November 25, 2024

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

Re: K242538
Trade/Device Name: 3M™ Attest™ Super Rapid Readout Biological Indicator 1493; 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG; 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: August 26, 2024
Received: August 26, 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: 2024.11.25 11:20:05 -05'00'

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)*

K242538

Device Name

3M™ Attest™ Super Rapid Readout Biological Indicator 1493;
3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG;
3M™ Attest™ Auto-reader 490;
3M™ Attest™ Auto-reader 490H;
3M™ Attest™ Mini Auto-reader 490M

Indications for Use *(Describe)*

3M™ Attest™ Super Rapid Readout Biological Indicator 1493:
Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1493 in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater, or the 3M™ Attest™ Mini Auto-reader 490M to qualify or monitor the following steam sterilization cycles:

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

3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG:
Use the 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater, or the 3M™ Attest™ Mini Auto-reader 490M to qualify or monitor the following steam sterilization cycles:

Cycle Type	Exposure Temperature	Exposure Time
Gravity Displacement	250°F (121°C)	30 minutes

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, 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™ 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 Readout Biological Indicator 1493, 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG, 3M™ Attest™ Auto-reader 490, 3M™ Attest™ Auto-reader 490H, 3M™ Attest™ Mini Auto-reader 490M
K242538

Sponsor Information:

3M Company
3M Center
2510 Conway Ave., Bldg. 275-5W-06
St. Paul, MN 55144-1000, USA

Contact: Michelle M. Larsen, Principal RA Specialist
Phone Number: (651) 467-3991
Fax Number: (651) 737-5320
Email: mmlarsen@solventum.com

Date of Summary: 19 November 2024

1. Device Name and Classification:

Common or Usual Name:	Biological Indicator (BI)
Proprietary Name:	3M™ Attest™ Super Rapid Readout Biological Indicator 1493, 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG, 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 Steam Biological Indicator 1592, 3M™ Attest™ Super Rapid Steam Challenge Pack 51582, 3M™ Attest™ Auto-reader 490, 3M™ Attest™ Auto-reader 490H, and 3M™ Attest™ Mini- Auto-reader 490M, K213809

3. Description of Device:

The 3M™ Attest™ Super Rapid Readout Biological Indicator (BI) 1493 is a self-contained biological indicator specifically designed for rapid and reliable qualification testing and routine monitoring of 121°C (250°F) dynamic-air-removal and gravity-displacement steam sterilization processes in healthcare facilities. The 1493 BI is used in conjunction with a 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, or a 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater, or a 3M™ Attest™ Mini Auto-reader 490M.

The 1493 BI is a single-use device composed of a plastic vial containing a spore carrier and media ampoule, enclosed with a color-coded cap. On each 1493 BI cap is a chemical process indicator that changes color from pink to light brown or darker when exposed to steam. The presence of fluorescence within the specified incubation time of the 1493 BI in the 490 Auto-reader, the 490H Auto-reader, or the 490M Mini Auto-reader indicates a steam sterilization process failure.

The 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG is specifically designed to qualify and monitor gravity steam sterilization processes at 250°F (121°C) in healthcare facilities.

The 1493PCDG Challenge Pack consists of a clear plastic shell with an opening to the cavity containing the monitoring products, all covered by a foil lid. The 1493PCDG is a single-use device. Each 1493PCDG Challenge Pack contains a 3M™ Attest™ Super Rapid Readout Biological Indicator (BI) 1493 and a 3M™ Attest™ Steam Chemical Integrator (CI) (Type 5 (Category i5) Integrating Indicator as categorized by ISO 11140-1:2014). The 3M™ Attest™ Steam Chemical Integrator offers an immediate ACCEPT or REJECT reading. A chemical process indicator is present on the cap of the 1493 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. 3M™ Attest™ 1493 BI controls are provided with the Challenge Pack.

