September 30, 2024

Kem Medical Products Corporation
Lisa Kruger
Vice President
400 Oser Avenue
Suite 2400
Hauppauge, New York 11788

Re: K241836
Trade/Device Name: Kem Medical Lead-free Chemical Indicators for Steam Sterilization
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: June 25, 2024
Received: June 25, 2024

Dear Lisa Kruger:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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: 2024.09.30 16:22:13 -04'00'

for: Christopher Dugard
Assistant Director
DHT4C: Division of Infection Control
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241836

Device Name

Kem Medical Lead-free Chemical Indicators for Steam Sterilization

Indications for Use *(Describe)*

The Kem Medical Lead-free Chemical Indicators for Steam Sterilization are designed for use by a health care provider 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. Use the Kem Medical Lead-free Chemical Indicators for Steam Sterilization in the validated steam sterilization processes described below:

*Gravity: 121 C/250 F - 30 minutes (wrapped/porous)
*Gravity: 132 C/270 F - 3 minutes (unwrapped/nonporous)
*Gravity: 132 C/270 F - 15 minutes (wrapped/porous)
*Gravity: 135 C/275 F - 3 minutes (unwrapped/nonporous)
*Gravity: 135 C/275 F - 10 minutes (wrapped/porous or unwrapped/nonporous, mixed load)
*Vacuum assisted (prevacuum): 132 C/270 F - 3 minutes (unwrapped/nonporous)
*Vacuum assisted (prevacuum): 132 C/270 F - 4 minutes (wrapped/porous)
*Vacuum assisted (prevacuum): 134 C/273 F - 4 minutes (wrapped/porous)
*Vacuum assisted (prevacuum): 135 C/275 F - 3 minutes (wrapped/porous or unwrapped/nonporous, mixed load)

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.

510(k) Summary

Prepared on: 2024-09-25

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Kem Medical Products Corporation
Applicant Address	400 Oser Avenue Suite 2400 Hauppauge NY 11788 United States
Applicant Contact Telephone	631-454-6565
Applicant Contact	Lisa Kruger
Applicant Contact Email	lisa@kemmed.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Kem Medical Lead-free Chemical Indicators for Steam Sterilization
Common Name	Sterilization process indicator
Classification Name	Indicator, Physical/Chemical Sterilization Process
Regulation Number	880.2800
Product Code(s)	JOJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K101528	3M Comply Process Indicators for Steam	JOJ

Device Description Summary

21 CFR 807.92(a)(4)

The Kem Medical Lead-free Chemical Indicators for Steam Sterilization are designed for use by a health care provider 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.

They are Type 1 Process Indicators per ISO 11140-1:2014 Sterilization of healthcare products-Chemical Indicators – Part 1 General Requirements, consisting of chemical indicator ink and paper substrate with a visual color change from light color (white/off-white) to dark color (cocoa/black) when exposed to a steam sterilization process.

The Kem Medical Lead-free Chemical Indicators for Steam Sterilization consist of indicator ink printed on a paper substrate with or without adhesive. The indicator ink is lead free. An example of this indicator is the ink printed onto adhesive-coated paper for autoclave labels, or “dots”, which are removed from a poly or paper backing for use.

Kem Medical manufactures indicators in various shapes and sizes printed on paper substrates with and without adhesive on the underside, and with or without labeling on each individual indicator.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Kem Medical Lead-free Chemical Indicators for Steam Sterilization are designed for use by a health care provider 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. Use the Kem Medical Lead-free Chemical Indicators for Steam Sterilization in the validated steam sterilization processes described below:

*Gravity: 121 C/250 F - 30 minutes (wrapped/porous)
*Gravity: 132 C/270 F - 3 minutes (unwrapped/nonporous)
*Gravity: 132 C/270 F - 15 minutes (wrapped/porous)
*Gravity: 135 C/275 F - 3 minutes (unwrapped/nonporous)
*Gravity: 135 C/275 F - 10 minutes (wrapped/porous or unwrapped/nonporous, mixed load)
*Vacuum assisted (prevacuum): 132 C/270 F - 3 minutes (unwrapped/nonporous)
*Vacuum assisted (prevacuum): 132 C/270 F - 4 minutes (wrapped/porous)
*Vacuum assisted (prevacuum): 134 C/273 F - 4 minutes (wrapped/porous)
*Vacuum assisted (prevacuum): 135 C/275 F - 3 minutes (wrapped/porous or unwrapped/nonporous, mixed load)

Indications for Use Comparison 21 CFR 807.92(a)(5)

Indications for Use for the Kem Medical Lead-free Chemical Indicators for Steam Sterilization are the same as the Predicate Device, the 3M Comply Lead-free Indicator Tape for Steam Sterilization. They are both designed for use by a healthcare provider to accompany individual units or loads (wrapped or unwrapped packs) to demonstrate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units or loads. For use in validated 121 – 135 degrees Celsius (250 – 275 degrees Fahrenheit) steam sterilization processes.

