March 1, 2019

Kem Medical Products Corp.
Douglas Kruger
President/CEO
400 Broadhollow Road, Suite 2
Farmingdale, New York 11735

Re: K181788
Trade/Device Name: 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: January 17, 2019
Received: January 18, 2019

Dear Douglas 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 (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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K181788

Device Name
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.

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

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510(k) Summary
For
Kem Medical Lead-free Chemical Indicators for Steam Sterilization

K181788

Date of Submission: February 28, 2019

Submission Number: K181788

Contact/Owner:
Douglas Kruger
President/CEO
Kem Medical Products Corp.
400 Broadhollow Road, Suite 2
Farmingdale, NY 11735
Phone: (631) 454-6565
Fax: (631) 454-8083
Email: dougk@kemmed.com

Trade Name: Lead-free Chemical Indicators for Steam Sterilization

Common Name: Sterilization Process Indicator for Steam

Classification Name: Indicator, Physical/Chemical Sterilization Process
(21 CFR800.2800, Product Code JOJ)

Predicate Device: 3M Comply Lead Free Process Indicators for Steam, K101528

There have not been any prior submissions for this device.

Device Summary: The Kem Medical Lead-free Chemical Indicators for Steam Sterilization provide immediate confirmation of the sterilization process. The indicator ink is lead-free and can be printed onto suitable paper substrates. As an example, the ink is printed onto adhesive-coated paper for autoclave labels, or "dots", which are removed from a poly or paper backing for use.

Technological Comparison: The predicate and our premarket device consist of chemical indicator ink printed onto paper with and without adhesive. The Kem Medical Lead-free Chemical Indicators for Steam Sterilization have the same technological characteristics of the predicate device (3M Comply Lead Free Process Indicators for Steam cleared under K101528), in design, material, chemical composition, and performance characteristics. A stated purpose of the predicate device submission was to replace the lead ink in the Comply Autoclave Tape.

Table 1- Comparison of the New Device to the Predicate

ELEMENT	NEW DEVICE K181788	PREDICATE (3M) K101528
Intended use:	process indicator for steam sterilization	process indicator for steam sterilization
Device design Aspects:	Paper dot/strip/card printed with bismuth sulfide based chemical indicator ink	Paper tape/card printed with bismuth sulfide based chemical indicator ink
Indicator agent:	Lead-free Steam Indicator Ink	Lead-free Steam Indicator Ink
Sterilization method and cycles:	*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)	*Gravity: 121 C/250 F - 30 minutes (wrapped) *Gravity: 132 C/270 F - 3 minutes (unwrapped) *Gravity: 132 C/270 F - 15 minutes (wrapped) *Gravity: 135 C/275 F - 3 minutes (unwrapped) *Gravity: 135 C/275 F - 10 minutes (wrapped) *Vacuum assisted (prevacuum): 132 C/270 F - 3 minutes (unwrapped) *Vacuum assisted (prevacuum): 132 C/270 F - 4 minutes (wrapped) *Vacuum assisted (prevacuum): 134 C/273 F - 3.5 minutes (unwrapped) *Vacuum assisted (prevacuum): 134 C/273 F - 4 minutes (wrapped)

		*Vacuum assisted (prevacuum): 135 C/275 F - 3 minutes (wrapped or unwrapped)
Endpoint specifications:	Dark brown/black color change	Dark brown/black color change
Shelf-life:	1 year from date of manufacture	18 months from date of manufacture
Performance Standards:	An independent study by Lexamed® confirms that Kem Medical Lead-free Chemical Indicators met the requirements defined in ISO 11140-2014-1;2014 Sterilization of healthcare products-Chemical Indicators – Part 1 General Requirements, including: • Data supporting endpoints with pass/fail criteria • Data supporting endpoint color stability • Data supporting integrator parameters • Data supporting shelf-life	Testing that was conducted met the process indicator requirements of the FDA's Premarket Notification (510K) Submissions for Chemical Indicators: Guidance for Industry and FDA Staff, Dec. 19, 2003 and ANSI/AAMI/ISO 11140-1:2005 Sterilization of health care products-Chemical Indicators, Part 1: General Requirements.

Indications for Use: 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:

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*Vacuum assisted (prevacuum): 135 C/275 F - 3 minutes (wrapped/porous or unwrapped/nonporous, mixed load)

Summary for Non-Clinical Testing:

The Kem Medical Lead-free Chemical Indicators for Steam Sterilization meet all ISO 11140-1:2014 performance criteria for Type 1 steam sterilization indicators. All BIER Steam Sterilizer cycles resulted in acceptable pass/fail criteria for all temperatures and times specified. Full autoclave cycles for both Gravity and Pre-vacuum were performed showing acceptable results for all temperatures and times specified. Dry heat, Color Change Stability, and Transference/Migration testing also resulted in acceptable results for all performance criteria of 11140-1:2014. The condition of the CI color change after exposure to a steam sterilization process remained unchanged for a period of not less of 6 months from the date of exposure.

The Lexamed® study results demonstrated the Kem Medical Lead-free Type 1 Chemical Indicator can be used as an external or internal chemical indicator for use in monitoring exposure to conditions of steam sterilization for the indicated gravity and pre-vacuum sterilizer cycles and comply with all applicable requirements defined in ISO 11140-1:2014, *Sterilization of healthcare products- Chemical Indicators- Part 1 General Requirements*.

Conclusion: The conclusions drawn from the nonclinical and clinical tests demonstrate that 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 devices cleared under K101528.