June 5, 2020

3M Company
Hilary Hovde
Regulatory Affairs Specialist
Bldg. 275-5W-06
St.Paul, Minnesota 55144

Re: K192550
Trade/Device Name: 3M™ Attest™ Super Rapid Steam Biological Indicator 1592, 3M™ Attest™ Super Rapid Steam Challenge Pack, 3M™ Attest™ Auto- Readers 490 and 490H
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: May 6, 2020
Received: May 7, 2020

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 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: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Kl92550

Device Name

3M™ Attest™ Super Rapid Steam Biological Indicator 1592 and 3M™ Attest™ Auto-reader 490 and 490H

Indications for Use *(Describe)*

Use the 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 in conjunction with the 3M™ AttestTM 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:

Cycle Type	Exposure Temperature	Exposure Time
Dynamic-air-removal (pre-vacuum and SFPP)	250°F (121°C)	15 minutes
Dynamic-air-removal (pre-vacuum and SFPP)	250°F (121°C)	20 minutes
Dynamic-air-removal (pre-vacuum and SFPP)	250°F (121°C)	30 minutes
Dynamic-air-removal (pre-vacuum and SFPP)	250°F (121°C)	35 minutes
Gravity Displacement	250°F (121°C)	30 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Kl92550

Device Name

3MTM AttestTM Super Rapid Steam Challenge Pack 51582 and 3M™ Attest™ Auto-reader 490 and 490H

Indications for Use *(Describe)*

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).

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

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

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

Submission Date: August 27, 2019

Device Name and Classification- Biological Indicator:

Trade Name:	3M™ Attest™ Super Rapid Steam Biological Indicator 1592 3M™ Attest™ Auto-reader 490 3M™ Attest™ Auto-reader 490H
Common/Usual Name:	Biological Indicator (BI)
Device Classification:	Class II
Classification Name:	Indicator, Biological Sterilization Process [21 CFR § 880.2800(a), FRC]

Predicate Device- Biological Indicator:

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

Indications for Use- 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 or the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater to qualify or monitor the following sterilization cycles:

Cycle Type	Exposure Temperature	Exposure Time
Dynamic-air-removal (pre-vacuum and SFPP)	250°F (121°C)	15 minutes
Dynamic-air-removal (pre-vacuum and SFPP)	250°F (121°C)	20 minutes
Dynamic-air-removal (pre-vacuum and SFPP)	250°F (121°C)	30 minutes
Dynamic-air-removal (pre-vacuum and SFPP)	250°F (121°C)	35 minutes
Gravity Displacement	250°F (121°C)	30 minutes

Description of Device- Biological Indicator

The 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 is a self-contained biological indicator (BI) specifically designed to be used 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 and gravity displacement steam sterilization cycles at 250°F (121°C).

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 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 1592 in the 490 Auto-reader or the 490H Auto-reader (having software version 4.0.0 or greater) indicates a sterilization failure.

Technological Characteristics Comparison Table – Biological Indicator

Feature	Submission Device: (K192550): 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 and 3M™ Attest™ Auto-reader 490 and 490H	Predicate Device (K173437): 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V 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 or the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater to qualify or monitor the following sterilization cycles: • Dynamic-air-removal (pre-vacuum and SFPP), 250°F (121°C), 15 minutes • Dynamic-air-removal (pre-vacuum and SFPP), 250°F (121°C), 20 minutes • Dynamic-air-removal (pre-vacuum and SFPP), 250°F (121°C), 30 minutes • Dynamic-air-removal (pre-vacuum and SFPP), 250°F (121°C), 35 minutes • Gravity Displacement, 250°F (121°C), 30 minutes	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)	The 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 is intended to qualify or monitor both dynamic-air-removal (pre-vacuum and SFPP) and gravity displacement cycles at various exposure times at 250°F (121°C). Whereas the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492Vis intended to qualify or monitor dynamic-air-removal steam sterilization cycles at various exposure times at 270°F (132°C) and 275°F (135°C). Both BIs are intended to be used in conjunction with the 3M™ Attest™ Auto-reader 490 and the 3M™ Attest™ Auto-reader 490H.
Indicator Organism	*Geobacillus stearothermophilus* traceable to ATCC™ 7953	*Geobacillus stearothermophilus* 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	When the enzyme that is naturally occurring in the spore is in its active state, it is detected by measuring the	Identical