The 1493 BI is specifically designed for rapid and reliable qualification testing and routine monitoring of steam sterilization process when used in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, a 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater, or a 3M™ Attest™ Mini Auto-reader 490M. The presence of fluorescence within the specified incubation time of the 1493 BI in the 490, 490H or 490M Auto-reader indicates a steam sterilization process failure.

4. Indications for Use

3M™ Attest™ Super Rapid Readout Biological Indicator 1493:
Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1493 in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater, or the 3M™ Attest™ Mini Auto-reader 490M to qualify or monitor the following steam sterilization cycles:

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

3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG:
Use the 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or

greater, the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater, or the 3M™ Attest™ Mini Auto-reader 490M to qualify or monitor the following steam sterilization cycles:

Cycle Type	Exposure Temperature	Exposure Time
Gravity Displacement	250°F (121°C)	30 minutes

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, 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™ 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 Readout Biological Indicator (BI) 1493, has the same intended use as the predicate device, the 3M™ Attest™ Super Rapid Steam Biological Indicator 1592. Both the submission device and the predicate device are Single Use biological sterilization indicators 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 BIs are intended to be used in conjunction with a 3M™ Attest™ Auto-reader 490, a 3M™ Attest™ Auto-reader 490H, or a 3M™ Attest™ Mini Auto-reader 490M to qualify or monitor gravity displacement and dynamic-air-removal (pre-vacuum and steam-flush pressure-pulse (SFPP)) steam sterilization cycles at 250°F (121°C). The predicate BI covers additional dynamic-air-removal steam sterilization cycles (270°F/132°C, 273°F/134°C and 275°F/135°C) compared to the submission BI. 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.

The submission device, the 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG, has the same intended use as the predicate device, the 3M™ Attest™ Super Rapid Steam Challenge Pack 51582. 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 challenge packs are intended to be used in conjunction with a 3M™ Attest™ Auto-reader 490, a 3M™ Attest™ Auto-reader 490H, or a 3M™ Attest™ Mini Auto-reader 490M to qualify or monitor gravity displacement steam sterilization cycles at 250°F (121°C). The predicate challenge pack also covers dynamic-air-removal (pre-vacuum and steam-flush pressure-pulse (SFPP)) steam sterilization cycles (250°F/121°C, 270°F/132°C, 273°F/134°C and 275°F/135°C) compared to the submission challenge pack. 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

Biological Indicator

The submission device, 3M™ Attest™ Super Rapid Readout Biological Indicator 1493, is the same design, materials, and construction as the previously cleared predicate device, 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 (cleared per K213809). The only difference is the 1493 BI is claiming use with fewer cycles compared to the 1592 BI. Both the submission device and the predicate device utilize the same spores to accomplish their intended use as biological sterilization indicators. The submission and predicate device are intended to qualify or monitor gravity displacement and dynamic-air-removal (pre-vacuum and steam-flush pressure-pulse (SFPP)) steam sterilization cycles at 250°F (121°C) while the predicate device covers additional dynamic-air-removal steam sterilization cycles at 270°F (132°C), 273°F (134°C) and 275°F (135°C). The Resistance Characteristics (D-Value, Survival/Kill Window) of the submission device and the predicate device both cover the monitoring of steam sterilization cycles at 250°F (121°C). The predicate device was cleared per K213809 for use with the 3M™ Attest™ Auto-reader 490, the 3M™ Attest™ Auto-reader 490H, and the 3M™ Attest™ Mini-Auto-reader 490M. 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 biological indicators are illustrated in the Device Technological Characteristics Comparison Table – Biological Indicator (**Table 1**).

