



September 25, 2026

Solventum US, LLC
Heidi Wallis
Senior Regulatory Affairs Specialist
12930 Ih 10 W.
San Antonio, Texas 78249

Re: K261992

Trade/Device Name: 3M™ Attest™ Steam Chemical Integrator (1243A, 1243B, 1243RE, 1243RES)
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: June 12, 2026
Received: June 15, 2026

Dear Heidi Wallis:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

STEPHEN A.
ANISKO -S

Digitally signed by
STEPHEN A. ANISKO -S
Date: 2026.09.25
14:50:02 -04'00'

Stephen Anisko
Assistant Director
DHT4C: Division of Infection
Control 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)

K261992

Device Name

3M™ Attest™ Steam Chemical Integrator (1243A, 1243B, 1243RE, 1243RES)

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 critical 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	5 minutes
Dynamic Air Removal	270°F/132°C	6 minutes
Dynamic Air Removal	270°F/132°C	7 minutes
Dynamic Air Removal	270°F/132°C	8 minutes
Dynamic Air Removal	270°F/132°C	9 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

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
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASaff@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 Integrator
1243A, 1243B, 1243RE, 1243RES**

Sponsor Information:

Solventum (previously 3M Health Care)
12930 IH 10 West
San Antonio, TX 78249

Contact: Heidi Wallis
Senior Regulatory Affairs Specialist
Phone Number: 651-381-2297

Date of Summary: September 24, 2026

510(k) Reference: K261992

1. Device Name and Classification:

Common or Usual Name: Chemical Indicators
Proprietary Name: 3M™ Attest™ Steam Chemical Integrator (1243A, 1243B, 1243RE, 1243RES)
Classification Name: Physical/chemical sterilization process indicator Class II,
Device Classification: 21 CFR § 880.2800(b)
Product Code: JOJ

2. Predicate Device:

K220942, 3M™ Attest™ Steam Chemical Integrator

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	5 minutes
Dynamic Air Removal	270°F/132°C	6 minutes

Dynamic Air Removal	270°F/132°C	7 minutes
Dynamic Air Removal	270°F/132°C	8 minutes
Dynamic Air Removal	270°F/132°C	9 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

Technological Characteristic Comparison Table

Feature	Submission Device (K261992): 3M™ Attest™ Steam Chemical Integrator	Predicate Device (K220942): 3M™ Attest™ Steam Chemical Integrator	Comparison																																																																																																						
Device Models	1243A, 1243B, 1243RE, 1243RES	1243A, 1243B, 1243RE, 1243RES	Identical																																																																																																						
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: <table><tr><th>Cycle Type</th><th>Temperature</th><th>Exposure Time</th></tr><tr><td>Gravity</td><td>250°F/121°C</td><td>30 minutes</td></tr><tr><td>Gravity</td><td>270°F/132°C</td><td>3 minutes</td></tr><tr><td>Gravity</td><td>270°F/132°C</td><td>4 minutes</td></tr><tr><td>Gravity</td><td>270°F/132°C</td><td>10 minutes</td></tr><tr><td>Gravity</td><td>270°F/132°C</td><td>15 minutes</td></tr><tr><td>Gravity</td><td>270°F/132°C</td><td>25 minutes</td></tr><tr><td>Gravity</td><td>275°F/135°C</td><td>3 minutes</td></tr><tr><td>Gravity</td><td>275°F/135°C</td><td>10 minutes</td></tr><tr><td>Dynamic Air Removal</td><td>250°F/121°C</td><td>30 minutes</td></tr><tr><td>Dynamic Air Removal</td><td>270°F/132°C</td><td>4 minutes</td></tr><tr><td>Dynamic Air Removal</td><td>270°F/132°C</td><td>5 minutes</td></tr><tr><td>Dynamic Air Removal</td><td>270°F/132°C</td><td>6 minutes</td></tr><tr><td>Dynamic Air Removal</td><td>270°F/132°C</td><td>7 minutes</td></tr><tr><td>Dynamic Air Removal</td><td>270°F/132°C</td><td>8 minutes</td></tr><tr><td>Dynamic Air Removal</td><td>270°F/132°C</td><td>9 minutes</td></tr><tr><td>Dynamic Air Removal</td><td>270°F/132°C</td><td>10 minutes</td></tr></table>	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	5 minutes	Dynamic Air Removal	270°F/132°C	6 minutes	Dynamic Air Removal	270°F/132°C	7 minutes	Dynamic Air Removal	270°F/132°C	8 minutes	Dynamic Air Removal	270°F/132°C	9 minutes	Dynamic Air Removal	270°F/132°C	10 minutes	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: <table><tr><th>Cycle Type</th><th>Temperature</th><th>Exposure Time</th></tr><tr><td>Gravity</td><td>250°F/121°C</td><td>30 minutes</td></tr><tr><td>Gravity</td><td>270°F/132°C</td><td>3 minutes</td></tr><tr><td>Gravity</td><td>270°F/132°C</td><td>4 minutes</td></tr><tr><td>Gravity</td><td>270°F/132°C</td><td>10 minutes</td></tr><tr><td>Gravity</td><td>270°F/132°C</td><td>15 minutes</td></tr><tr><td>Gravity</td><td>270°F/132°C</td><td>25 minutes</td></tr><tr><td>Gravity</td><td>275°F/135°C</td><td>3 minutes</td></tr><tr><td>Gravity</td><td>275°F/135°C</td><td>10 minutes</td></tr><tr><td>Dynamic Air Removal</td><td>250°F/121°C</td><td>30 minutes</td></tr><tr><td>Dynamic Air Removal</td><td>270°F/132°C</td><td>4 minutes</td></tr><tr><td>Dynamic Air Removal</td><td>270°F/132°C</td><td>5 minutes</td></tr><tr><td>Dynamic Air Removal</td><td>270°F/132°C</td><td>6 minutes</td></tr><tr><td>Dynamic Air Removal</td><td>270°F/132°C</td><td>7 minutes</td></tr><tr><td>Dynamic Air Removal</td><td>270°F/132°C</td><td>8 minutes</td></tr><tr><td>Dynamic Air Removal</td><td>270°F/132°C</td><td>9 minutes</td></tr><tr><td>Dynamic Air Removal</td><td>270°F/132°C</td><td>10 minutes</td></tr></table>	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	5 minutes	Dynamic Air Removal	270°F/132°C	6 minutes	Dynamic Air Removal	270°F/132°C	7 minutes	Dynamic Air Removal	270°F/132°C	8 minutes	Dynamic Air Removal	270°F/132°C	9 minutes	Dynamic Air Removal	270°F/132°C	10 minutes	Identical
	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	5 minutes																																																																																																						
	Dynamic Air Removal	270°F/132°C	6 minutes																																																																																																						
	Dynamic Air Removal	270°F/132°C	7 minutes																																																																																																						
	Dynamic Air Removal	270°F/132°C	8 minutes																																																																																																						
	Dynamic Air Removal	270°F/132°C	9 minutes																																																																																																						
	Dynamic Air Removal	270°F/132°C	10 minutes																																																																																																						
	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	5 minutes																																																																																																							
Dynamic Air Removal	270°F/132°C	6 minutes																																																																																																							
Dynamic Air Removal	270°F/132°C	7 minutes																																																																																																							
Dynamic Air Removal	270°F/132°C	8 minutes																																																																																																							
Dynamic Air Removal	270°F/132°C	9 minutes																																																																																																							
Dynamic Air Removal	270°F/132°C	10 minutes																																																																																																							

