



April 23, 2018

3M Company
Hilary Hovde
Regulatory Affairs Associate
3M Center, Building 275-5W-06
St Paul, Minnesota 55144

Re: K173519

Trade/Device Name: 3M Attest Super Rapid Readout Steam Challenge Pack 1496V, 3M Attest Super Rapid 5 Steam-Plus Challenge Pack 41482V, 3M Attest Auto-reader 490, 3M Attest Auto-reader 490H

Regulation Number: 21 CFR 880.2800

Regulation Name: Sterilization Process Indicator

Regulatory Class: Class II

Product Code: FRC

Dated: March 19, 2018

Received: March 22, 2018

Dear Hilary Hovde:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.

Pamidimukkala -S

for Tina Kiang, Ph.D.

Acting Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

Device Name

3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V, 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V, 3M™ Attest™ Auto-reader 490, and 3M™ Attest™ Auto-reader 490H

Indications for Use (Describe)

Use the 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V and 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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TRADITIONAL PREMARKET NOTIFICATION [510(k)]

3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V

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

3M™ Attest™ Auto-reader 490 and 490H



510(k) Summary for
3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V
3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V
3M™ Attest™ Auto-reader 490
3M™ Attest™ Auto-reader 490H (software version 4.0.0 or greater)

3M Health Care
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Submission Date: April 19, 2018

K173519

TRADITIONAL PREMARKET NOTIFICATION [510(k)]

3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V

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

3M™ Attest™ Auto-reader 490 and 490H

Device Name and Classification:

Common or Usual Name: Biological Indicator

Proprietary Name: 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V
3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V
3M™ Attest™ Auto-reader 490
3M™ Attest™ Auto-reader 490H

Classification Name: Indicator, Biological Sterilization Process
(21 CFR § 880.2800(a))

Device Classification: Class II

Product Code: FRC

Predicate Device:

- 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V, 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V, and 3M™ Attest™ Auto-reader 490, K121593

Reference Device:

- 3M™ Attest™ Auto-reader 490H, K171003

Description of Device:

The 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V and the 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V are specifically designed 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).

The 1496V and 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 Packs have the same design as the predicate device. Each 1496V Challenge Pack contains a 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V while the 41482V Challenge Pack contains a 1492V BI and a 3M™ SteriGage™ Steam Chemical Integrator (Type 5 Integrating Indicators as categorized by ISO 11140-1:2014). 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. 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.

TRADITIONAL PREMARKET NOTIFICATION [510(k)]

3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V

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

3M™ Attest™ Auto-reader 490 and 490H

Nonclinical Comparison to the Predicate Device

This submission is addressing a software change to the 3M™ Attest™ Auto-reader 490 to reduce the final fluorescent readout for the 1492V BI from 1 hour to 24 minutes, and to change the incubation temperature from 56°C to 60°C making the 490 Auto-reader identical to the 490H Auto-reader (software version 4.0.0 or greater). The 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V, the 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V, and the 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V are the same design as the previously cleared devices of the same model numbers. The Comply™ SteriGage™ Steam Chemical Integrators contained within the 41482V challenge pack are the same as those in the predicate device. The device has the same materials and fundamental scientific technology.

Summary of Nonclinical Testing

As the change is to the 3M™ Attest™ Auto-reader software, testing was conducted on the biological indicators and the challenge packs following the FDA guidance and the standards below:

- *Guidance for Industry and FDA Staff, Biological Indicator Premarket Notification [510(k)] Submissions, October 4, 2007*
- *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*
- *ANSI/AAMI/ISO 18472:2006 Sterilization of Health Care Products – Biological and Chemical Indicators: Test Equipment*
- *United States Pharmacopeia, Chapter <1035> Biological Indicators for Sterilization and Chapter <55> Biological Indicators – Resistance Performance Tests*

TRADITIONAL PREMARKET NOTIFICATION [510(k)]

