ Attest™ Super Rapid Steam Biological Indicator

3M™ Attest™ Super Rapid Steam Biological Indicator 1592

3M™ Attest™ Super Rapid Steam Challenge Pack 51582

3M™ Attest™ Auto-readers 490 and 490H

3M™ Attest™ Mini Auto-reader 490M

Feature	Submission Device: 3M™ Attest™ Super Rapid Steam Biological Indicator 1592, 3M™ Attest™ Auto-reader 490 and 490H, and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device (K192550): 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 and 3M™ Attest™ Auto-reader 490 and 490H	Comparison
			1592 BI has a 24 minute readout and can be used in conjunction with a 490 or 490H Auto-reader having software version 4.0.0 or greater or a 490M Auto-reader.
Viable spore population	$\geq 1 \times 10^6$	$\geq 1 \times 10^6$	Identical
Resistance	$D_{121} \geq 1.5 \text{ min}$ $D_{132} \geq 10 \text{ s}$ $D_{134 \text{ or } 135} \geq 8 \text{ s}$	$D_{121} \geq 1.5 \text{ min}$	The submission BI is indicated for qualifying and monitoring sterilization cycles at 121°C, 132°C, 134°C, and 135°C whereas the predicate BI is indicated for qualifying and monitoring sterilization cycles at 121°C.
Survival Time	Meets the longer of FDA and ISO 11138-1 and ISO 11138-3 requirements	Meets the longer of FDA and ISO 11138-1 and ISO 11138-3 requirements	Identical
Kill Time	Meets the ISO 11138-1 and ISO 11138-3 requirements	Meets the ISO 11138-1 and ISO 11138-3 requirements	Identical
Carrier material	Plastic	Plastic	Identical
Incubation temperature	$60 \pm 2^\circ\text{C}$	$60 \pm 2^\circ\text{C}$	Identical
Readout time	24 minute final fluorescent result in: <ul style="list-style-type: none"> • The 490 Auto-reader having software version 4.0.0 or greater or • The 490H Auto-reader having software version 4.0.0 or greater or • The 490M Mini Auto-reader 	24 minute final fluorescent result in: <ul style="list-style-type: none"> • The 490 Auto-reader having software version 4.0.0 or greater or • The 490H Auto-reader having software version 4.0.0 or greater 	Both the submission and predicate BIs are intended to be used in conjunction with the 3M™ Attest™ Auto-reader 490 or the 3M™ Attest™ Auto-reader 490H. The intent of this submission is to expand the indications for use to include the use of the reference

3M™ Attest™ Super Rapid Steam Biological Indicator 1592

3M™ Attest™ Super Rapid Steam Challenge Pack 51582

3M™ Attest™ Auto-readers 490 and 490H

3M™ Attest™ Mini Auto-reader 490M

Feature	Submission Device: 3M™ Attest™ Super Rapid Steam Biological Indicator 1592, 3M™ Attest™ Auto-reader 490 and 490H, and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device (K192550): 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 and 3M™ Attest™ Auto-reader 490 and 490H	Comparison
	Optional visual pH color change result in 7 days.	Optional visual pH color change result in 7 days	device, the 3M™ Attest™ Mini Auto-reader 490M (cleared per K200092). The 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 BI has a 24 minute readout and can be used in conjunction with a 490 or 490H Auto-reader having software version 4.0.0 or greater or a 490M Auto-reader.
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
Shelf-life	12 months	6 months	Shelf life will be extended as real time data is available.

Technical Characteristics Comparison Table – Auto-readers

Both the submission and predicate BIs are intended to be used in conjunction with the 3M™ Attest™ Auto-reader 490 or the 3M™ Attest™ Auto-reader 490H (both having software version 4.0.0 or greater). The intent of this submission is to expand the indications for use to include the use of the reference device, the 3M™ Attest™ Mini Auto-reader 490M (cleared per K200092). The table below is a comparison of the three Auto-reader models that can be used in conjunction with the 3M™ Attest™ Super Rapid Steam Biological Indicator 1592.