Table 1: Device Technological Characteristics Comparison Table - Biological Indicator

Feature	Submission Device: (K242538) 3M™ Attest™ Super Rapid Readout Biological Indicator 1493, 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K213809) 3M™ Attest™ Super Rapid Steam Biological Indicator 1592, 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Comparison
Intended Use	Single Use sterilization process indicator	Single Use sterilization process indicator	Identical
Indications for use	Use the 3M™ Attest™ Super Rapid Readout Biological Indicator 1493 in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater, or the 3M™ Attest™ Mini Auto-reader 490M to qualify or monitor the following steam sterilization cycles: • Gravity Displacement, 250°F (121°C), 30 minutes • Dynamic-air-removal	Use the 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, 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: • Gravity Displacement, 250°F (121°C), 30 minutes • Dynamic-air-removal	Both the predicate and submission BIs are indicated for qualifying and monitoring gravity displacement and dynamic-air-removal steam sterilization cycles at 250°F (121°C). The predicate BI is indicated for qualifying and monitoring additional dynamic-air-removal steam sterilization cycles (270°F/132°C, 273°F/134°C and 275°F/135°C).

Feature	Submission Device: (K242538) 3M™ Attest™ Super Rapid Readout Biological Indicator 1493, 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K213809) 3M™ Attest™ Super Rapid Steam Biological Indicator 1592, 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Comparison
	(pre-vacuum and SFPP), 250°F (121°C), 15, 20, 30, or 35 minutes	(pre-vacuum and SFPP), 250°F (121°C), 15, 20, 30, or 35 minutes • Dynamic-air-removal (pre-vacuum and SFPP), 270°F (132°C), 3, 3.5, 4, 5.5, or 6 minutes • Dynamic-air-removal (pre-vacuum and SFPP), 273°F (134°C), 3 or 4 minutes • Dynamic-air-removal (pre-vacuum and SFPP), 275°F (135°C), 3, 3.5, or 10 minutes	Both the predicate and submission BIs are intended to be used in conjunction with the same auto-readers.
General Design/Construction	Plastic vial containing a spore carrier and media ampoule, enclosed with a color-coded cap with chemical process	Plastic vial containing a spore carrier and media ampoule, enclosed with a color-coded cap with chemical process	Identical

Feature	Submission Device: (K242538) 3M™ Attest™ Super Rapid Readout Biological Indicator 1493, 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K213809) 3M™ Attest™ Super Rapid Steam Biological Indicator 1592, 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Comparison
	indicator located on top of cap.	indicator located on top of cap.	
Carrier Material	Plastic	Plastic	Identical
Media Ampoule	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 indicator	Turns from pink to light brown or darker upon steam exposure	Turns from pink to light brown or darker upon steam exposure	Identical
Indicator Organism	*Geobacillus stearothermophilus* traceable to ATCC™ 7953	*Geobacillus stearothermophilus* traceable to ATCC™ 7953	Identical
Viable spore population	$\geq 1 \times 10^6$	$\geq 1 \times 10^6$	Identical
Mechanism of Action	When the enzyme that is naturally occurring in the spore is in its active state, it is detected by measuring the fluorescence produced by the enzymatic hydrolysis of a non-fluorescent substrate. The resultant fluorescent by-product is detected by the Auto-reader. The presence of	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	Identical

Feature	Submission Device: (K242538) 3M™ Attest™ Super Rapid Readout Biological Indicator 1493, 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K213809) 3M™ Attest™ Super Rapid Steam Biological Indicator 1592, 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Comparison
	fluorescence upon incubation in the Auto-reader indicates a sterilization process failure.	fluorescence upon incubation in the Auto-reader indicates a sterilization process failure.	
• D-value	D-Value ≥ 1.5 min at 121°C	D-Value ≥ 1.5 min at 121°C D-value ≥ 10 seconds at 132°C D-value ≥ 8 seconds at 134°C, 135°C	Both the predicate and submission BIs are indicated for qualifying and monitoring gravity displacement and dynamic-air-removal steam sterilization cycles at 250°F (121°C). The predicate BI is indicated for qualifying and monitoring additional dynamic-air-removal steam sterilization cycles (270°F/132°C, 273°F/134°C and 275°F/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: (K242538) 3M™ Attest™ Super Rapid Readout Biological Indicator 1493, 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K213809) 3M™ Attest™ Super Rapid Steam Biological Indicator 1592, 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Comparison
Incubation temperature	60 ± 2°C	60 ± 2°C	Identical
Readout time	24 minute final fluorescent result in: • The 490 Auto-reader having software version 4.0.0 or greater **or** • The 490H Auto-reader having software version 4.0.0 or greater **or** • The 490M Mini Auto-reader Optional visual pH color change result in 7 days.	24 minute final fluorescent result in: • The 490 Auto-reader having software version 4.0.0 or greater **or** • The 490H Auto-reader having software version 4.0.0 or greater **or** • The 490M Mini Auto-reader Optional visual pH color change result in 7 days.	Identical
Shelf Life	24 months	24 months	Identical
Accessories (Auto-readers)	3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, 3M™ Attest™ Auto-reader, or 490H having software version 4.0.0 or greater, or 3M™ Attest™ Mini Auto-reader 490M	3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, 3M™ Attest™ Auto-reader, or 490H having software version 4.0.0 or greater, or 3M™ Attest™ Mini Auto-reader 490M	Identical

