June 1, 2020

3M Company
Mary Fretland
Senior Regulatory Affairs Associate
3M Center, Building 275-5W-06
St. Paul, Minnesota 55144

Re: K200536
Trade/Device Name: 3M™ Attest™ Rapid 5 Steam-Plus Test Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: March 2, 2020
Received: March 3, 2020

Dear Mary Fretland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Christopher K. Dugard, M.S.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K200536

Device Name
3M™ Attest™ Rapid 5 Steam-Plus Test Pack 41382

Indications for Use *(Describe)*

3M™ Attest™ Rapid 5 Steam-Plus Test Pack 41382:
Use the 3M™ Attest™ Rapid 5 Steam-Plus Test Pack 41382 to qualify or monitor:
• 121°C (250°F) 30-minute gravity steam sterilization cycles;
• 132°C (270°F) 4-minute dynamic-air-removal steam sterilization cycles.

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 K200536

3M™ Attest™ Rapid 5 Steam-Plus Test Pack 41382

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

Contact: Mary Fretland
Senior Regulatory Affairs Associate
Phone Number: (651) 737-2296
FAX Number: (651) 737-5320

Date of Summary: March 3, 2020

Device Names and Classification:

Trade Name:	**3M™ Attest™ Rapid 5 Steam-Plus Test Pack 41382**
Common/Usual Name:	Biological Indicator (BI) Challenge Pack
Device Classification:	Class II
Classification Name:	Indicator, Biological Sterilization Process [21 CFR § 880.2800(a), FRC]

Predicate Device:

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

Indications for Use:

3M™ Attest™ Rapid 5 Steam-Plus Test Pack 41382:

Use the 3M™ Attest™ Rapid 5 Steam-Plus Test Pack 41382 to qualify or monitor:

- 121°C (250°F) 30-minute gravity steam sterilization cycles;
- 132°C (270°F) 4-minute dynamic-air-removal steam sterilization cycles.

Description of Device:

The 3M™ Attest™ Rapid 5 Steam-Plus Test Pack 41382 is specifically designed to qualify and monitor 250°F (121°C) gravity and 270°F (132°C) dynamic-air-removal steam sterilization processes in healthcare facilities. The test pack consists of multiple layers of medical index cards, some of which are die-cut to contain the monitoring products. Each test pack has a process indicator on the pack label that changes from yellow to brown or darker when exposed to steam. This convenient disposable test pack presents a challenge to the sterilization process equivalent to the user-assembled biological indicator (BI) challenge test pack (16-towel PCD) recommended by the Association for the Advancement of Medical Instrumentation (AAMI). The test pack is a single use device.

Each test pack contains a 3M™ Attest™ Rapid Readout Biological Indicator 1292 (brown cap, hereinafter referred to as a 1292 BI), a 3M™ Attest™ Steam Chemical Integrator, and a record keeping sheet. AAMI recommends that steam sterilization loads containing an implant be monitored with a process challenge device (PCD) containing a biological indicator and an integrating indicator. 3M™ Attest™ Steam Chemical Integrators are Type 5 (Category i5) Integrating Indicators as categorized by ISO 11140-1:2014. 3M™ Attest™ Steam Chemical Integrators are single-use chemical indicators consisting of a paper wick and a steam and temperature sensitive chemical pellet contained in a paper/film/foil laminate. The chemical pellet melts and migrates as a dark color along the paper wick. The migration is visible through a green window marked ACCEPT or a red window marked REJECT; the extent of migration depends on steam, time, and temperature. The 3M™ Attest™ Steam Chemical Integrator offers an immediate Accept/Reject reading that allows for implant load early release in emergency situations as defined in AAMI ST-79.

3M™ Attest™ Rapid Readout Biological Indicators 1292 comply with the requirements of ISO 11138-1:2017 and ISO 11138-3:2017. The 1292 BI is a dual readout biological indicator specifically designed for rapid and reliable monitoring of steam sterilization process when used in conjunction with the 3M™ Attest™ 290 Auto-reader or the 3M™ Attest™ Auto-reader 390. When steam processed, the process indicator on the 1292 BI label changes from rose to brown/black. Control 1292 BIs are provided with the test packs.

The 1292 BI detects the presence of *Geobacillus stearothermophilus* by detecting the activity of alpha-glucosidase, an enzyme present within the organism. The presence of the enzyme is detected by reading fluorescence produced by the enzymatic breakdown of a non-fluorescent substrate. This creates a fluorescence change, which is detected by the auto-reader. A fluorescence change indicates a steam sterilization process failure.