3M™ Attest™ Super Rapid Steam Biological Indicator 1592

3M™ Attest™ Super Rapid Steam Challenge Pack 51582

3M™ Attest™ Auto-readers 490 and 490H

3M™ Attest™ Mini Auto-reader 490M

Feature	Submission Device: 3M™ Attest™ Auto-reader 490, 3M™ Attest™ Auto-reader 490H, 3M™ Attest™ Mini Auto-reader 490M,		Reference Device (K200092): 3M™ Attest™ Mini Auto-reader 490M	Comparison
Indications for use	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.	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 indications for use for Attest™ Biological Indicators are provided in the product’s Instructions for Use.	Both the submission and predicate BIs are intended to be used in conjunction with the 3M™ Attest™ Auto-reader 490 or the 3M™ Attest™ Auto-reader 490H. The intent of this submission is to expand the indications for use to include the use of the reference device, the 3M™ Attest™ Mini Auto-reader 490M.
	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.		
	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		

TRADITIONAL PREMARKET NOTIFICATION [510(k)]

K213809

3M™ Attest™ Super Rapid Steam Biological Indicator 1592

3M™ Attest™ Super Rapid Steam Challenge Pack 51582

3M™ Attest™ Auto-readers 490 and 490H

3M™ Attest™ Mini Auto-reader 490M

Feature	Submission Device: 3M™ Attest™ Auto-reader 490, 3M™ Attest™ Auto-reader 490H, 3M™ Attest™ Mini Auto-reader 490M,		Reference Device (K200092): 3M™ Attest™ Mini Auto-reader 490M	Comparison
		fluorescent result at 24 minutes. The indications for use for Attest™ Biological Indicators are provided in the product's Instructions for Use.		
Incubation temperature	490	60 ± 2°C	60 ± 2°C	Identical
	490H	60 ± 2°C		
	490M	60 ± 2°C		
Readout time	490	24 minutes	24 minutes	Identical
	490H	24 minutes		
	490M	24 minutes		

3M™ Attest™ Super Rapid Steam Biological Indicator 1592

3M™ Attest™ Super Rapid Steam Challenge Pack 51582

3M™ Attest™ Auto-readers 490 and 490H

3M™ Attest™ Mini Auto-reader 490M

Technical Characteristics Comparison Table – Challenge Pack

Feature	Submission Device: 3M™ Attest™ Super Rapid Steam Challenge Pack 51582, 3M™ Attest™ Auto-reader 490 and 490H, and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device (K192550): 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 and 3M™ Attest™ Auto-reader 490 and 490H	Comparison
Indications for use	<p>Use the 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, 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:</p> <ul style="list-style-type: none"> • Gravity Displacement, 250°F (121°C), 30 minutes • Dynamic-air-removal (pre-vacuum and SFPP), 250°F (121°C), 30 minutes • Dynamic-air removal (pre-vacuum and SFPP), 270°F (132°C), 4 minutes • Dynamic-air removal (pre-vacuum and SFPP), 273°F (134°C), 4 minutes • Dynamic-air removal (pre-vacuum and SFPP), 275°F (135°C), 3 minutes 	<p>Use the 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater or the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater to qualify or monitor dynamic-air removal (pre-vacuum and SFPP) or gravity displacement steam sterilization cycles of 30 minutes at 250°F (121°C).</p>	<p>Both the predicate and the submission Challenge Packs are indicated for use in Gravity Displacement and Dynamic air-removal (pre-vacuum and SFPP) steam sterilization cycles at 250°F (121°C). The intent of this submission is to expand the indications for use to include Dynamic air-removal (pre-vacuum and SFPP) sterilization cycles at 270°F (132°C), 273°F (134°C), and 275°F (135°C).</p> <p>Both the submission and predicate Challenge Packs contain a 1592 BI that is intended to be used in conjunction with the 3M™ Attest™ Auto-reader 490 or the 3M™ Attest™ Auto-reader 490H. The intent of this submission is to expand the indications for use to include the use of the reference device, the 3M™ Attest™ Mini Auto-reader 490M (cleared per K200092).</p>
General Design	Layers of medical index cards, some of which are die-cut to contain indicators,	Layers of medical index cards, some of which are die-cut to contain indicators,	Identical

