October 18, 2024

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

Re: K241959
Trade/Device Name: 3M™ Attest™ Super Rapid Steam Clear Challenge Pack (1492PCD); 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: September 19, 2024
Received: September 19, 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,

PAULO LARANJEIRA -S

Digitally signed by PAULO LARANJEIRA -S
Date: 2024.10.18 11:49:41 -04'00'

for: Christopher 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.

Submission Number *(if known)*

K241959

Device Name

3M™ Attest™ Super Rapid Steam Clear Challenge Pack (1492PCD);
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 Clear Challenge Pack (1492PCD):
Use the 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD 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 cycles:

Cycle Type	Exposure Temperature		Exposure Time
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.

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.

510(k) Summary
for
3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD, 3M™ Attest™ Auto-reader 490, 3M™ Attest™ Auto-reader 490H, 3M™ Attest™ Mini Auto-reader 490M
K241959

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) 467-3991
Fax Number: (651) 737-5320
Email: mmlarsen@solventum.com

Date of Summary: 09 October 2024

1. **Device Name and Classification:**

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

Proprietary Name:	3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD, 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:

3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V, K193154

3. Description of Device:

The 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD is designed to qualify and monitor dynamic-air-removal steam sterilization processes at 270°F (132°C), 273°F (134°C), and 275°F (135°C) in healthcare facilities.

The 1492PCD Challenge Pack consists of a clear plastic shell, and 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 1492PCD is a single-use device.

Each 1492PCD 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 Clear Challenge Pack (1492PCD):
Use the 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD 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 cycles:

Cycle Type	Exposure Temperature	Exposure Time
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 submission device, the 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD, has the same intended use as the predicate device, the 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V. 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 predicate test packs are indicated for use in conjunction with the 3M™ Attest™ Auto-readers 490 and 490H, and 3M™ Attest™ Mini Auto-reader 490M to qualify or monitor dynamic-air-removal steam sterilization cycles. The predicate device is indicated for use in dynamic-air-removal steam sterilization cycles of 4 minutes at 270°F (132°C) and 3 minutes at 275°F (135°C). The submission device covers an additional cycle ((4 minutes at 273°F (134°C)) compared to the predicate device. 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

Both the submission and predicate challenge packs are designed to increase resistance beyond that measured with a standalone BI and both represent a challenge to the sterilization process equivalent to the AAMI reference PCD. The 3M™ Attest™ Super Rapid Steam Clear 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 whereas the predicate challenge pack consists of layers of medical index cards, some of which are die-cut to contain indicators, overwrapped and secured with a label. Both the submission and predicate challenge pack utilize the same Biological Indicator, the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V and the same Chemical Integrator, the 3M™ Attest™ Steam Chemical Integrator. The process indicator on the predicate challenge pack is present on the outer label of the overwrapped challenge pack whereas the process indicator on the submission device is present on the cap of the 1492V BI which is visible through the clear challenge pack. Both the submission and predicate challenge packs contain a visible process indicator that changes color upon steam exposure that is used by the customer to distinguish processed and unprocessed challenge packs. The accessories (Auto-readers) are the same for both the submission and predicate device and the readout time or the time to a result is the same for both the submission and predicate device.

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

Table 1: Device Comparison Table

Feature	Submission Device: (K241959) 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K193154) 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V	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 Clear Challenge Pack 1492PCD 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™ Min Auto-reader 490M to qualify or monitor dynamic-air-removal (pre-vacuum and SFPP) steam sterilization cycles of: • 4 minutes at 270°F (132°C), • 4 minutes at 273°F (134°C), and • 3 minutes at 275°F (135°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).	Both the submission and predicate test packs are used to qualify or monitor dynamic-air-removal steam sterilization cycles. The submission device is indicated for an additional sterilization cycle of 4 minutes at 273°F (134°C). Both the submission and predicate test packs utilize the same Biological Indicator (BI) and Chemical Integrator (CI). The 1492V BI is indicated for use in 270°F (132°C) and 275°F (135°C) dynamic-air-removal steam sterilization cycles (per K173437). 510(k) (K241710) is pending clearance to expand the Indications for Use for the 1492V BI to also include the 273°F (134°C) steam sterilization cycle. The 1243R CI is indicated for use in

Feature	Submission Device: (K241959) 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K193154) 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V	Comparison
			270°F (132°C), 273°F (134°C) and 275°F (135°C) dynamic-air-removal steam sterilization cycles (per K220942). The 1492V BI contained in both the predicate and submission test packs are intended to be used in conjunction with the 3M™ Attest™ Auto-reader 490 or the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater to qualify or monitor dynamic-air removal steam sterilization cycles. The 1492V BI was cleared for use with the 3M™ Attest™ Mini Auto-reader 490M per K200092.
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.	Layers of medical index cards, some of which are die-cut to contain indicators, overwrapped and secured with a label.	Both the submission and predicate challenge packs are designed to increase resistance beyond that measured with a standalone BI and both represent a challenge to the sterilization process equivalent to the AAMI reference PCD.
Biological Indicator	3M™ Attest™ Super Rapid Readout Biological Indicator 1492V with ≥ 1 x	3M™ Attest™ Super Rapid Readout Biological Indicator 1492V with ≥ 1 x	Identical

Feature	Submission Device: (K241959) 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K193154) 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V	Comparison
	10^6 *Geobacillus stearothermophilus* spores	10^6 *Geobacillus stearothermophilus* spores	
Biological Indicator Incubation temperature	60 ± 2°C	60 ± 2°C	Identical
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.	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 software versions less than 4.0.0. Optional visual pH color change result in 48 hours for 490 or 490H Auto-readers.	The 1492V BI contained in both the predicate and submission test packs are intended to be used in conjunction with the 3M™ Attest™ Auto-reader 490 or the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater to qualify or monitor dynamic-air removal steam sterilization cycles. The 1492V BI was cleared for use with the 3M™ Attest™ Mini Auto-reader 490M per K200092.
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.	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.	Identical