Feature	Submission Device (K261992): 3M™ Attest™ Steam Chemical Integrator				Predicate Device (K220942): 3M™ Attest™ Steam Chemical Integrator				Comparison
	Dynamic Air Removal	273°F/134°C	3 minutes		Dynamic Air Removal	273°F/134°C	3 minutes		
	Dynamic Air Removal	273°F/134°C	4 minutes		Dynamic Air Removal	273°F/134°C	4 minutes		
	Dynamic Air Removal	275°F/135°C	3 minutes		Dynamic Air Removal	275°F/135°C	3 minutes		
Indicator Agent	Proprietary formulation.				Proprietary formulation.				Similar.
Sterilization method and cycles	Steam sterilization processes 250°F to 275°F (121°C to 135°C).				Steam sterilization processes 250°F to 275°F (121°C to 135°C).				Identical
Endpoint Specifications (Minimum Stated Values)	The minimum stated values for the 3M™ Attest™ Steam Chemical Integrators as determined using a resistometer are provided in the table below.				The minimum stated values for the 3M™ Attest™ Steam Chemical Integrators as determined using a resistometer are provided in the table below.				Identical
	250°F/121° C	270°F/132° C	273°F/134° C	275°F/135° C	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	16.5 Minutes	2.0 Minutes	1.4 Minutes	1.2 Minutes	
Shelf life	Three (3) years				Three (3) years				Identical

5. Nonclinical Testing Comparison to the Predicate Device

3M™ Attest™ Steam Chemical Integrators are identical to the previously cleared devices which are sold under the same tradename 3M™ Attest™ Steam Chemical Integrators (**K220942**). There has been no change to the device materials, performance specifications, or fundamental technology.

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

Table 6.1: Summary of Nonclinical Testing

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 250°F/121°C	≥ 16.5 minutes	Pass
		SV at 270°F/132°C	≥ 2.0 minutes	
		SV at 273°F/134°C	≥ 1.4 minutes	
		SV at 275°F/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
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

6. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, 3M™ Attest™ Steam Chemical Integrators are as safe, as effective, and performs at least as well as the predicate, Attest™ Steam Chemical Integrator cleared under K220942, Class II (CFR § 880.2800(b)), product code JOJ.