Challenge Pack

The submission device, the 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG, consists of a clear plastic shell with a cavity opening in the shell to the monitoring products, all heat sealed with a foil lid. The predicate device, the 3M™ Attest™ Super Rapid Steam Challenge Pack 51582, 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 device 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. The predicate device utilizes the 3M™ Attest™ Super Rapid Steam Biological Indicator 1592 that was cleared per K213809. The submission device utilizes the 3M™ Attest Super Rapid Readout Biological Indicator 1493 which is the subject biological indicator of this submission. The submission BI (1493) is the same design, materials, and construction as the previously cleared predicate BI (1592). The only difference is the 1493 BI is claiming use with fewer cycles compared to the 1592 BI. Both the submission and predicate device utilize the same Chemical Integrator (CI), the 3M™ Attest™ Steam Chemical Integrator (cleared per K220942). The process indicator dot on the predicate device is present on the outer label of the overwrapped device whereas the process indicator on the submission device is present on the cap of the 1493 BI which is visible through the clear challenge pack. Both the submission and predicate device 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 packs are illustrated in the Device Technological Characteristics Comparison Table – Challenge Pack (**Table 2**).

Table 2: Device Technological Characteristics Comparison Table – Challenge Pack

Feature	Submission Device: (242538) 3M™ Attest™ Super Rapid Readout Biological Indicator 1493, 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K213809) 3M™ Attest™ Super Rapid Steam Biological Indicator 1592, 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	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 Gravity Clear Challenge Pack 1493PCDG in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater, or the 3M™ Attest™ Mini Auto-reader 490M to qualify or monitor the following steam sterilization cycles: • Gravity Displacement, 250°F (121°C), 30 minutes	Use the 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, the 3M™ Attest™ Auto-reader 490H having software version 4.0.0 or greater, or the 3M™ Attest™ Mini Auto-reader 490M to qualify or monitor the following steam sterilization cycles: • Gravity Displacement, 250°F (121°C), 30 minutes • Dynamic-air-removal (pre-vacuum and SFPP), 250°F (121°C), 30 minutes	Both the submission and predicate challenge packs are indicated for qualifying and monitoring gravity displacement steam sterilization cycles at 250°F (121°C). The predicate challenge pack is also indicated for qualifying and monitoring dynamic-air-removal steam sterilization cycles (250°F/121°C, 270°F/132°C, 273°F/134°C, and 275°F/135°C). The submission BI (1493) that is contained in the submission PCD is

Feature	Submission Device: (242538) 3M™ Attest™ Super Rapid Readout Biological Indicator 1493, 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K213809) 3M™ Attest™ Super Rapid Steam Biological Indicator 1592, 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Comparison
		• 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	the same design, materials, and construction as the predicate BI (1592) that is contained in the predicate PCD (51582). Both the predicate and submission BIs are indicated for qualifying and monitoring gravity displacement and dynamic-air-removal steam sterilization cycles at 250°F (121°C). The predicate BI is indicated for qualifying and monitoring additional dynamic-air-removal steam sterilization cycles (270°F/132°C, 273°F/134°C and 275°F/135°C). Both the submission and predicate

