March 15, 2024

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

Re: K233814
Trade/Device Name: 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack (1295PCD); 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: February 14, 2024
Received: February 14, 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.

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: 2024.03.15 11:42:02 -04'00'

for Christopher Dugard
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices

OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233814

Device Name

3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack (1295PCD);
3M™ Attest™ Auto-reader (490);
3M™ Attest™ Auto-reader (490H);
3M™ Attest™ Mini Auto-reader (490M)

Indications for Use *(Describe)*

3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack (1295PCD):
Use the 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater or a 3M™ Attest™ Mini Auto-reader 490M or a 3M™ Attest™ Auto-reader 490H as a standard method of routine monitoring and performance qualification of vaporized hydrogen peroxide sterilization processes in the follow systems:
STERRAD 100S® Sterilization System,
STERRAD NX® Sterilization System (Standard and Advanced cycles),
STERRAD 100NX® Sterilization System (Standard, Flex, Express, and Duo cycles),
STERRAD NX® with ALLClear® Technology Sterilization System (Standard and Advanced cycles),
STERRAD 100NX® with ALLClear® Technology Sterilization System (Standard, Flex, Express, and Duo cycles),
V-PRO® 1 Low Temperature Sterilization System (Lumen cycle),
V-PRO® 1 Plus Low Temperature Sterilization System (Lumen and Non Lumen cycles),
V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles),
V-PRO® 60 Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles),
V-PRO® maX 2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast Non Lumen cycles),
V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles)

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.

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510(k) Summary
for
3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD, 3M™ Attest™ Auto-reader 490, 3M™ Attest™ Auto-reader 490H, 3M™ Attest™ Mini Auto-reader 490M
K233814

Sponsor Information:

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

Contact: Michelle M. Larsen
Advanced Regulatory Affairs Specialist
Phone Number: (651) 467-3991
Fax Number: (651) 737-5320
Email: mmlarsen@solventum.com

Date of Summary: 13, March 2024

1. **Device Name and Classification:**

   Common or Usual Name: Sterilization Biological Indicator

Proprietary Name:	3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD, 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:

Sterilucent Self-Contained Biological Indicator, Sterilucent Lumen Cycle Process Challenge Device, Sterilucent Flexible Cycle Process Challenge Device, K192001

3. Description of Device:

The 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD is designed as a standard method of rapid and reliable routine monitoring and performance qualification of vaporized hydrogen peroxide sterilization processes.

The 1295PCD Challenge Pack consists of a clear plastic shell, with two individual channels allowing for air removal and sterilant penetration. Those two individual channels connect to a cavity containing the monitoring products and all are covered by a foil lid. The 1295PCD is a single-use device.

Each 1295PCD Challenge Pack contains a 3M™ Attest™ Rapid Readout Biological Indicator (BI) 1295 (pink cap) and a 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator (CI) 1348. The 1348 CI verifies that the stated values for the three critical parameters of exposure time, temperature, and concentration of vaporized hydrogen peroxide have been achieved and offers an ACCEPT or REJECT reading. The 1295 BI is specifically designed for rapid and reliable routine monitoring of vaporized hydrogen peroxide sterilization processes when used in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater or a 3M™ Attest™ Mini Auto-reader 490M or a 3M™ Attest™ Auto-reader 490H. The presence of fluorescence within the specified incubation time for the 1295 BI in the 490, 490M, or the 490H Auto-reader indicates a sterilization process failure. A printed chemical process indicator is present on the cap of the 1295 BI and is visible through the clear plastic shell of the challenge pack. The

process indicator turns color upon exposure to vaporized hydrogen peroxide and is used by the customer to verify that the challenge pack was exposed to vaporized hydrogen peroxide.

