May 23, 2022

3M Company
Yumi Wackerfuss
Senior Regulatory Affairs Associate
2510 Conway Avenue, Bldg. 275-5W-06
St. Paul, Minnesota 55144-1000

Re: K220564
Trade/Device Name: 3M Comply Lead Free Steam Indicator Tape 1322, 3M Attest Lead Free Steam Indicator Tape 1355
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: February 25, 2022
Received: February 28, 2022

Dear Yumi Wackerfuss:

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,

Clarence W. Murray, III, PhD
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K220564

Device Name

3M™ Comply™ Lead Free Steam Indicator Tape 1322
3M™ Attest™ Lead Free Steam Indicator Tape 1355

Indications for Use *(Describe)*

3M™ Comply™ Lead Free Steam Indicator Tape 1322 is designed for use by a health care provider to accompany individual units (e.g. wrapped packs) to demonstrate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units.
Use the 3M™ Comply™ Lead Free Steam Indicator Tape 1322 in steam process below:

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	15, 20, 30 minutes
Dynamic air-removal	270 °F/132°C	3, 3.5, 4, 5.5, 6, 9, 10, 15 minutes
Dynamic air-removal	273 °F/134°C	3, 3.5, 4 minutes
Dynamic air-removal	275 °F/135°C	3, 3.5, 4, 10 minutes

Use the 3M™ Comply™ Lead Free Steam Indicator Tape 1322 to demonstrate that packs have been exposed to the sterilization process. The 3M™ Comply™ Lead Free Steam Indicator Tape 1322 is designed to secure packs wrapped with untreated woven and disposable non-woven paper and paper/plastic wraps.

3M™ Attest™ Lead Free Steam Indicator Tape 1355 for disposable wraps is designed for use by a health care provider to accompany individual units (e.g., wrapped packs) to demonstrate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units. Use the 3M™ Attest™ Lead Free Steam Indicator Tape 1355 in steam process below:

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	15, 20, 30 minutes
Dynamic air-removal	270 °F/132°C	3, 3.5, 4, 5.5, 6, 9, 10, 15 minutes
Dynamic air-removal	273 °F/134°C	3, 3.5, 4 minutes
Dynamic air-removal	275 °F/135°C	3, 3.5, 4, 10 minutes

Use the 3M™ Attest™ Lead Free Steam Indicator Tape 1355 to demonstrate that packs have been exposed to the sterilization process. The 3M™ Attest™ Lead Free Steam Indicator Tape 1355 is designed to secure packs wrapped with disposable non-woven, paper and paper/plastic wraps.

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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3M™ Comply™ Lead Free Steam Indicator Tape 1322
3M™ Attest™ Lead Free Steam Indicator Tape 1355

1. Device Name and Classification:

Common or Usual Name	Sterilization Process Indicator
Proprietary Name:	3M™ Comply™ Lead Free Steam Indicator Tape 1322
	3M™ Attest™ Lead Free Steam Indicator Tape 1355
Classification Name:	Indicator, physical/chemical sterilization process
Submission Number	K220564
Device Classification:	Class II, 21 CFR § 880.2800(b)
Product Code:	JOJ

2. Date of Preparation: May 18, 2022

3. Predicate Device:

K101528, Comply 1322 Lead Free Indicator Tape

4. Device Description:

3M™ Comply™ Lead Free Steam Indicator Tape 1322
The 3M™ Comply™ Lead Free Indicator Tape 1322 for steam sterilization consists of an adhesive, backing, and chemical indicator stripes. The adhesive is an aggressive, pressure-sensitive adhesive designed to adhere to a variety of wraps, including untreated woven (i.e., reusable 100% cotton and cotton/poly blends) and disposable non-woven, paper and paper/plastic wraps in order to secure the pack during steam sterilization. After sterilization, the tape is designed to remove easily and cleanly from untreated woven wraps. The backing is a beige colored crepe paper and provides the stretch needed for pack expansion during sterilization. The chemical indicator lines will show a visual color change from off-white/tan to darker color when exposed to a steam sterilization process. 3M™ Comply™ Lead Free Steam Indicator Tape is a Type 1 (Category e1) Process Indicator as categorized by ISO 11140-1:2014.
This Product Is Not Made With Natural Rubber Latex.

3M™ Attest™ Lead Free Steam Indicator Tape 1355
The 3M™ Attest™ Lead Free Steam Indicator Tape 1355 for disposable wraps consists of an adhesive, backing, and chemical indicator stripes. The adhesive is an aggressive, pressure-sensitive adhesive designed to adhere to a variety of disposable non-woven, paper and paper/plastic wraps in order to secure the pack during steam sterilization. The backing is blue-colored crepe paper and provides the stretch needed for pack expansion during sterilization. The chemical indicator lines will show a visual color change from off-white/tan to darker color when exposed to a steam sterilization process. 3M™ Attest™ Lead Free Steam Indicator Tape for Disposable Wraps is a Type 1 (Category e1) Process Indicator as categorized by ISO 11140-1:2014.
This Product Is Not Made With Natural Rubber Latex.