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			challenge packs utilize the same Chemical Integrator (CI). The 1243R CI is indicated for use in 250°F (121°C) gravity and 250°F (121°C), 270°F (132°C), 273°F (134°C) and 275°F (135°C) dynamic-air-removal steam sterilization cycles (per K220942). Both the predicate and submission challenge packs are intended to be used in conjunction with the same auto-readers.
General Design/Construction	Clear plastic tray with a cavity opening in the shell to 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

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			challenge to the sterilization process equivalent to the AAMI reference PCD.
Biological Indicator	3M™ Attest™ Super Rapid Readout Biological Indicator 1493	3M™ Attest™ Super Rapid Steam Biological Indicator 1592	The predicate BI and the submission BI are the same design, materials, and construction.
Biological Indicator Incubation temperature	60 ± 2°C	60 ± 2°C	Identical
Biological Indicator Readout time	24 minute final fluorescent result in: • The 490 Auto-reader having software version 4.0.0 or greater **or** • The 490H Auto-reader having software version 4.0.0 or greater **or** • The 490M Mini Auto-reader	24 minute final fluorescent result in: • The 490 Auto-reader having software version 4.0.0 or greater **or** • The 490H Auto-reader having software version 4.0.0 or greater **or** • The 490M Mini Auto-reader	Identical
Chemical Integrator	3M™ Attest™ Steam Chemical Integrator	3M™ Attest™ Steam Chemical Integrator	Identical

Feature	Submission Device: (242538) 3M™ Attest™ Super Rapid Readout Biological Indicator 1493, 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K213809) 3M™ Attest™ Super Rapid Steam Biological Indicator 1592, 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Comparison
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
Mechanism to distinguish processed and unprocessed challenge pack	Process indicator present on 1493 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 challenge pack 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	24 months	24 months	Identical

Feature	Submission Device: (242538) 3M™ Attest™ Super Rapid Readout Biological Indicator 1493, 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Predicate Device: (K213809) 3M™ Attest™ Super Rapid Steam Biological Indicator 1592, 3M™ Attest™ Super Rapid Steam Challenge Pack 51582 and 3M™ Attest™ Auto-reader 490 and 490H and 3M™ Attest™ Mini Auto-reader 490M	Comparison
Accessories (Auto-readers)	3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, 3M™ Attest™ Auto-reader, or 490H having software version 4.0.0 or greater, or 3M™ Attest™ Mini Auto-reader 490M	3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater, 3M™ Attest™ Auto-reader, or 490H having software version 4.0.0 or greater, or 3M™ Attest™ Mini Auto-reader 490M	Identical

6. Nonclinical Comparison to the Predicate Device

Biological Indicator
The differences between the submission and predicate device have been evaluated through performance tests for the 3M™ Attest™ Super Rapid Readout Biological Indicator 1493.

Three lots of 3M™ Attest™ Super Rapid Readout Biological Indicators 1493 were tested for minimum spore Population. Testing was completed per the *Guidance for Industry and FDA Staff, Biological Indicator Premarket Notification [510(k)] Submissions*, October 4, 2007, and ISO 11138-1:2017 Sterilization of Health Care Products—Biological Indicators—Part 1: General Requirements.

Three lots of 3M™ Attest™ Super Rapid Readout Biological Indicators 1493 were tested for Positive Control, D-Value, Z-value, Survival, Kill, and Component Inhibition Studies. Testing was completed per the *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,

and ISO 11138-3:2017 *Sterilization of health care products – Biological indicators - Part 3: Biological indicators for moist heat sterilization processes.*

Two lots of 3M™ Attest™ Super Rapid Readout Biological Indicators 1493 was tested for a Holding Time Assessment. Testing was completed per the *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, and ISO 11138-3:2017 *Sterilization of health care products – Biological indicators - Part 3: Biological indicators for moist heat sterilization processes*.