4. Indications for Use

3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack (1295PCD):
Use the 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater or a 3M™ Attest™ Mini Auto-reader 490M or a 3M™ Attest™ Auto-reader 490H as a standard method of routine monitoring and performance qualification of vaporized hydrogen peroxide sterilization processes in the follow systems:

STERRAD 100S® Sterilization System
STERRAD NX® Sterilization System (Standard and Advanced cycles)
STERRAD 100NX® Sterilization System (Standard, Flex, Express, and Duo cycles)
STERRAD NX® with ALLClear® Technology Sterilization System (Standard and Advanced cycles)
STERRAD 100NX® with ALLClear® Technology Sterilization System (Standard, Flex, Express, and Duo cycles)
V-PRO® 1 Low Temperature Sterilization System (Lumen cycle)
V-PRO® 1 Plus Low Temperature Sterilization System (Lumen and Non Lumen cycles)
V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles)
V-PRO® 60 Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles)
V-PRO® maX 2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast Non Lumen cycles)
V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles)

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.

5. Comparison of Subject Device to Predicate Device

Indications for Use

The 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD and the predicate device Sterilucent Process Challenge Device (PCD) test pack have the same intended use. Both the subject 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. The Indications for Use are similar in that both the predicate and subject challenge test packs are specifically designed as a method of routine monitoring and performance qualification of vaporized hydrogen peroxide sterilization processes. The subject device covers different sterilizers and cycles compared to the predicate device. The differences in Indications for Use do not alter the fundamental Intended Use of these products as sterilization process monitors and do not raise new questions of safety and effectiveness.

Technological Characteristics

The 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD has similar technological characteristics compared to the predicate Sterilucent Process Challenge Device (PCD) test pack. The subject device is designed and constructed with a clear plastic tray with channels to the cavity containing the Biological Indicator and Chemical Indicator sealed with a foil lid whereas the predicate device consists of a clear polymer vial containing the Biological Indicator and a challenge tube on one end. Both the subject 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 based on worse case cycle with load. The process indicator on the predicate challenge pack is present on the PCD whereas the process indicator on the subject device is present on the 1295 BI cap which is visible through the clear test pack. Both process indicators change color upon exposure to vaporized hydrogen peroxide (VH_2O_2) and is used by the customer to verify the challenge pack was exposed to VH_2O_2.

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

Table 1: Device Comparison Table

Feature	Submission Device: 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device (K192001): Sterilucent Self-Contained Biological Indicator, Sterilucent Lumen Cycle Process Challenge Device, Sterilucent Flexible Cycle Process Challenge Device	Comparison
Intended Use	Single Use sterilization process indicator	Single Use sterilization process indicator	Identical
Indications for use	Use the 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater or a 3M™ Attest™ Mini Auto-reader 490M or a 3M™ Attest™ Auto-reader 490H as a standard method of routine monitoring and performance qualification of vaporized hydrogen peroxide sterilization processes in the follow systems: STERRAD 100S® Sterilization System, STERRAD NX® Sterilization System (Standard and Advanced cycles), STERRAD 100NX® Sterilization System (Standard, Flex, Express, and Duo cycles), STERRAD NX® with ALLClear® Technology Sterilization	The Sterilucent Process Challenge Device (PCD) test pack is used for routine monitoring of the Sterilucent HC 80TT Sterilizer Lumen and Flexible Cycles. The Sterilucent PCD may also be used for performance qualification of the Sterilucent HC 80TT sterilizer Lumen and Flexible Cycles during initial installation, after relocation, major repairs or mal functions, or after sterilization process failures. Both the Sterilucent Lumen Cycle PCD and the Sterilucent Flexible Cycle PCD are intended to have greater resistance than the stand alone SCBI. Both devices are designed to have increased resistance beyond the sterilization half-cycle, but complete inactivation upon	The Indications for Use are similar in that the subject device and the predicate device are used for routine monitoring and performance qualification of vaporized hydrogen peroxide sterilization processes. The subject device covers different sterilizers and cycles compared to the predicate device. The Indications for Use for the subject device are identical to the 3M 1295 BI (K210277) and 3M Tri-Metric CI 1348 (K203284) in terms of sterilizers and cycles covered. The subject challenge pack contains the 3M 1295 BI which is