TRADITIONAL PREMARKET NOTIFICATION [510(k)]

K213809

3M™ Attest™ Super Rapid Steam Biological Indicator 1592

3M™ Attest™ Super Rapid Steam Challenge Pack 51582

3M™ Attest™ Auto-readers 490 and 490H

3M™ Attest™ Mini Auto-reader 490M

Feature	Submission Device: 3M™ Attest™ Super Rapid Steam Challenge Pack 51582, 3M™ Attest™ Auto-reader 490 and 490H, and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device (K192550): 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 and 3M™ Attest™ Auto-reader 490 and 490H	Comparison
	overwrapped and secured with a label.	overwrapped and secured with a label.	
Biological Indicator	3M™ Attest™ Super Rapid Steam Biological Indicator 1592	3M™ Attest™ Super Rapid Steam Biological Indicator 1592	Identical
Biological Indicator Incubation temperature	60 ± 2°C	60 ± 2°C	Identical
Biological Indicator Readout time	24 minute final fluorescent result in the 490 or 490H Auto-readers having software versions 4.0.0 or greater or the 490M Mini Auto-reader.	24 minute final fluorescent result in both the 490 and 490H Auto-readers having software versions 4.0.0 or greater.	Both the submission and the predicate BIs have a 24 minute readout and are indicated to be used with a 490 or 490H Auto-reader having software version 4.0.0 or greater. The intent of this submission is to expand the indications for use to include the use of the reference device, the 3M™ Attest™ Mini Auto-reader 490M which also has a 24 minute readout (cleared per K200092).
Resistance Comparison to the AAMI ST79 16 Towel PCD	Equivalent in resistance to the AAMI ST79 16 Towel PCD	Equivalent in resistance to the AAMI ST79 16 Towel PCD	Identical
Chemical Integrator	3M™ Attest™ Chemical Integrator	3M™ Attest™ Chemical Integrator	Identical
External Chemical Process Indicator	Turns from yellow to brown or darker upon steam exposure	Turns from yellow to brown or darker upon steam exposure	Identical
Shelf-life	12 months	6 months	Shelf life will be extended as real time data is available.

Summary of Non-Clinical Testing

The differences between the subject and predicate devices have been evaluated through performance tests to provide evidence of substantial equivalence for the 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 and the 3M™ Attest™ Super Rapid Steam Challenge Pack 51582.

The device performance was verified through the following tests:

Item Tested	Test	Standard	Purpose	Acceptance Criteria	Results
1592 BI	Population	ISO 11138-1, ISO 11138-3, USP 34-NF29, and FDA Guidance document ¹	To evaluate the total viable spore count	$\geq 10^6$ spores	Passed
1592 BI	D-Value	ISO 11138-1, ISO 11138-3, and FDA Guidance document ¹	To evaluate the resistance characteristics of the BI.	$D_{121} \geq 1.5$ min $D_{132} \geq 10$ s $D_{134 \text{ or } 135} \geq 8$ s	Passed
1592 BI	Z-Value	ISO 11138-1, ISO 11138-3, and FDA Guidance document ¹		$\geq 10^\circ\text{C}$	Passed
1592 BI	Survival Time	ISO 11138-1, ISO 11138-3, and FDA Guidance document ¹		Meets the longer of FDA and ISO 11138-1 and ISO 11138-3 requirements	Passed
1592 BI	Kill Time	ISO 11138-1, ISO 11138-3, and FDA Guidance document ¹		Meets ISO 11138-1 and ISO 11138-3 requirements	Passed
1592 BI	Component Inhibition Studies	ISO 11138-1 and FDA Guidance document ¹		To evaluate the effects of carrier and packaging materials on the resistance characteristics of the BI.	Components have no impact on the recovery of 10-100 organisms
1592 BI	Hold Time Assessment	ISO 11138-1 and FDA Guidance document ¹	To evaluate the effect of the labeled holding time on the resistance characteristics	D-value does not change when activated 7 days post sterilization	Passed