Three lots of 3M™ Attest™ Super Rapid Readout Biological Indicators 1493 were tested for Reduced Incubation Time. Testing was completed per the *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, and ISO 11138-8:2021 *Sterilization of health care products – Biological indicators - Part 8: Method for validation of a reduced incubation time for a biological indicator.*

Three lots of 3M™ Attest™ Super Rapid Readout Biological Indicators 1493 were evaluated for simulated use testing in the claimed cycles. Testing was completed per the *Guidance for Industry and FDA Staff, Biological Indicator Premarket Notification [510(k)] Submissions*, October 4, 2007.

One lot of 3M™ Attest™ Super Rapid Readout Biological Indicators 1493 were evaluated for performance in the 3M™ Attest™ Auto-reader 490 and 3M™ Attest™ Mini Auto-reader 490M. Testing was completed per the *Guidance for Industry and FDA Staff, Biological Indicator Premarket Notification [510(k)] Submissions*, October 4, 2007, and ISO 11138-1:2017 Sterilization of Health Care Products—Biological Indicators—Part 1: General Requirements.

Performance of the 1493 Biological Indicator (BI) was verified through the following tests:

Test Performed	Device Description	Applicable Standards	Purpose	Acceptance Criteria	Results
Population	1493 BI	FDA Guidance[1], ISO 11138-1:2017[2]	To evaluate the total viable spore count	$\geq 10^6$ spores	Acceptance criteria met
Positive Control Test	1493 BI	FDA Guidance[1], ISO 11138-1:2017[2] and ISO 11138-3:2017[3]	To evaluate performance of BI without steam exposure	All BIs must be fluorescent positive at 24 minutes and visual pH color change positive (yellow) at 168 hours	Acceptance criteria met

Test Performed	Device Description	Applicable Standards	Purpose	Acceptance Criteria	Results
D-value for 121°C (250°F) cycles	1493 BI	FDA Guidance[1], ISO 11138-1:2017[2] and ISO 11138-3:2017[3]	To evaluate the resistance characteristics of the BI	D-value must be ≥ 1.5 minutes	Acceptance criteria met
Z-value for 121°C (250°F) cycles	1493 BI	FDA Guidance[1], ISO 11138-1:2017[2] and ISO 11138-3:2017[3]		Z-value must be ≥ 10°C	Acceptance criteria met
Survival for 121C° (250°F) cycles	1493 BI	FDA Guidance[1], ISO 11138-1:2017[2] and ISO 11138-3:2017[3]		Meets the requirements for Calculated survival time* or 5 minutes, whichever is longer * ISO 11138-1:2017	Acceptance criteria met
Kill for 121C° (250°F) cycles	1493 BI	FDA Guidance[1], ISO 11138-1:2017[2] and ISO 11138-3:2017[3]		Meets the requirements for Calculated kill time* * ISO 11138-1:2017	Acceptance criteria met
Component Inhibition Studies	1493 BI	FDA Guidance[1], ISO 11138-1:2017[2] and ISO 11138-3:2017[3]	To evaluate the effects of carrier and packaging materials on the resistance characteristics of the BI	Components have no impact on the recovery of 10-100 organisms	Acceptance criteria met
Holding Time Assessment for 121°C (250°F) cycles	1493 BI	FDA Guidance[1], ISO 11138-1:2017[2] and ISO 11138-3:2017[3]	To evaluate the effect of the labeled holding time on the D-value	D-value must be within +/- 20% of the initial D-value calculated per ISO 11138-1:2017	Acceptance criteria met
Reduced Incubation Time for 121°C (250°F) cycles	1493 BI	FDA Guidance[1], ISO 11138-1:2017[2] and ISO 11138-8:2021[4]	To validate the reduction in incubation time from 7 days (visual color change) to 24 minutes (fluorescent readout)	Meets FDA's requirements for Reduced Incubation Time with ≥ 97% alignment with the conventional incubation time of 7 days for	Acceptance criteria met