Feature	Submission Device: 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device (K192001): Sterilucent Self-Contained Biological Indicator, Sterilucent Lumen Cycle Process Challenge Device, Sterilucent Flexible Cycle Process Challenge Device	Comparison
	System (Standard and Advanced cycles), STERRAD 100NX® with ALLClear® Technology Sterilization System (Standard, Flex, Express, and Duo cycles), V-PRO® 1 Low Temperature Sterilization System (Lumen cycle), V-PRO® 1 Plus Low Temperature Sterilization System (Lumen and Non Lumen cycles), V-PRO® maX Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles), V-PRO® 60 Low Temperature Sterilization System (Lumen, Non Lumen, and Flexible cycles), V-PRO® maX 2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast Non Lumen cycles), V-PRO® s2 Low Temperature Sterilization System (Lumen, Non Lumen, Flexible, and Fast cycles)	exposure to the full cycle.	intended to be used in conjunction with the 3M™ Attest™ Auto-reader 490 or the 3M™ Attest™ Auto-reader 490H or the 3M™ Attest™ Mini Auto-reader 490M cleared under K210277.
Biological Indicator (BI)	3M™ Attest™ Rapid Readout Biological Indicator 1295 with ≥ 1 x 10^6 *Geobacillus*	Sterilucent HC 80TT SCBI, quartz fiber carrier inoculated with >10^6 *Geobacillus*	Both the subject device and the predicate device utilize Biological

Feature	Submission Device: 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device (K192001): Sterilucent Self-Contained Biological Indicator, Sterilucent Lumen Cycle Process Challenge Device, Sterilucent Flexible Cycle Process Challenge Device	Comparison
	stearothermophilus spores	*stearothermophilus* spores per disc	Indicators with $>10^6$ *Geobacillus stearothermophilus* spores.
BI - Mechanism of Action	The 1295 BI utilizes an enzyme system, which is generated naturally within growing cells of *Geobacillus stearothermophilus.* The enzyme in its active state is detected by measuring the fluorescence produced by the enzymatic reaction with a non-fluorescent substrate. The resultant fluorescent by product is detected in an Auto-reader. The presence of fluorescence within the specified incubation time in the Auto-reader indicates a sterilization process failure. The 1295 BI can also indicate the presence of *G. stearothermophilus* organisms by a visual pH color change reaction.	The Sterilucent HC 80TT SCBI indicates the presence of *G. stearothermophilus* organisms by a visual pH color change reaction.	Similar, the 1295 BI utilizes a fluorescence result and also a visual pH color change reaction.

Feature	Submission Device: 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device (K192001): Sterilucent Self-Contained Biological Indicator, Sterilucent Lumen Cycle Process Challenge Device, Sterilucent Flexible Cycle Process Challenge Device	Comparison
BI – Resistance Characteristics • D-value	(Tested at 10 mg/L vaporized hydrogen peroxide) ≥ 1 sec.	5.7 – 9.1 sec.	Similar, both BIs are characterized with a D-value.
BI – Resistance Characteristics • Survival/Kill Window	(Tested at 10 mg/L vaporized hydrogen peroxide) Survival Time ≥ 5 sec. Kill Time = 7 min.	25.0 sec. (All survive) 140 sec. (All kill)	Similar, both BIs are characterized with Survival and Kill testing.
BI – 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 modified Tryptic Soy Broth with a pH indicator	Similar
Chemical Indicator (CI)	3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348	NA	The Chemical Indicator in the subject challenge pack is able to independently monitor three critical parameters: exposure time, temperature, and concentration of vaporized hydrogen peroxide. The predicate device does not contain a separate chemical indicator.
CI – Endpoint Specifications (Minimum Stated Values)	VH2O2 Concentration – 5.1 mg/L Exposure Time – 1 minute Temperature – 50°C		
CI – Color change	Blue toward pink along the reactive chemistry strip		
General Design/Construction	Clear plastic tray with channels to the cavity	Clear polymer vial with polymer caps and	Both the subject and predicate challenge

Feature	Submission Device: 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device (K192001): Sterilucent Self-Contained Biological Indicator, Sterilucent Lumen Cycle Process Challenge Device, Sterilucent Flexible Cycle Process Challenge Device	Comparison
	containing the indicators, acting as a challenge to limit air removal and VH_2O_2 penetration, sealed with a foil lid.	challenge tube on one end. Tube of various inner diameter and lengths tailored to individual sterilization cycle.	packs are designed to increase resistance beyond that measured with a standalone BI and both represent a challenge to the sterilization process based on worse case cycle with load.
Mechanism to distinguish processed and unprocessed challenge pack	Process indicator present on 1295 BI cap is visible through PCD and turns color from blue towards pink upon vaporized hydrogen peroxide exposure.	SPSmedical VH_2O_2 Chemical Indicator placed on the outside of the vial.	Both the subject and predicate device contain a process indicator that changes color upon vaporized hydrogen peroxide exposure that is used by the customer to verify that the challenge pack was exposed to VH_2O_2.
Shelf Life	6 months	12 months from date of manufacture	Shelf life will be extended as real time data is available.