Feature	Submission Device: (K241959) 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K193154) 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V	Comparison
Biological Indicator Resistance Characteristics • D-value • Survival/Kill Window	D-value ≥ 10 seconds at 132°C D-value ≥ 8 seconds at 134°C D-value ≥ 8 seconds at 135°C 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	D-value ≥ 10 seconds at 132°C D-value ≥ 8 seconds at 135°C Survival Time = Calculated survival time* or 1 minute at 132°C and 40 seconds at 135°C, whichever is longer Kill Time = Calculated kill time* at 132°C and at 135°C	Both the submission and predicate test packs utilize the same BI (1492V). The BI is indicated for use in 270°F (132°C) and 275°F (135°C) dynamic-air-removal steam sterilization cycles (per K173437). 510(k) (K241710) is pending clearance to expand the Indications for Use for the 1492V BI to also include the 273°F (134°C) steam sterilization cycle. The Resistance Characteristics (D-Value, Survival/Kill Window) of the 1492V BI have been updated to include the monitoring of steam sterilization cycles at 273°F (134°C).
Biological Indicator Culture Conditions	Crushable glass ampoule containing a growth media and a fluorescence indicator which is correlated to an optional use pH indicator.	Crushable glass ampoule containing a growth media and a fluorescence indicator which is correlated to an optional use pH indicator.	Identical
Chemical Integrator	3M™ Attest™ Steam Chemical Integrator	3M™ Attest™ Steam Chemical Integrator	Identical
Chemical Integrator Endpoint Specifications (Minimum Stated Values)	250°F/121°C: 16.5 minutes 270°F/132°C: 2.0 minutes 273°F/134°C: 1.4 minutes 275°F/135°C: 1.2 minutes	250°F/121°C: 16.5 minutes 270°F/132°C: 2.0 minutes 273°F/134°C: 1.4 minutes 275°F/135°C: 1.2 minutes	Identical
Chemical Integrator Color Change	Dark color migrates along strip visible through a green window (ACCEPT) or red window (REJECT)	Dark color migrates along strip visible through a green window (ACCEPT) or red window (REJECT)	Identical

Feature	Submission Device: (K241959) 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K193154) 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V	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.	External Chemical Process Indicator turns from yellow to brown or darker upon steam exposure.	Both the submission and predicate device contain a process indicator that changes color upon steam exposure that is used by the customer to verify that the challenge pack was exposed to steam.
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
Shelf Life	21 months	21 months	Identical
Accessories (Auto-readers)	3M™ Attest™ Auto-reader 490 or the 3M™ Attest™ Auto-reader 490H or the 3M™ Attest™ Mini Auto-reader	3M™ Attest™ Auto-reader 490 or the 3M™ Attest™ Auto-reader 490H	The 1492V BI contained in both the predicate and submission test packs are intended to be used in conjunction with the 3M™ Attest™ Auto-reader 490 or the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater to qualify or monitor dynamic-air-removal steam sterilization cycles. The 1492V BI was cleared for use with the 3M™ Attest™ Mini Auto-reader 490M per K200092.

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 Clear Challenge Pack 1492PCD.

Three lots of 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD, 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 Clear Challenge Pack 1492PCD, 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 Clear Challenge Pack 1492PCD 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*.

Three lots of 3M™ Attest™ Super Rapid Steam Clear Challenge Pack 1492PCD were tested for peel force of the heat seal foil lid from the plastic shell, pre and post sterilization. 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 1492PCD challenge pack was verified through the following tests:

Test Performed	Device Description	Applicable Standards	Purpose	Acceptance Criteria	Results
Resistance of 1492PCD Challenge Pack compared to AAMI 16 Towel PCD in claimed cycles	1492PCD 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 1492PCD Challenge Pack is equivalent to the performance of the AAMI 16 Towel PCD in the claimed cycles	Indicators contained in the 1492PCD Challenge Pack must demonstrate equivalent resistance as compared to the indicators contained in the	Acceptance criteria met

Test Performed	Device Description	Applicable Standards	Purpose	Acceptance Criteria	Results
				AAMI 16 Towel PCD in the claimed cycles	
Resistance of 1492PCD Challenge Pack compared to standalone indicators in claimed cycles	1492PCD Challenge Pack	FDA Guidance[1]	Demonstrate the 1492PCD Challenge Pack provides a greater challenge than the standalone indicators in the claimed cycles	Indicators contained in the 1492PCD Challenge Pack must demonstrate greater resistance compared to the standalone indicators in the claimed cycles	Acceptance criteria met
1492PCD Peel Force	1492PCD 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 1492PCD heat seal foil lid from plastic shell	≥4.25lbF and ≤16lbF	Acceptance criteria met
1492PCD Peel Force	1492PCD 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 1492PCD heat seal foil lid from plastic shell, pre and post sterilization	≥4.25lbF and ≤16lbF	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 Clear Challenge Pack 1492PCD, the 3M™ Attest™ Auto-reader 490, the 3M™ Attest™ Auto-reader 490H, and the 3M™ Attest™ Mini Auto-reader 490M, are as safe and as effective as the legally marketed predicate device, the 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V for use with the 3M™ Attest™ Auto-reader 490, and the 3M™ Attest™ Auto-reader 490H (cleared per K193154), and the 3M™ Attest™ Mini Auto-reader 490M (cleared per K200092) Class II (21 CFR 880.2800), product code FRC.