January 28, 2025

3M Company
Michelle Larsen
Principal RA Specialist
3M Center
2510 Conway Ave., Building 275-5W-06
St. Paul, Minnesota 55144

Re: K243501
Trade/Device Name: 3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE; 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: November 11, 2024
Received: November 12, 2024

Dear Michelle Larsen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2025.01.28 14:11:26 -05'00'

for: Christopher K. Dugard
Assistant Director
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243501

Device Name
3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE; 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 Extended Cycle Clear Challenge Pack 1492PCDE: Use the 3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE in conjunction with the 3M™ Attest™ Auto-reader 490, 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 cycle:

Cycle Type	Exposure Temperature	Exposure Time
Dynamic-air-removal	270°F (132°C)	10 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 1493, 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, 1492V, and 1493 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 1493, at 60°C for a final fluorescent result at 24 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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510(k) Summary
for
3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE, 3M™ Attest™ Auto-reader 490, 3M™ Attest™ Auto-reader 490H, 3M™ Attest™ Mini Auto-reader 490M
K243501

Sponsor Information:

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

Contact: Michelle M. Larsen
Principal RA Specialist
Phone Number: (651) 394-8173
Fax Number: (651) 737-5320
Email: mmlarsen@solventum.com

Date of Summary: 14 January 2025

1. **Device Name and Classification:**

   Common or Usual Name: Biological Indicator (BI) Challenge Pack

Proprietary Name:	3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE, 3M™ Attest™ Auto-reader 490, 3M™ Attest™ Auto-reader 490H, 3M™ Attest™ Mini Auto-reader 490M
Classification Name:	Indicator, Biological Sterilization Process
Device Classification:	Class II, 21 CFR 880.2800(a)
Product Code:	FRC

2. Predicate Device:

VERIFY All-In-One STEAM Reusable Test Pack employing the Celerity Xtend 10 Assembly, K182931

3. Description of Device:

The 3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE is designed to qualify and monitor extended dynamic-air-removal steam sterilization processes at 270°F (132°C) in healthcare facilities.

The 1492PCDE Challenge Pack consists of a clear plastic shell, with a tortuous channel allowing for air removal and sterilant penetration. The channel connects to a cavity containing the monitoring products and all are covered by a foil lid. The 1492PCDE is a single-use device.

Each 1492PCDE Challenge Pack contains a 3M™ Attest™ Super Rapid Readout Biological Indicator (BI) 1492V (brown cap) and a 3M™ Attest™ Steam Chemical Integrator (CI). The CI verifies that the stated values for the three critical parameters of exposure time, temperature, and steam saturation have been achieved. Upon exposure to steam a dark color visible through a window migrates along the indicator strip and offers an ACCEPT or REJECT reading. The 1492V Biological Indicator (BI) is specifically designed for rapid and reliable qualification testing and routine monitoring of steam sterilization processes when used in conjunction with the 3M™ Attest™ Auto-reader 490, 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 1492V BI in the 490, 490H or 490M Auto-reader indicates a steam sterilization process failure. A chemical process indicator is present on the brown cap of the 1492V BI and is visible through the clear plastic shell of the challenge pack. The process indicator on the BI cap turns color from pink

to light brown or darker upon exposure to steam. The process indicator is used by the customer to verify that the challenge pack was exposed to steam.

4. Indications for Use

3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE:
Use the 3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE in conjunction with the 3M™ Attest™ Auto-reader 490, 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 cycle:

Cycle Type	Exposure Temperature	Exposure Time
Dynamic-air-removal	270°F (132°C)	10 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 1493, 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, 1492V, and 1493 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 1493, at 60°C for a final fluorescent result at 24 minutes.

The submission device, the 3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE, has the same intended use as the predicate device, the VERIFY All-In-One STEAM Reusable Test Pack employing the Celerity™ Xtend 10 Assembly. Both the submission device and the predicate device are Single Use biological indicator process challenge devices that are intended to be used in healthcare facilities to accompany products being sterilized and to monitor adequacy of the sterilization process.