3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V

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

3M™ Attest™ Auto-reader 490 and 490H

The functionality of the 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V and the 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V in conjunction with the 3M™ Attest™ Auto-reader 490 and the 3M™ Attest™ Auto-reader 490H (software version 4.0.0 or greater) with a final fluorescent readout of 24 minutes and an incubation temperature of 60°C was demonstrated in the following tests:

| Test | Acceptance Criteria | Results |
|--|--|---------|
| Resistance of the Challenge Pack as compared to 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 |
| Resistance of the Challenge Pack as compared to the Biological Indicator alone | Challenge Pack provides a greater resistance than the Biological Indicator alone | Passed |
| Auto-reader Maintenance of Incubation Temperature | Auto-reader maintains incubation temperature of $60 \pm 2^\circ\text{C}$ over a period of 7 days | Passed |

The results of these evaluations showed that the 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V and the 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V present a challenge to the sterilization process equivalent to the biological indicator AAMI 16 Towel PCD described in ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*.

The Attest™ Auto-readers were tested for safety by Underwriters Laboratory to verify compliance to:

- IEC 61010-1 (2010) 3rd Edition; *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements*, and
- IEC 61010-2-010 (2014) 3rd Edition; *Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials*

In addition the 3M™ Attest™ Auto-readers 490 and 490H have been tested by a certified Testing Laboratory to verify electromagnetic compatibility per:

- USA Title 47, Code of Federal Regulations for:
 - Radiated Emissions (FCC Part 15, Subpart B, Class A)
 - Conducted Emissions (FCC Part 15, Subpart B, Class A), and
- IEC 61326-1:2012 *Electrical Equipment for Measurement, Control, and Laboratory Use – EMC Requirements*

TRADITIONAL PREMARKET NOTIFICATION [510(k)]

3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V

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

3M™ Attest™ Auto-reader 490 and 490H

Summary of Clinical Testing

No clinical data was included in this premarket application submission.

Indications for Use

Use the 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V and 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).

TRADITIONAL PREMARKET NOTIFICATION [510(k)]**3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V****3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V****3M™ Attest™ Auto-reader 490 and 490H****Comparison to Predicate Device**

| Feature | Submission Device: 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V and 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V | Predicate Device (K121593): 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V and 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V |
|---|---|--|
| Indications for use | Use the 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V and 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 Readout Steam Challenge Pack 1496V and the 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V in conjunction with the 3M™ Attest™ Auto-reader 490 to qualify or monitor dynamic-air-removal (pre-vacuum) steam sterilization cycles 270°F (132°C) at 4 minutes and 275°F (135°C) at 3 minutes. The 3M™ Attest™ Super Rapid Readout Biological Indicator 1492V contained in the challenge pack provides a final fluorescent result in 1 hour. An optional visual pH color change result is observed in 48 hours. |
| General Design | 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 | Identical |
| Biological Indicator Incubation temperature | 60 ± 2°C | 56 ± 2°C |
| 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. | 1 hour final fluorescent result in 490 Auto-readers. |
| Resistance Comparison to the AAMI ST79 16 Towel PCD | Equivalent in resistance to the AAMI ST79 16 Towel PCD | Identical |
| Chemical Integrator | The 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V does not contain a chemical integrator. The 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V contains a 3M™ SteriGage™ Chemical Integrator | Identical |
| External Chemical Process Indicator | Turns from yellow to brown or darker upon steam exposure | Identical |
| Shelf-life | 21 months | Identical |

TRADITIONAL PREMARKET NOTIFICATION [510(k)]

3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V

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

3M™ Attest™ Auto-reader 490 and 490H

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V, the 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V, the 3M™ Attest™ Auto-reader 490, and the 3M™ Attest™ Auto-reader 490H are as safe, as effective, and perform as well as or better than the 3M™ Attest™ Super Rapid Readout Steam Challenge Pack 1496V, the 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V, and the 3M™ Attest™ Auto-reader 490 (K121593).