Feature	Submission Device: 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device (K192001): Sterilucent Self-Contained Biological Indicator, Sterilucent Lumen Cycle Process Challenge Device, Sterilucent Flexible Cycle Process Challenge Device	Comparison
Accessories	3M™ Attest™ Auto-reader 490 or the 3M™ Attest™ Auto-reader 490H or the 3M™ Attest™ Mini Auto-reader	NA	The subject challenge pack contains the 3M 1295 BI which is intended to be used in conjunction with the 3M™ Attest™ Auto-reader 490 or the 3M™ Attest™ Auto-reader 490H or the 3M™ Attest™ Mini Auto-reader 490M cleared under K210277.

6. Nonclinical Comparison to the Predicate Device

The differences between the subject and predicate device have been evaluated through performance tests for the 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD.

Three lots of 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD, containing three lots of 1295 BIs and three lots of 1348 CIs, were tested side by side with standalone indicators 1295 BIs and 1348CIs. Testing was completed per the *Guidance for Industry and FDA Staff, Biological Indicator Premarket Notification [510(k)] Submissions,* October 4, 2007, and ANSI/AAMI/ISO 11138-1:2017 *Sterilization of Health Care Products—Biological Indicators—Part 1: General Requirements*.

Four lots of 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD were subjected to simulated use testing in healthcare sterilizers. Testing was completed per the *Guidance for Industry and FDA Staff, Biological Indicator Premarket Notification [510(k)] Submissions,* October 4, 2007.

Three lots of 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD 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*.

The device performance was verified through the following tests:

Item Tested	Test	Standard	Purpose	Acceptance Criteria	Results
1295PCD Challenge Packs and Standalone chemical and biological indicators	PCD Resistance Characterization	FDA Guidance[1] and, ANSI/AAMI/ISO 11138-1:2017 *Sterilization of Health Care Products—Biological Indicators—Part 1: General Requirements*	Demonstrate indicators within the 3M™ Attest Vaporized Hydrogen Peroxide Clear Test Pack 1295PCD have greater resistance compared to standalone indictors in a fractional exposure cycle.	Indicators perform as intended	Passed

Item Tested	Test	Standard	Purpose	Acceptance Criteria	Results
1295PCD Challenge Packs	PCD Functionality	FDA Guidance[1] and, ANSI/AAMI/ISO 11138-1:2017 *Sterilization of Health Care Products—Biological Indicators—Part 1: General Requirements*	Demonstrate performance of the 3M™ Attest Vaporized Hydrogen Peroxide Clear Test Pack 1295PCD in a pass cycle.	Indicators perform as intended	Passed
1295PCD Challenge Packs	PCD Functionality	FDA Guidance[1] and, ANSI/AAMI/ISO 11138-1:2017 *Sterilization of Health Care Products—Biological Indicators—Part 1: General Requirements*	Demonstrate performance of the 3M™ Attest Vaporized Hydrogen Peroxide Clear Test Pack 1295PCD in a fail cycle.	Indicators perform as intended	Passed
1295PCD Challenge Pack	PCD Peel Force	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 1295PCD heat seal foil lid from plastic shell	≥8.5lbF and ≤20lbF lbF = pounds force	Passed

Item Tested	Test	Standard	Purpose	Acceptance Criteria	Results
1295PCD Challenge Pack	Cycle Performance	FDA Guidance[1]	Demonstrate performance of the 3M™ Attest Vaporized Hydrogen Peroxide Clear Test Pack 1295PCD in the claimed sterilizers and cycles in the Indications for Use.	Indicators perform as intended	Passed

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 subject devices, the 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD, 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 Sterilucent Process Challenge Device (PCD) test pack (cleared under K192001), Class II (21 CFR 880.2800), product code FRC.