Both the submission and the predicate challenge packs are indicated to monitor 10-minute 270°F (132°C) dynamic-air-removal steam sterilization cycles. The submission challenge pack is intended to be used in conjunction with the 3M™ Attest™ Auto-readers 490 and 490H, and 3M™ Attest™ Mini Auto-reader 490M. The 1492V Biological Indicator that is contained in the submission challenge pack was cleared for use with the Auto-readers per

K241710. The differences in Indications for Use do not alter the fundamental Intended Use of these products as biological indicator process challenge devices and do not raise new questions of safety and effectiveness.

5. Comparison of Technological Characteristics with the Predicate Device

The submission challenge pack consists of a clear plastic shell and a tortuous channel connected to a cavity in the shell containing the monitoring products, all heat sealed with a foil lid. The predicate challenge pack consists of a reusable aluminum tube with a removable aluminum plug to allow loading of a single use assembly, containing the indicators, and a tortuous path challenge for air removal and steam penetration at the other sealed end. Both the submission and predicate challenge pack are designed to increase the resistance beyond that measured with a standalone biological indicator and both represent a challenge to the sterilization process equivalent to the AAMI reference PCD. Both the submission challenge pack and the predicate challenge pack contain a Biological Indicator (BI) that has been verified to qualify or monitor dynamic-air-removal steam sterilization cycles and both utilize a fluorescent result to indicate a steam sterilization process failure. Both the submission challenge pack and the predicate challenge pack contain a Chemical Indicator (CI) that are able to independently monitor and react to all critical parameters of the intended steam sterilization cycles. The process indicator present on the cap of the BI is visible through the clear plastic shell of the submission challenge pack whereas the chemical indicator is visible through the clear plastic sleeve assembly of the predicate challenge pack. Both the submission and predicate challenge pack contain a visible indicator that changes color upon steam exposure that is used by the customer to distinguish processed and unprocessed challenge packs. Both the submission challenge pack and the predicate challenge pack utilize a Biological Indicator which is intended to be used in conjunction with an incubator/reader to indicate a steam sterilization process failure.

The differences in technological characteristics between the submission and predicate challenge pack are illustrated in the Device Technological Characteristics Comparison Table (**Table 1**).

Table 1: Device Technological Characteristics Comparison Table

Feature	Submission Device: (K243501) 3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K182931) VERIFY All-In-One STEAM Reusable Test Pack employing the Celerity™ Xtend 10 Assembly	Comparison
Intended Use	Single Use biological indicator process challenge device	Single Use biological indicator process challenge device	Identical
Indications for use	Use the 3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE in conjunction with the 3M™ Attest™ Auto-reader 490, 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 cycle: • Dynamic-air-removal, 270°F (132°C), 10 minutes	The VERIFY All-In-One STEAM Reusable Test Pack employing the Celerity Xtend 10 Assembly with a Celerity 20 STEAM Biological Indicator and a Celerity 10 STEAM Chemical Indicator can be used for routine monitoring of 10-minute 270°F/132°C dynamic air removal steam sterilization cycles. The sleeve assembly is intended to be used only with the VERIFY All-In-One STEAM Reusable Test Pack.	The Indications for Use are similar in that the subject device and predicate device are used to monitor 10-minute 270°F/132°C dynamic-air-removal steam sterilization cycles. The subject challenge pack is intended to be used in conjunction with the 3M™ Attest™ Auto-readers 490 and 490H and the 3M™ Attest™ Mini Auto-reader 490M. The 1492V BI contained in the subject challenge pack was cleared for use with the Auto-readers per K241710.
General Design/Construction	Clear plastic tray with a tortuous channel to the cavity containing the indicators, acting as a challenge to limit air removal and steam penetration, sealed with a foil lid.	The VERIFY All-in-One STEAM Reusable Test Pack consists of a reusable aluminum tube with a removable aluminum plug to allow loading of the Celerity Xtend 10 Assembly, containing the indicators, and a tortuous path challenge for air removal and steam penetration at the other sealed end.	Both the subject challenge pack and the predicate challenge pack consist of a BI and CI and are designed and constructed with a tortuous path to challenge air removal and steam penetration. The subject challenge pack is a single-use test pack.
Biological Indicator	3M™ Attest™ Super Rapid Readout Biological Indicator 1492V with ≥ 1	Celerity 20 STEAM Biological Indicator with 1.0 – 4.0 x 10^6 *Geobacillus stearothermophilus* spores	Both the subject device and the predicate device utilize Self-Contained Biological Indicators with ≥10^6