Feature	Submission Device: (K192550): 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 and 3M™ Attest™ Auto-reader 490 and 490H	Predicate Device (K173437): 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V and 3M™ Attest™ Auto-reader 490 and 490H	Comparison
	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.	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.	
Auto-reader	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	3M™ Attest™ Auto-reader 490 or 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater	The 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 BI has a 24 minute readout and is intended to be used with a 490 or 490H having software version 4.0.0 or greater. Indications for a 24 minute time to result were cleared under K173437.
Viable spore population	$\geq 1 \times 10^6$	$\geq 1 \times 10^6$	Identical
Resistance	$D_{121} \geq 1.5$ min	D_{121} is N/A $D_{132} \geq 10$ s $D_{135} \geq 8$ s	The 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 BI is indicated for qualifying and monitoring sterilization cycles at 121°C whereas the predicate device is indicated for qualifying and monitoring sterilization cycles at 132°C and 135°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

Feature	Submission Device: (K192550): 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 and 3M™ Attest™ Auto-reader 490 and 490H	Predicate Device (K173437): 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V and 3M™ Attest™ Auto-reader 490 and 490H	Comparison
Carrier material	Plastic	Plastic	Identical
Incubation temperature	60 ± 2ºC	60 ± 2ºC	Identical
Readout time	24 minute final fluorescent result in both the 490 and 490H Auto-readers having software version 4.0.0 or greater. Optional visual pH color change result in 7 days	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.	The 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 BI has a 24 minute readout and is intended to be used with a 490 or 490H having software version 4.0.0 or greater. Indications for a 24 minute time to result were cleared under K173437.
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	6 months	21 months	Real-time testing is ongoing.

Summary of Nonclinical Testing- Biological Indicator

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*
- United States Pharmacopeia, Chapter <1035> Biological Indicators for Sterilization and Chapter <55> Biological Indicators – Resistance Performance Tests

The performance testing below demonstrate that the subject device met the acceptance criteria of the specified standards:

Test	Results
Population (Total Viable Spore Count) Greater than or equal to 10^6 spores	Passed
D-Value Greater than or equal to 1.5 minutes at 121°C	Passed
Z-Value Greater than or equal to 10°C	Passed
Survival Time Meets the longer of FDA and ISO 11138-1 and ISO 11138-3 requirements	Passed
Kill Time Meets ISO 11138-1 and ISO 11138-3 requirements	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
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 time: • Fluorescent result in 24 minutes	Passed
Simulated Use Verification of performance in claimed cycles	Passed

3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater and 3M™ Attest™ Auto-reader 490H

The 3M™ Attest™ Auto-reader 490 and the 3M™ Attest™ Auto-reader 490H were cleared for use with the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V under K173437. This submission extends the use of 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 the 3M™ Attest™ Super Rapid Steam Biological Indicator 1592.

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 are designed to incubate at 60°C and automatically read the 1592 BI for a fluorescent result within 24 minutes. The fluorescent readout at 24 minutes meets the FDA's requirement of > 97% alignment with the result after conventional incubation time of 7 days.

Device Name and Classification- Challenge Pack:

Trade Name:	3M™ Attest™ Super Rapid Steam Challenge Pack 51582
Common/Usual Name:	Biological Indicator (BI) Challenge Pack
Device Classification:	Class II
Classification Name:	Indicator, Biological Sterilization Process [21 CFR § 880.2800(a), FRC]

Predicate Device- Challenge Pack:

3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V, 3M™ Attest™ Auto-reader 490, and 3M™ Attest™ Auto-reader 490H, K173519

Indications for Use- 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 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).

Description of Device- Challenge Pack

The 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 is specifically designed 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).

The 51582 Challenge Pack consists of multiple layers of medical index cards, some of which are die-cut to contain monitoring products. The pack is overwrapped and secured with a label. The Challenge Packs have the same design as the predicate device but contain different monitoring products. 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. The 1592 BI is specifically designed for a rapid fluorescent result when used 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. The detection of fluorescence upon incubation of the 1592 in the 490 Auto-reader or the 490H Auto-reader (having software version 4.0.0 or greater) indicates a sterilization failure. 3M™ Attest™ 1592 BI controls are provided with the Challenge Packs. 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.