TRADITIONAL PREMARKET NOTIFICATION [510(k)]

K213809

3M™ Attest™ Super Rapid Steam Biological Indicator 1592

3M™ Attest™ Super Rapid Steam Challenge Pack 51582

3M™ Attest™ Auto-readers 490 and 490H

3M™ Attest™ Mini Auto-reader 490M

Item Tested	Test	Standard	Purpose	Acceptance Criteria	Results
			and spore recovery.		
1592 BI	Reduced Incubation Time	ISO 11138-1 and FDA Guidance document ¹	To validate the reduction in incubation time from 7 days to 24 minutes.	Meets FDA's requirements for Reduced Incubation Time with > 97% alignment with the conventional incubation time of 7 days for the following readout time: Fluorescent result in 24 minutes	Passed
1592 BI	Reduced Incubation Time	ISO 11138-1 and ISO 11138-8	To validate the reduction in incubation time from 7 days to 24 minutes.	Meets requirement for Reduced Incubation Time specified in ISO 11138-8	Passed
1592 BI	Simulated Use	FDA Guidance document ¹	Verification of performance in claimed cycles	BI performs as intended in claimed cycles	Passed

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

Item Tested	Test	Purpose	Acceptance Criteria	Results
490 Auto-reader and 490M Mini Auto-reader	Verification of equivalent performance- 1592 BI in 490 Auto-reader and 490M Mini Auto-reader	Cross-over study of 1592 BI in 490 Auto-reader and 490M Mini Auto-reader	1592 BI performs the same in 490 Auto-reader as compared to 490M Mini Auto-reader	Passed

3M™ Attest™ Super Rapid Steam Biological Indicator 1592

3M™ Attest™ Super Rapid Steam Challenge Pack 51582

3M™ Attest™ Auto-readers 490 and 490H

3M™ Attest™ Mini Auto-reader 490M

Item Tested	Test	Standard	Purpose	Acceptance Criteria	Results
51582 Challenge Pack	Resistance of the 51582 Challenge Pack as compared to AAMI 16 Towel PCD in claimed cycles	ANSI/AAMI ST79 and FDA Guidance document ¹	To evaluate the 51582 Challenge Pack as compared to the AAMI 16 Towel PCD in claimed cycles	51582 Challenge Pack demonstrates equivalent resistance as compared to the AAMI 16 Towel PCD in claimed cycles	Passed
51582 Challenge Pack	Resistance of the 51582 Challenge Pack as compared to the 1592 Biological Indicator and the 3M™ Attest™ Chemical Integrator alone in claimed cycles	FDA Guidance document ¹	To evaluate the 51582 Challenge Pack as compared to the 1592 Biological Indicator itself and the 3M™ Attest™ Chemical Integrator alone in claimed cycles	51582 Challenge Pack provides a greater challenge than 1592 Biological Indicator and 3M™ Attest™ Chemical Integrator itself in claimed cycles	Passed

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

Conclusion

Based on the intended use, technological characteristics, and non-clinical performance data, the subject devices, the 3M™ Attest™ Super Rapid Steam Biological Indicator 1592, the 3M™ Attest™ Super Rapid Steam Challenge Pack 51582, the 3M™ Attest™ Auto-reader 490, the 3M™ Attest™ Auto-reader 490H, and the 3M™ Attest™ Mini Auto-reader 490M, are substantially equivalent to, and are as safe and as effective as the legally marketed predicate device, the 3M™ Attest™ Super Rapid Steam Biological Indicator 1592, 3M™ Attest™ Super Rapid Steam Challenge Pack 51582, 3M™ Attest™ Auto-reader 490, 3M™ Attest™ Auto-reader 490H (cleared under K192550) and the reference device, the 3M™ Attest™ Mini Auto-reader 490M (cleared under K200092), Class II (21 CFR 880.2800), product code FRC.