Feature	Submission Device: (K243501) 3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K182931) VERIFY All-In-One STEAM Reusable Test Pack employing the Celerity™ Xtend 10 Assembly	Comparison
	x 10^6 *Geobacillus stearothermophilus* spores		*Geobacillus stearothermophilus* spores
Biological Indicator – Resistance Characteristics • D value	D-value ≥ 10 seconds at 132°C D-value ≥ 8 seconds at 134°C D-value ≥ 8 seconds at 135°C	$D_{121} \geq 1.5$ min $D_{132} \geq 10$s $D_{135} \geq 8$s	Similar, both BIs are characterized with Resistance Characteristics (D-value and Survival/Kill) that meet FDA and ISO requirements.
Biological Indicator – Resistance Characteristics • Survival/Kill	Survival Time = Calculated survival time* or 1 minute at 132°C and 40 seconds at 134°C and 135°C, whichever is longer Kill Time = Calculated kill time* at 132°C, 134°C and at 135°C	Survival Time – Meets the longer of FDA and ISO 11138-3 requirements Kill Time – Meets the shorter of FDA and ISO 11138-3 requirements	
Biological Indicator Incubation temperature	60 ± 2°C	55-60°C	Similar, both the subject device and the predicate device contain a BI that has been verified to qualify or monitor dynamic-air-removal steam sterilization cycles. The subject device has different readout times than the predicate device.
Biological Indicator - Readout time	24 minute final fluorescent result in both the 490 and 490H Auto-readers having software version 4.0.0 or greater or in a 490M Auto-reader. 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 for 490, 490H or 490M Auto-readers.	20 minute final fluorescent result in Celerity™ Steam Incubator.	

Feature	Submission Device: (K243501) 3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K182931) VERIFY All-In-One STEAM Reusable Test Pack employing the Celerity™ Xtend 10 Assembly	Comparison
Biological Indicator - 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. There is an optional visual pH color change which indicates a steam sterilization process failure.	An enzyme, which is produced by the organism, reacts with a fluorogenic substrate within the defined nutrient media to produce a fluorescent moiety	Similar, both the subject device and the predicate device utilize a fluorescent result. The subject device also utilizes an optional visual pH color change.
Chemical Indicator	3M™ Attest™ Steam Chemical Integrator	Celerity 10 STEAM Chemical Indicator	The chemical indicators in the subject challenge pack and predicate challenge pack are able to independently monitor and react to all critical parameters of the intended sterilization cycle. The CI in the subject device is a Type 5 moving front integrator whereas the CI in the predicate device is a Type 6 emulating indicator.
Chemical Indicator - Color Change	Dark color migrates along strip visible through a green window (ACCEPT) or red window (REJECT)	The Celerity 10 STEAM Chemical Indicator indicates a pass by a color change of yellow to blue/purple or a fail indicated by no color change or an incomplete color change.	