The 1292 BI can also indicate the presence of *G. stearothermophilus* organisms by a visual pH color change reaction. Biochemical activity of the *G. stearothermophilus* organism produces acid by-products that cause the media to change color from purple to yellow, which also indicates a steam sterilization process failure. Use of this indication method is optional and is typically restricted to special studies. Due to the high sensitivity of the 3-hour fluorescent results, however, there is no advantage to incubating the 1292 BI beyond 3 hours.

Nonclinical Comparison to the Predicate Device

This submission is addressing a change to the 3M™ Attest™ Steam Chemical Integrator contained within the 3M™ Attest™ Rapid 5 Steam-Plus Test Pack 41382. The design, fundamental technology and performance specifications for 3M™ Attest™ Steam Chemical Integrators are similar to the previously cleared device which is sold under the tradename 3M™ Comply™ SteriGage™ Chemical Integrator for Steam (K771080).

There have been no changes to the integrator's performance specifications or fundamental scientific technology. The changes to the integrator included an expansion of the indications for use, re-branding of the device, and a modification to the materials used to construct the device. Test Packs have the same intended use as the previously marketed devices and make use of the same fundamental scientific technology.

Technical Characteristics Comparison Table

Feature	Submission Device (K200536): 3M™ Attest™ Rapid 5 Steam-Plus Test Pack 41382	Predicate Device (K193154): 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V	Comparison
Indications for use	Use the 3M™ Attest™ Rapid 5 Steam-Plus Test Pack 41382 to qualify or monitor: • 121°C (250°F) 30-minute gravity steam sterilization cycles; • 132°C (270°F) 4-minute dynamic-air-removal steam sterilization cycles.	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).	One shared cycle with predicate device, one unique cycle.
General Design	Layers of medical index cards, some of which are die-cut to contain indicators, overwrapped and secured with a label.	Layers of medical index cards, some of which are die-cut to contain indicators, overwrapped and secured with a label.	Identical
Biological Indicator	3M™ Attest™ Rapid Readout Biological Indicator 1292 (cleared via K090569)	3M™ Attest™ Super Rapid Readout Biological Indicator 1492V (cleared via K173437)	Different BI
Biological Indicator Incubation temperature	60 ± 2°C	60 ± 2°C	Identical
Biological Indicator Readout time	3-hour final fluorescent result in both the 290 and 390 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.	Similar
Resistance Comparison to the AAMI ST79 16 Towel PCD	Equivalent in resistance to the AAMI ST79 16 Towel PCD	Equivalent in resistance to the AAMI ST79 16 Towel PCD	Identical
Chemical Integrator	3M™ Attest™ Steam Chemical Integrator (cleared via K191236)	3M™ Attest™ Steam Chemical Integrator (cleared via K191236)	Identical
External Chemical Process Indicator	Turns from yellow to brown or darker upon steam exposure	Turns from yellow to brown or darker upon steam exposure	Identical
Shelf-life	Two (2) years	21 months	Similar

Summary of Non-clinical Testing

Testing was conducted on the Test Pack following the FDA guidance and the standards below:

- *Guidance for Industry and FDA Staff, Biological Indicator Premarket Notification [510(k)] Submissions,* October 4, 2007
- *Premarket Notification [510(k)] Submission for Chemical Indicators: Guidance for Industry and FDA Staff,* December 19, 2003
- ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*
- ISO 11138-1:2017 *Sterilization of health care products – Biological indicators, Part 1: General Requirements*
- ISO 11138-3:2017 *Sterilization of health care products – Biological indicators, Part 3: Biological indicators for moist heat sterilization processes*
- ISO 11140-1:2014 *Sterilization of health care products – Chemical indicators, Part 1: General Requirements*
- United States Pharmacopeia, Chapter <1035> Biological Indicators for Sterilization and Chapter <55> Biological Indicators – Resistance Performance Tests

Performance testing to demonstrate substantial equivalence to the predicate device has been completed and is summarized below:

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

Conclusion

The conclusion drawn from the non-clinical tests performed demonstrates that the subject device is as safe, as effective, and perform as well as or better than the legally marketed predicate device, the 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V (cleared under K193154), Class II (21 CFR 880.2800), product code FRC.