Test Performed	Device Description	Applicable Standards	Purpose	Acceptance Criteria	Results
				the following readout times: • Fluorescent result in 24 minutes	
Attest 1493 Simulated Use	1493 BI	FDA Guidance[1]	Verification of performance in claimed cycles	BI performs as intended in claimed cycles	Acceptance criteria met
490 and 490M Auto-reader Performance	1493 BI	FDA Guidance[1], ISO 11138-1:2017[2]	Verify equivalent performance of the 1493BI with the 3M™ Attest 490 and 490M Auto-readers	BIs must be fluorescent positive in 24 minutes and visual pH color change (growth) positive at 168 hours	Acceptance criteria met

1 FDA *Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions*, October 4, 2007
2 ISO 11138-1:2017 *Sterilization of health care products – Biological indicators - Part 1: General Requirements*
3 ISO 11138-3:2017 *Sterilization of health care products – Biological indicators - Part 3: Biological indicators for moist heat sterilization processes*
4 ISO 11138-8:2021 *Sterilization of health care products – Biological indicators - Part 8: Method for validation of a reduced incubation time for a biological indicator*

Challenge Pack

The differences between the submission and predicate device have been evaluated through performance tests for the 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG.

Three lots of 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG, containing three lots of 1493 BIs and three lots of 1243R CIs, were tested side by side with the AAMI 16 Towel PCD containing 1493 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 Gravity Clear Challenge Pack 1493PCDG, containing three lots of 1493 BIs and three lots of 1243R CIs, were tested side by side with standalone indicators 1493 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 Gravity Clear Challenge Pack 1493PCDG 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 Gravity Clear Challenge Pack 1493PCDG 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 1493PCDG challenge pack was verified through the following tests:

Test Performed	Device Description	Applicable Standards	Purpose	Acceptance Criteria	Results
Resistance of 1493PCDG Challenge Pack compared to AAMI 16 Towel PCD in claimed cycle	1493PCDG 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 1493PCDG Challenge Pack is equivalent to the performance of the AAMI 16 Towel PCD in the claimed cycle	Indicators contained in the 1493PCDG Challenge Pack must demonstrate equivalent resistance as compared to the indicators contained in the AAMI 16 Towel PCD in the claimed cycle	Acceptance criteria met
Resistance of 1493PCDG Challenge Pack compared to standalone indicators in claimed cycle	1493PCDG Challenge Pack	FDA Guidance[1]	Demonstrate the 1493PCDG Challenge Pack provides a greater challenge than the standalone indicators in the claimed cycle	Indicators contained in the 1493PCDG Challenge Pack must demonstrate greater resistance compared to the standalone indicators in the claimed cycle	Acceptance criteria met
1493PCDG Peel Force	1493PCDG Challenge Pack	ASTM F88 / F88M-15: *Standard Test Method for Seal Strength of Flexible Barrier* and ASTM F2824 – 10: *Standard Test Method for*	Demonstrate acceptable peel force of Clear Challenge Pack 1493PCDG heat seal foil lid from plastic shell	≥2.75lbF and ≤10lbF	Acceptance criteria met

Test Performed	Device Description	Applicable Standards	Purpose	Acceptance Criteria	Results
		Mechanical Seal Strength Testing for Round Cups and Bowl Containers with Flexible Peelable Lids			
1493PCDG Peel Force	1493PCDG 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 1493PCDG heat seal foil lid from plastic shell, pre and post sterilization	≥2.75lbF and ≤10lbF	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 biological indicator or submission challenge pack.

8. Conclusion

Based on the intended use, technological characteristics, and non-clinical performance data, the submission device, the 3M™ Attest™ Super Rapid Readout Biological Indicator 1493, the 3M™ Attest™ Super Rapid Steam Gravity Clear Challenge Pack 1493PCDG, 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 or better than the legally marketed predicate device, the 3M™ Attest™ Super Rapid Steam Biological Indicator 1592, the 3M™ Attest™ Super Rapid Steam Challenge Pack 51582, the 3M™ Attest™ Auto-reader 490, the 3M™ Attest™ Auto-reader 490H, and the 3M™ Attest™ Mini Auto-reader 490M (cleared per K213809) Class II (21 CFR 880.2800), product code FRC.