Technological Comparison 21 CFR 807.92(a)(6)

Technological Characteristics Comparison Table

Element	Subject Device (K241836)	Predicate Device (K101528)	Comparison
Intended Use	Process indicator for steam sterilization	Process Indicator for steam sterilization	Same
Product Code	JOJ	JOJ	Same
Regulation	21 CFR§ 880.2800	21 CFR§ 880.2800	Same
Indications for Use	The Kem Medical Lead-free Chemical Indicator for Steam Sterilization are designed for use by a health care provider 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. Use the Kem Medical Lead-free Chemical Indicators for Steam Sterilization in the validated steam sterilization processes described below:	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 68200 Lead Free Record Card * Comply 1 322 Lead Free Indicator Tape * Lead Free Test Pack Labels to be used on test packs including the following - Comply 4 13 80 Steam-Plus Test Pack - Comply 4 1360 Steam Test Pack -3M Attest™ 1276 Steam	Same

	*Gravity: 121 C/250 F - 30 minutes (wrapped/porous) *Gravity: 132 C/270 F - 3 minutes (unwrapped/nonporous) *Gravity: 132 C/270 F - 15 minutes (wrapped/porous) *Gravity: 135 C/275 F - 3 minutes (unwrapped/nonporous) *Gravity: 135 C/275 F - 10 minutes (wrapped/porous or unwrapped/nonporous, mixed load) *Vacuum assisted (prevacuum): 132 C/270 F - 3 minutes (unwrapped/nonporous) *Vacuum assisted (prevacuum): 132 C/270 F - 4 minutes (wrapped/porous) *Vacuum assisted (prevacuum): 134 C/273 F - 4 minutes (wrapped/porous) *Vacuum assisted (prevacuum): 135 C/275 F - 3 minutes (wrapped/porous or unwrapped/nonporous, mixed load)	Test Pack - 3M Attest™ 1296 Steam Test Pack - 3M Attest™ 4 1382 Steam-Plus Test Pack - Comply 1233LF, 001 32LF, 0013 5LF Bowie Dick Test Packs	
Intended Use	Process indicator for steam sterilization	Process indicator for steam sterilization	Same
Indicator Agent	Lead-free Steam Indicator Ink	Lead Free Steam Indicator Ink	Same
Endpoint Specification	Cocoa/Black color change	Dark brown/black color change	Different ink chemical composition
Endpoint Stability	8 months	6 months	Different
Shelf Life	3 years from date of manufacture, validated real time at 0, 1, 2, 3 years	18 months from date of manufacture	Different validation testing schedule

Non-Clinical and/or Clinical Tests Summary & Conclusions **21 CFR 807.92(b)**

Non-Clinical Testing

Qualification of the Kem Medical Products Type 1 Chemical Indicators for Steam Sterilization was performed by True Indicating LLC for 0-, 1-, 2- and 3-years real time. Testing was done to demonstrate that the CI's (Chemical Indicator's) performance meets the requirements defined in ISO 11140-1: 2014 Sterilization of Healthcare Products- Chemical Indicators- General Requirements for a Type 1 Chemical Indicator, and to determine substantial equivalence to the 3M Comply Lead Free Indicator Tape for Steam Sterilization. The CIs are for use as an external or internal chemical indicator in monitoring exposure to conditions of steam sterilization for 121°C – 135°C gravity and pre-vacuum sterilizer cycles.

Cycles for validation testing included BIER Vessel runs, with "pass/fail" criteria, of Saturated Steam 121°C for 2 minutes "fail" and 10 minutes "pass", Saturated Steam 132°C, 134°C and 135°C for 0.3 minutes "fail" and for 2 minutes "pass". Autoclave cycles were also used to test for reaction to Dry Heat 140°C for 30 minutes, and

performance in the following standard autoclave cycles:

Autoclave Pre- vac cycle 132°C for 3 minutes, Pre-vac cycle 132°C for 4 minutes, Pre-vac cycle 134°C for 3 minutes, Pre-vac cycle 135°C for 3 minutes; and Autoclave Gravity cycle 121°C for 30 minutes, Autoclave Gravity cycle 132°C for 15 minutes, Autoclave Gravity cycle 135°C for 10 minutes. Failure cycles were run for Pre-vac 132°C for 0 minutes and Pre-vac 135°C for 0 minutes.

Chemical indicator results for all testing performed under the validation protocol met the acceptance criteria listed and as required in ISO 11140-1:2014 for Type 1 chemical indicators to achieve the target 3-year shelf life. All indicators exposed to either BIER sterilization parameters at "pass" test criteria (121°C for 10 minutes and at 132°C, 134°C and 135°C for 2 minutes) showed a dark color change. All indicators exposed to either BIER sterilization parameters at "fail" test criteria (121°C for 2 minutes and at 132°C, 134°C and 135°C for .3 minutes) and dry heat (140o C for 30 minutes) showed either no color change or a slight color change. All samples also met the endpoint/color change requirements per the ISO standard.

Summary of Non-Clinical Testing

Test	Purpose	Acceptance Criteria		Result
Saturated Steam Testing; ISO 11140-1:2014	Meets the requirements for Type I process indicator for steam.	2 min at 121 °C	No change or change that is markedly different from the visible color change	Pass
		10 min at 121 °C	Visible color change	
		0.3 min at 132 °C / 134 °C /135 °C	No change or change that is markedly different from the visible color change	
		2 min at 132 °C / 134 °C /135 °C	Visible color change	
Standard Autoclave cycles	Meets performance criteria in standard autoclave cycles	Endpoint color reached when exposed to standard autoclave cycles. Endpoints color not reached when exposed to failing conditions in autoclave cycles.		Pass
Dry heat	Verify device requires the presence of saturated steam to turn to reach endpoint	30 min at 140 °C	No change	Pass
Transference ISO 11140-1:2014	Demonstrate the chemical indicators do not bleed or offset to substrate which it's applied according to	The chemical indicators shall not offset or bleed, penetrate the substrate to which it is applied, or materials in which it is in contact before, during or after the sterilization cycles for which it is designed		Pass
Endpoint color stability	Endpoint color maintained	Endpoint color remained unchanged for 8 months		Pass

Clinical Testing

Not Applicable

Conclusion

The conclusions drawn from the nonclinical testing demonstrate that the subject device, Kem Medical Lead-Free Chemical Indicators for Steam Sterilization, are as safe, as effective and performs as well as or better than the legally marketed predicate, 3M Comply Process Indicators for Steam, K101528.