5. Indications for Use

3M™ Comply™ Lead Free Steam Indicator Tape 1322

3M™ Comply™ Lead Free Steam Indicator Tape 1322 is designed for use by a health care provider to accompany individual units (e.g. wrapped packs) to demonstrate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units. Use the 3M™ Comply™ Lead Free Steam Indicator Tape 1322 in steam process below:

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	15, 20, 30 minutes
Dynamic air-removal	270 °F/132°C	3, 3.5, 4, 5.5, 6, 9, 10, 15 minutes
Dynamic air-removal	273 °F/134°C	3, 3.5, 4 minutes
Dynamic air-removal	275 °F/135°C	3, 3.5, 4, 10 minutes

Use the 3M™ Comply™ Lead Free Steam Indicator Tape 1322 to demonstrate that packs have been exposed to the sterilization process. The 3M™ Comply™ Lead Free Steam Indicator Tape 1322 is designed to secure packs wrapped with untreated woven and disposable non-woven paper and paper/plastic wraps.

3M™ Attest™ Lead Free Steam Indicator Tape 1355

3M™ Attest™ Lead Free Steam Indicator Tape 1355 for disposable wraps is designed for use by a health care provider to accompany individual units (e.g., wrapped packs) to demonstrate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units. Use the 3M™ Attest™ Lead Free Steam Indicator Tape 1355 in steam process below:

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	15, 20, 30 minutes
Dynamic air-removal	270 °F/132°C	3, 3.5, 4, 5.5, 6, 9, 10, 15 minutes
Dynamic air-removal	273 °F/134°C	3, 3.5, 4 minutes
Dynamic air-removal	275 °F/135°C	3, 3.5, 4, 10 minutes

Use the 3M™ Attest™ Lead Free Steam Indicator Tape 1355 to demonstrate that packs have been exposed to the sterilization process. The 3M™ Attest™ Lead Free Steam Indicator Tape 1355 is designed to secure packs wrapped with disposable non-woven, paper and paper/plastic wraps.

6. Summary of Technological Characteristics compared to Predicate Device

<table>
<tr><th>Element</th><th>Subject Devices: K220564
3M™ Comply™ Lead Free Steam Indicator Tape 1322
3M™ Attest™ Lead Free Steam Indicator Tape 1355</th><th>Predicate Device (K101528)
Comply 1322 Lead Free Indicator Tape</th><th>Comparison</th></tr>
<tr><td>Indications for use</td><td>3M™ Comply™ Lead Free Steam Indicator Tape 1322 is designed for use by a health care provider to accompany individual units (e.g. wrapped packs) to demonstrate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units.

Use the 3M™ Comply™ Lead Free Steam Indicator Tape 1322 in steam process below:
<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>
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<tr><td>Gravity</td><td>275 °F/135°C</td><td>3, 10 minutes</td></tr>
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<tr><td>Dynamic air-removal</td><td>275 °F/135°C</td><td>3, 3.5, 4, 10 minutes</td></tr>
</table>
Use the 3M™ Comply™ Lead Free Steam Indicator Tape 1322 to demonstrate that packs have been exposed to the sterilization process. The 3M™ Comply™ 1322 Lead Free Steam Indicator Tape 1322 is designed to</td><td>The 3M™ Comply™ Lead Free Process Indicators for Steam are designed to demonstrate that the unit or load has been exposed to a steam sterilization process and to distinguish between processed and unprocessed units or loads.
3M Comply Lead Free Process indicators for Steam include:
• Comply 1322 Lead Free Indicator Tape
Use the 3M™ Comply™ Lead Free Process Indicators for Steam in steam sterilization processes described below.
<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 (wrapped)</td></tr>
<tr><td>Gravity</td><td>270 °F/132°C</td><td>≥3 minutes (unwrapped)
≥15 minutes (wrapped)</td></tr>
<tr><td>Gravity</td><td>275 °F/135°C</td><td>≥3 minutes (unwrapped)
≥10 minutes (wrapped)</td></tr>
<tr><td>Vacuum-assisted (prevacuum)</td><td>270 °F/132°C</td><td>≥3 minutes (unwrapped)
≥4 minutes (wrapped)</td></tr>
</table></td><td>Similar. The indications for use for the subject devices include specific cycle exposure times compared to the predicate with a maximum exposure time provided.

The subject devices may be utilized in a Dynamic Air Removal cycle compared to the predicate which is intended for “Vacuum-assisted (prevacuum)” cycles.

The subject device can be used for both wrapped and</td></tr>
</table>

<table>
<tr><th>Element</th><th>Subject Devices: K220564
3M™ Comply™ Lead Free Steam Indicator Tape 1322
3M™ Attest™ Lead Free Steam Indicator Tape 1355</th><th colspan="3">Predicate Device (K101528)
Comply 1322 Lead Free Indicator Tape</th><th>Comparison</th></tr>
<tr><td></td><td>secure packs wrapped with untreated woven and disposable non-woven paper and paper/plastic wraps.

