November 22, 2019

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

Re: K191236
Trade/Device Name: 3M™ Attest™ Steam Chemical Integrators
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: October 22, 2019
Received: October 23, 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 Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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)*
K191236

Device Name
3M™ Attest™ Steam Chemical Integrators

Indications for Use *(Describe)*
The 3M™ Attest™ Steam Chemical Integrators are designed to respond to all critical parameters over a specified range of steam sterilization cycles. The integrating indicator is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles:

Cycle Type	Temperature	Exposure Time
Gravity	250°F/121°C	30 minutes
Gravity	270°F/132°C	3, 4, 10, 15, 25 minutes
Gravity	275°F/135°C	3, 10 minutes
Dynamic Air Removal	250°F/121°C	30 minutes
Dynamic Air Removal	270°F/132°C	4, 10 minutes
Dynamic Air Removal	273°F/134°C	3, 4 minutes
Dynamic Air Removal	275°F/135°C	3 minutes

Minimum Stated Values for 3M™ Attest™ Steam Chemical Integrators as determined in a resistometer:
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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
for
3M™ Attest™ Steam Chemical Integrators

Sponsor Information:

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
Email: mfretland@mmm.com

Date of Summary: November 21, 2019

Submission Number: K191236

1. Device Name and Classification:

Common or Usual Name:	Chemical Indicators
Trade Name:	3M™ Attest™ Steam Chemical Integrators
Classification Name:	Physical/chemical sterilization process indicators
Device Classification:	Class II, 21 CFR § 880.2800(b)
Product Code:	JOJ

2. Predicate Device:

3M™ Comply™ SteriGage™ Chemical Integrator for Steam (K101249)

3. Description of Device:

3M™ Attest™ Steam Chemical Integrators are 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 window marked ACCEPT or window marked REJECT; the extent of migration depends on steam, time, and temperature.

4. Indications for Use

The 3M™ Attest™ Steam Chemical Integrators are designed to respond to all critical parameters over a specified range of steam sterilization cycles. The integrating indicator is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles:

Cycle Type	Temperature	Exposure Time
Gravity	250°F/121°C	30 minutes
Gravity	270°F/132°C	3 minutes
Gravity	270°F/132°C	4 minutes
Gravity	270°F/132°C	10 minutes
Gravity	270°F/132°C	15 minutes
Gravity	270°F/132°C	25 minutes
Gravity	275°F/135°C	3 minutes
Gravity	275°F/135°C	10 minutes
Dynamic Air Removal	250°F/121°C	30 minutes
Dynamic Air Removal	270°F/132°C	4 minutes
Dynamic Air Removal	270°F/132°C	10 minutes
Dynamic Air Removal	273°F/134°C	3 minutes
Dynamic Air Removal	273°F/134°C	4 minutes
Dynamic Air Removal	275°F/135°C	3 minutes

Minimum Stated Values for 3M™ Attest™ Steam Chemical Integrators as determined in a resistometer:

250°F/121°C	**270°F/132°C**	**273°F/134°C**	**275°F/135°C**
16.5 Minutes	2.0 Minutes	1.4 Minutes	1.2 Minutes

5. Nonclinical Comparison to the Predicate Device

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 has been no change to the device's performance specifications or fundamental scientific technology. The intent of this submission is to expand the indications for use, re-brand the device, and modify the materials used to construct the device.

The differences between 3M™ Attest™ Steam Chemical Integrator and the predicate do not raise any new questions of safety and effectiveness as demonstrated by the performance testing and biocompatibility assessment.

6. Technical Characteristics

Technological Characteristics Comparison Between Subject and Predicate Device:

Feature	Submission Device: 3M™ Attest™ Steam Chemical Integrators	Predicate Device (K101249): 3M™ Comply™ SteriGage™ Chemical Integrators for Steam
Device Models	1243RE and 1243RES	1243RE
Device Design	3M™ Attest™ Steam Chemical Integrators are chemical indicators consisting of a paper wick and 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 window marked ACCEPT or window marked REJECT; the extent of migration depends on steam, time, and temperature.	Identical.
Indicator Agent	Proprietary formulation.	Identical.
Sterilization method and cycles	Steam sterilization processes 250°F to 275°F (121°C to 135°C)	Identical.
Shelf-life	One (1) year	Three (3) years

Indications for Use Comparison:

Cycle Type	Temperature	Submission Device: 3M™ Attest™ Steam Chemical Integrators **Exposure Time**	Predicate Device (K101249): 3M™ Comply™ SteriGage™ Chemical Integrators for Steam **Exposure Time**
Gravity	250°F/121°C	30 minutes	≥ 30 minutes
Gravity	270°F/132°C	3 minutes 4 minutes 10 minutes 15 minutes 25 minutes	≥ 3 minutes (unwrapped)
Gravity	275°F/135°C	3 minutes 10 minutes	Not present.
Dynamic Air Removal	250°F/121°C	30 minutes	Not present.
Dynamic Air Removal	270°F/132°C	4 minutes 10 minutes	≥ 3 minutes (unwrapped) ≥ 4 minutes (wrapped)
Dynamic Air Removal	273°F/134°C	3 minutes 4 minutes	≥ 3.5 minutes (unwrapped) ≥ 4 minutes (wrapped)
Dynamic Air Removal	275°F/135°C	3 minutes	≥ 3 minutes

<table>
<tr><th>Feature</th><th>Submission Device:
3M™ Attest™ Steam Chemical Integrators</th><th>Predicate Device (K101249):
3M™ Comply™ SteriGage™ Chemical Integrators for Steam</th></tr>
<tr><td>Endpoint Specifications (Minimum Stated Values)</td><td>The minimum stated values for the 3M™ Attest™ Steam Chemical Integrators as determined using a resistometer are provided in the table below.

Minimum Stated Values for 3M™ Attest™ Steam Chemical Integrators
<table>
<tr><th>250°F/ 121°C</th><th>270°F/ 132°C</th><th>273°F/ 134°C</th><th>275°F/ 135°C</th></tr>
<tr><td>16.5 Minutes</td><td>2.0 Minutes</td><td>1.4 Minutes</td><td>1.2 Minutes</td></tr>
</table></td><td>The minimum stated values for the 3M™ Comply™ SteriGage™ Chemical Integrators for Steam as determined using a resistometer are provided in the table below.

Minimum Stated Values for 3M™ Comply™ SteriGage™ Steam Chemical Integrators
<table>
<tr><th>250°F/ 121°C</th><th>270°F/ 132°C</th><th>273°F/ 134°C</th><th>275°F/ 135°C</th></tr>
<tr><td>16.5 Minutes</td><td>2.0 Minutes</td><td>1.4 Minutes</td><td>1.1 Minutes</td></tr>
</table></td></tr>
</table>

7. Summary of Nonclinical Testing

Nonclinical testing of the 3M™ Attest™ Steam Chemical Integrators was conducted in accordance with the *FDA Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators, issued December 19, 2003* as well as ANSI/AAM/ISO 11140-1:2014.

The effectiveness of the 3M™ Attest™ Steam Chemical Integrator was demonstrated in the following tests:

Test Name	Purpose	Acceptance Criteria		Results
Stated Value (SV) Testing	To identify the critical parameters required to achieve a stated inactivation, by referring to a stated test organism with stated D and z values. The integrator must turn to "ACCEPT" end point at the stated value time and must also remain "REJECT" when exposed to conditions of -1°C/-15% set point of the SV time. All testing is completed in a saturated steam resistometer. Integrator temperature coefficient and correlation coefficient are calculated to confirm alignment to biological indicator performance.	SV at 121°C	≥ 16.5 minutes	PASS
		SV at 132°C	≥ 2.0 minutes	
		SV at 134°C	≥ 1.4 minutes	
		SV at 135°C	≥ 1.2 minutes	
		Integrator temperature coefficient	10 - 27°C	
		Correlation coefficient	≥ 0.9	
Health Care Facility Simulated Use Testing	Confirm integrators provide acceptable performance in cleared customer use sterilization cycles.	Device reaches "ACCEPT" endpoint reaction when exposed to customer use cycles. Device does not reach endpoint ("REJECT") when exposed to failing conditions in customer use cycles.		PASS

Test Name	Purpose	Acceptance Criteria	Results
Dry Heat Testing	Verify device requires the presence of saturated steam to turn to reach endpoint.	Endpoint must not be met following dry heat exposure at 140°C for 30 min.	PASS
Side-by-Side Testing with Biological Indicator	Confirm integrators are parallel in performance to biological indicators (BI).	Chemical integrator parallels performance of BI and does not reach endpoint before BI is inactivated.	PASS
Endpoint Color Stability	Confirm endpoint color stability for samples exposed to passing and failing conditions in a steam resistometer.	Endpoint decision must remain unchanged after 6 months.	PASS

The results of performance testing on 3M™ Attest™ Steam Chemical Integrator demonstrate the device performs as intended in the claimed steam sterilization cycles.

8. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the 3M™ Attest™ Steam Chemical Integrator is as safe, as effective and performs as well as or better than the legally marketed predicate, 3M™ Comply™ SteriGage™ Chemical Integrator for Steam cleared under K101249, Class II (CFR 880.2800, product code JOJ).