



July 2, 2020

3M Center
Mary Fretland
Senior Regulatory Affairs Associate
2510 Conway Avenue, Building 275-5W-06
St. Paul, MN 55144

Re: K200766

Trade/Device Name: 3M™ Attest™ Steam Chemical Integrator Test Pack 41360
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: June 03, 2020
Received: June 04, 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,

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

Indications for Use

510(k) Number (if known)

K200766

Device Name

3M™ Attest™ Steam Chemical Integrator Test Pack 41360

Indications for Use (Describe)

Use the 3M™ Attest™ Steam Chemical Integrator Test Pack 41360 to monitor:

- 121°C (250°F) gravity displacement steam sterilization cycle at 30 minutes
- 132°C (270°F) dynamic-air-removal steam sterilization cycle at 4 minutes
- 135°C (275°F) dynamic-air-removal steam sterilization cycle at 3 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™ Steam Chemical Integrator Test Pack 41360
K200766

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: July 02, 2020

**TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Attest™ Steam Chemical Integrator Test Pack 41360**

Device Names and Classification:

Trade Name:	3M™ Attest™ Steam Chemical Integrator Test Pack 41360
Common/Usual Name:	Chemical Indicator (CI) Challenge Pack
Device Classification:	Class II
Classification Name:	Indicator, Biological Sterilization Process [21 CFR § 880.2800(b), FRC]

Predicate Device:

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

Indications for Use:

3M™ Attest™ Steam Chemical Integrator Test Pack 41360:

Use the 3M™ Attest™ Steam Chemical Integrator Test Pack 41360 to monitor:

- 121°C (250°F) gravity displacement steam sterilization cycle at 30 minutes
- 132°C (270°F) dynamic-air-removal steam sterilization cycle at 4 minutes
- 135°C (275°F) dynamic-air-removal steam sterilization cycle at 3 minutes

Description of Device:

3M™ Attest™ Steam Chemical Integrator Test Pack 41360 is specifically designed to routinely challenge the steam sterilization process in healthcare facilities. This convenient disposable process challenge device presents a challenge to the sterilization process equivalent to the 16-towel process challenge device (PCD) recommended by the Associate for the Advancement of Medical Instrumentation (AAMI). Each test pack contains a process indicator on the outside that changes from yellow to brown or darker when steam processed.

Each pack contains a 3M™ Attest™ Steam Chemical Integrator and a record keeping sheet. The 3M™ Attest™ Steam Chemical Integrator consists of a paper wick and a steam and temperature sensitive chemical pellet contained in a paper/film/foil laminate. When exposed to steam sterilization conditions, the chemical pellet melts and migrates as a dark color along the paper wick. The migration is visible through a window marked REJECT or ACCEPT. The extent of migration depends on steam, time, and temperature.

Nonclinical Comparison to the Predicate Device

This submission is addressing a change to the 3M™ Attest™ Steam Chemical Integrator contained within the 3M™ Attest™ Steam Chemical Integrator Test Pack 41360. 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™ Steam Chemical Integrator Test Pack (K894399).

TRADITIONAL PREMARKET NOTIFICATION [510(k)]**3M™ Attest™ Steam Chemical Integrator Test Pack 41360**

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	Subject Device (K200766): 3M™ Attest™ Steam Chemical Integrator Test Pack 41360	Predicate Device (K193154): 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V	Comparison
Indications for use	Use the 3M™ Attest™ Steam Chemical Integrator Test Pack 41360 to monitor: <ul style="list-style-type: none"> • 121°C (250°F) gravity displacement steam sterilization cycle at 30 minutes • 132°C (270°F) dynamic-air-removal steam sterilization cycle at 4 minutes • 135°C (275°F) dynamic-air-removal steam sterilization cycle at 3 minutes 	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).	Two shared cycles 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	NA	3M™ Attest™ Super Rapid Readout Biological Indicator 1492V (cleared via K173437)	Subject device does not contain a BI.
Biological Indicator Incubation temperature	NA	60 ± 2°C	Subject device does not contain a BI.
Biological Indicator Readout time	NA	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.	Subject device does not contain a BI.
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
Shelf-life	Two (2) years	21 months	Similar

TRADITIONAL PREMARKET NOTIFICATION [510(k)]
3M™ Attest™ Steam Chemical Integrator Test Pack 41360

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 11140-1:2014 Sterilization of health care products – Chemical indicators, Part 1: General Requirements*

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.