3M™ Attest™ Lead Free Steam Indicator Tape 1355 for disposable wraps is designed for use by a health care provider to accompany individual units (e.g., wrapped packs) to demonstrate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units. Use the 3M™ Attest™ Lead Free Steam Indicator Tape 1355 in steam process below:
<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>
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<tr><td>Dynamic air-removal</td><td>275 °F/135°C</td><td>3, 3.5, 4, 10 minutes</td></tr>
</table>
Use the 3M™ Attest™ Lead Free Steam Indicator Tape 1355 to demonstrate that packs have been exposed to the sterilization process. The 3M™ Attest™ Lead Free Steam Indicator Tape 1355 is designed to secure packs</td><td colspan="3">
<table>
<tr><td>Vacuum-assisted (prevacuum)</td><td>273 °F/134°C</td><td>≥3.5 minutes (unwrapped)
≥4 minutes (wrapped)</td></tr>
<tr><td>Vacuum-assisted (prevacuum)</td><td>275 °F/135°C</td><td>≥3 minutes (wrapped or unwrapped)</td></tr>
</table>
</td><td>unwrapped loads.</td></tr>
</table>

Element	Subject Devices: K220564 3M™ Comply™ Lead Free Steam Indicator Tape 1322 3M™ Attest™ Lead Free Steam Indicator Tape 1355	Predicate Device (K101528) Comply 1322 Lead Free Indicator Tape	Comparison
	wrapped with disposable non-woven, paper and paper/plastic wraps.		
Indicator Type	Type 1 (Category e1) Process Indicators per ISO 11140-1: 2014	Class 1 Process Indicator per ANSI/AAMI/ISO11140-1:2005	Similar. Subject devices claim Type 1 (Category e1) Process Indicators per ISO 11140-1:2014
Device Design	The chemical indicator ink can be printed onto suitable paper substrates	The chemical indicator ink can be printed onto suitable paper substrates.	Same.
Indicator agent	Proprietary	Proprietary	Same.
Endpoint Specifications	Turns darker color when exposed to the sterilization process	A dark brown or black color on the indicator	Similar. Endpoint specification is updated for darker color which includes dark brown and black.
Endpoint Stability	6 months	6 months	Same.
Shelf life	18 months	18 months	Same.

7. Nonclinical Comparison to the Predicate Device

3M conducted performance tests in the newly claimed sterilization cycle and conditions, nonclinical testing was performance in accordance with :

- *FDA Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators,* issued December 19, 2003
- *ISO 11140-1:2014 Sterilization of healthcare products—Chemical Indicators—Part1: General requirements for Type 1 (e1) Process Indicators*.

Reference **Table 6.1** for summary of nonclinical testing.

There is no change to the indicator ink (fundamental technology) for the subject devices, therefore, the mechanism of action is identical. The description of the end point specification for the subject devices was updated from dark brown or black color to darker color for more customer clarity since the type 1 (e1) process indicator is intended to distinguish between exposed or not exposed to a steam sterilization process.

Table 6.1 Summary of Nonclinical Testing

Test Name	Purpose	Acceptance Criteria		Result
Saturated Steam Testing (ISO 11140-1: 2014, Type 1)	Confirm device meets the Type 1 process indicator for steam requirements. All testing is completed in a saturated steam Resistometer.	2.0 Min at 121°C	No change or change that is markedly different from the visible color change.	Pass
		10.0 Min at 121°C	Visible color change.	
		0.3 Min at 134°C	No change or change that is markedly different from the visible color change.	
		2.0 Min at 134°C	Visible color change.	
Dry Heat Testing (ISO 11140-1: 2014, Type 1)	Verify device requires the presence of saturated steam to turn to reach endpoint.	30 min at 140°C	No change or change that is markedly different from the visible color change.	Pass
Health Care Facility Simulated Use Testing	Confirm device provides acceptable performance in cleared customer use sterilization cycles.	Device reaches endpoint color when exposed to customer use cycles. Device does not reach endpoint when exposed to failing conditions in customer use cycles.		Pass
End Point Color Stability for 6 months	Confirm endpoint color stability for samples exposed to passing and failing conditions in a steam Resistometer.	Endpoint decision remains unchanged after 6 months.		Pass

7. Conclusion

The conclusions drawn from the nonclinical testing demonstrate that the subject devices, 3M™ Comply™ Lead Free Steam Indicator Tape 1322 and 3M™ Attest™ Lead Free Steam Indicator Tape 1355, are as safe, as effective, and performs as well as or better than the legally marketed predicate, 3M Comply 1322 Lead Free Steam Indicator Tape (K101528), Class II (21 CFR 880.2800), product code JOJ.