Feature	**Submission Device: (K243501)** **3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M**	**Predicate Device: (K182931)** **VERIFY All-In-One STEAM Reusable Test Pack employing the Celerity™ Xtend 10 Assembly**	**Comparison**
Mechanism to distinguish processed and unprocessed challenge pack	Process indicator present on 1492V BI cap is visible through PCD and turns color from pink to light brown or darker upon steam exposure.	The Celerity 10 STEAM Chemical Indicator can be evaluated for a pass or fail prior to opening the assembly. A change in color from yellow to blue/purple indicates a pass.	Both the subject and predicate device contain an indicator that changes color upon exposure to steam that is used by the customer to verify the challenge pack was exposed to steam.
Accessories	3M™ Attest™ Auto-reader 490 or the 3M™Attest™ Auto-reader 490H or the 3M™ Attest™ Mini Auto-reader	Celerity STEAM Incubator/reader	Similar, both the subject device and the predicate device utilize a BI which is intended to be used in conjunction with an incubator/reader.

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

6. Nonclinical Comparison to the Predicate Device

The differences between the submission and predicate device have been evaluated through performance tests for the 3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE.

Three lots of 3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE, containing three lots of 1492V BIs and three lots of 1243R CIs, were tested side by side with standalone indicators 1492V BIs and 1243R CIs. Testing was completed per the *Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions,* October 4, 2007.

Three lots of 3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE, containing three lots of 1492V BIs and three lots of 1243R CIs, were tested side by side with the AAMI 16 Towel PCD containing 1492V BIs and 1243R CIs. Testing was completed per the *Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions,* October 4, 2007, and ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.*

Three lots of 3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE were tested for peel force of the heat seal foil lid from the plastic shell. The validated method used to perform the testing is based on ASTM F88 / F88M-15: *Standard Test Method for Seal Strength of Flexible Barrier* and ASTM F2824 – 10: *Standard Test Method for Mechanical Seal Strength Testing for Round Cups and Bowl Containers with Flexible Peelable Lids*.

Performance of the 1492PCDE challenge pack was verified through the following tests:

Test Performed	Device Description	Applicable Standards	Purpose	Acceptance Criteria	Results
Resistance of 1492PCDE Challenge Pack compared to AAMI 16 Towel PCD in claimed cycles	1492PCDE Challenge Pack	FDA Guidance[1] and ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*	Demonstrate the performance of the 1492PCDE Challenge Pack is equivalent to the performance of the AAMI 16 Towel PCD in the claimed cycles	Indicators contained in the 1492PCDE Challenge Pack must demonstrate equivalent resistance as compared to the indicators contained in the AAMI 16 Towel PCD in the claimed cycles	Acceptance criteria met
Resistance of 1492PCDE Challenge	1492PCDE Challenge Pack	FDA Guidance[1]	Demonstrate the 1492PCDE Challenge	Indicators contained in the 1492PCDE	Acceptance criteria met

Test Performed	Device Description	Applicable Standards	Purpose	Acceptance Criteria	Results
Pack compared to standalone indicators in claimed cycles			Pack provides a greater challenge than the standalone indicators in the claimed cycles	Challenge Pack must demonstrate greater resistance compared to the standalone indicators in the claimed cycles	
1492PCDE Peel Force	1492PCDE Challenge Pack	ASTM F88 / F88M-15: *Standard Test Method for Seal Strength of Flexible Barrier* and ASTM F2824 – 10: *Standard Test Method for Mechanical Seal Strength Testing for Round Cups and Bowl Containers with Flexible Peelable Lids*	Demonstrate acceptable peel force of Clear Challenge Pack 1492PCDE heat seal foil lid from plastic shell	≥30.2 lbf	Acceptance criteria met

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

7. Clinical Comparison to the Predicate Device

Clinical testing was not required or completed for the submission device.

8. Conclusion

Based on the intended use, technological characteristics, and non-clinical performance data, the submission device, the 3M™ Attest™ Super Rapid Steam Extended Cycle Clear Challenge Pack 1492PCDE, the 3M™ Attest™ Auto-reader 490, the 3M™ Attest™ Auto-reader 490H, and the 3M™ Attest™ Mini Auto-reader 490M, is as safe, as effective and performs as well as or better than the legally marketed predicate device, the VERIFY All-In-One STEAM Reusable Test Pack employing the Celerity Xtend 10 Assembly (cleared per K182931) Class II (21 CFR 880.2800), product code FRC.