Technological Characteristics Comparison Table – Challenge Pack

Feature	Submission Device: (K192550): 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 and 3M™ Attest™ Auto-reader 490 and 490H	Predicate Device (K173519): 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V and 3M™ Attest™ Auto-reader 490 and 490H	Comparison
Indications for use	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).	Use the 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V in conjunction with the 3M™ Attest™ Auto-reader 490 or 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater to qualify or monitor dynamic-air-removal steam sterilization cycles of 4 minutes at 270°F (132°C) and 3 minutes at 275°F (135°C).	The 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 is intended to qualify or monitor both dynamic-air-removal (pre-vacuum and SFPP) and gravity displacement sterilization cycles of 30 minutes at 250°F (121°C). Whereas the 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack is intended to qualify or monitor dynamic-air-removal steam sterilization cycles at various exposure times at 270°F (132°C) and 275°F (135°C).
General Design	Layers of medical index cards, some of which are die-cut to contain indicators, overwrapped and secured with a label.	Layers of medical index cards, some of which are die-cut to contain indicators, overwrapped and secured with a label.	Identical
Biological Indicator	3M™ Attest™ Super Rapid Steam Biological Indicator 1592	3M™ Attest™ Super Rapid Readout Biological Indicator 1492V	The 51582 Challenge Pack contains the new 1592 BI as proposed in this submission.
Biological Indicator Incubation temperature	60 ± 2ºC	60 ± 2ºC	Identical
Biological Indicator Readout time	24 minute final fluorescent result in both the 490 and 490H Auto-readers having software versions 4.0.0 or greater.	24 minute final fluorescent result in both the 490 and 490H Auto-readers having software versions 4.0.0 or greater. 1 hour final fluorescent result in 490 Auto-readers having	The 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 BI has a 24 minute readout and is intended to be used with a 490 or

Feature	Submission Device: (K192550): 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 and 3M™ Attest™ Auto-reader 490 and 490H	Predicate Device (K173519): 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V and 3M™ Attest™ Auto-reader 490 and 490H	Comparison
		software versions less than 4.0.0.	490H having software version 4.0.0 or greater. Indications for a 24 minute time to result were cleared under K173519.
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™ SteriGage™ Chemical Integrator	Both integrators meet FDA requirements and are Type 5 Integrating Indicators as classified per ISO 11140-1.
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	6 months	21 months	Real-time testing is ongoing.

Summary of Nonclinical Testing- Challenge Pack

Testing was conducted on the challenge packs following the FDA guidance and the standards below:

- *Guidance for Industry and FDA Staff, Biological Indicator Premarket Notification [510(k)] Submissions,* October 4, 2007
- *Premarket Notification [510(k)] Submission for Chemical Indicators: Guidance for Industry and FDA Staff,* December 19, 2003
- ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*
- 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*

- ISO 11140-1:2014 *Sterilization of health care products – Chemical indicators, Part 1: General Requirements*
- United States Pharmacopeia, Chapter <1035> Biological Indicators for Sterilization and Chapter <55> Biological Indicators – Resistance Performance Tests

The performance testing below demonstrate that the subject device met the acceptance criteria of the specified standards:

Test	Acceptance Criteria	Results
Resistance of the Challenge Pack as compared to AAMI 16 Towel PCD	Challenge Pack is at least as resistant as the biological indicator AAMI 16 Towel Process Challenge Device (PCD) described in ANSI/AAMI ST79: 2017	Passed
Resistance of the Challenge Pack as compared to the Biological Indicator alone	Challenge Pack provides a greater resistance than the Biological Indicator alone	Passed

Conclusion

The conclusions drawn from the non-clinical tests performed, the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices, the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V, 3M™ Attest™ Auto-reader 490, and 3M™ Attest™ Auto-reader 490H (cleared under K173437) and the 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V, 3M™ Attest™ Auto-reader 490, and 3M™ Attest™ Auto-reader 490H (cleared under K173519), Class II (21 CFR 880.2800), product code FRC.