February 7, 2020

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

Re: K193154
Trade/Device Name: 3M Attest Super Rapid 5 Steam-Plus Challenge Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: November 1, 2019
Received: November 14, 2019

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 Sreekanth Gutala, Ph.D.
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)*
K193154

Device Name
3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V

Indications for Use *(Describe)*
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).

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 5 Steam-Plus Challenge Pack 41482V
K193154

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: February 04, 2020

Device Name and Classification:

Trade Name:	3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V
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 Challenge Pack 41482V, 3M™ Attest™ Auto-reader 490, and 3M™ Attest™ Auto-reader 490H, K173519

Indications for Use

Use 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).

Description of Device:

The 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V is specifically designed to qualify or routinely challenge dynamic-air-removal steam sterilization cycles of 4 minutes at 270°F (132°C) and 3 minutes at 275°F (135°C).

The 41482V Challenge Packs consist of multiple layers of medical index cards, some of which are die-cut to contain monitoring products. The pack is overwrapped and secured with a label. The Challenge Pack has the same design as the predicate device except for a change to the chemical integrator contained within the Challenge Pack. Each 41482V Challenge Pack contains a 1492V BI and a 3M™ Attest™ Steam Chemical Integrator. The 1492V BI is specifically designed for a rapid fluorescent result when used in conjunction with the 3M™ Attest™ Auto-reader 490 or the 3M™ Attest™ Auto-reader 490H (software version 4.0.0 or greater). A fluorescence change indicates a steam sterilization process failure. 3M™ Attest™ 1492V BI controls are provided with the Challenge Packs. The 3M™ Attest™ Chemical Integrator offers an immediate Accept/Reject result that allows for implant load early release in emergency situations as defined in AAMI ST79. Each Challenge Pack has a process indicator on the outside of the device that changes from yellow to brown or darker when exposed to steam.

Technological Characterization

Provided below is a comparison of the technological similarities and differences between the subject device and the predicate device.

Technical Characteristics Comparison Table

Feature	Subject Device: K193154 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V	Predicate Device (K173519): 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V and 3M™ Attest™ Auto-reader 490 and 490H	Comparison
Indications for use	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).	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).	Identical
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™ Super Rapid Readout Biological Indicator 1492V	3M™ Attest™ Super Rapid Readout Biological Indicator 1492V	Identical
Biological Indicator Incubation temperature	60 ± 2°C	60 ± 2°C	Identical
Biological Indicator Readout time	24 minute final fluorescent result in both the 490 and 490H Auto-readers having software versions 4.0.0 or greater. 1 hour final fluorescent result in 490 Auto-readers having software versions less than 4.0.0.	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.	Identical
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	3M™ Comply™ SteriGage™ Chemical Integrator for Steam	Both integrators meet FDA requirements for a chemical integrator

Feature	Subject Device: K193154 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V	Predicate Device (K173519): 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V and 3M™ Attest™ Auto-reader 490 and 490H	Comparison
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	21 months	21 months	Identical

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 (K101249). 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. There have been no other changes to the 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V nor to the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V contained within the Challenge Pack. Other than the change to the integrator, the Challenge Pack has the same materials and fundamental scientific technology.

Summary of Non-clinical Testing

Testing was conducted on the Challenge 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 performs as well as or better than the legally marketed predicate devices the 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V, 3M™ Attest™ Auto-reader 490, and 3M™ Attest™ Auto-reader 490H (cleared under K173519), Class II (21 CFR 880.2800), product code FRC.