May 28, 2026

Dukal LLC
William Bagnasco
Sr. Director of Quality Assurance & Regulatory Affairs
2 Fleetwood Court
Ronkonkoma, New York 11779

Re: K252823
Trade/Device Name: Dukal Crepe Paper Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: April 22, 2026
Received: April 22, 2026

Dear William Bagnasco:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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: 2026.05.28 15:22:05 -04'00'

Stephen Anisko
Acting 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

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.

510(k) Number *(if known)*
K252823

Device Name
Dukal Crepe Paper Sterilization Wrap

Indications for Use *(Describe)*
The Dukal Crepe Paper sterilization wraps are intended to be used to enclose another medical device that is to be sterilized by a healthcare provider using:

• In 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131˚F / 55˚C and 40-80% relative humidity for 120 minutes.
o The wrap was validated for aeration times for EO sterilization of 24 hours at 40.0˚C.

Dukal Crepe Paper sterilization wraps are intended to allow sterilization of the enclosed medical device(s), and also to maintain sterility of the enclosed device(s) until opened. The devices are intended for over-the-counter use and are single use disposable sterilization wraps.

Dukal Crepe Paper Sterilization Wrap Models	**Intended Loads**	**Maximum Wrapped Package Content Weights Used in Sterility Maintenance Validation Study**	**Descriptions of Loads Used in Sterility Maintenance Validation Study**
Dukal Crepe Paper Sterilization Wrap (60gsm)	Fabric (for example: cloth gowns, towel packs, and similar devices)	6 lbs.	44 huck towels (17”x26”)
	Metal (for example: general use metal medical instruments, delicate sharps, including those with hinges and mated surfaces)	25 lbs.	4 tray liners 20”x25” stacked 10”x10”x2-1/2” tray containing 23 lbs. of metal mass

Note: The loads used in each Sterility Validation Study corresponded to the maximum wrapped package content weights in the above table.

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.

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510(k) SUMMARY
510(k) Premarket Notification for Dukal Crepe Paper Sterilization Wrap
K252823

1. **Submitter**: Dukal LLC
   2 Fleetwood Court
   Ronkonkoma NY 11779
   Phone: 631-656-3800
   Fax: 631-656-3810

2. **FDA Registration Number**: 2435946

3. **Regulatory Affairs Contact**: William Bagnasco
   Senior Director of Quality Assurance & Regulatory Affairs
   2 Fleetwood Court
   Ronkonkoma NY 11779
   Telephone Number: 631-468-6820
   Fax Number: 631-656-3810

4. **Date Summary Prepared**: May 28, 2026

5. **Name of Device**: Dukal Crepe Paper Sterilization Wrap

6. **Trade Name**: Dukal Crepe Paper Sterilization Wrap

7. **Common/Classification Name**: Sterilization Wrap

8. **Regulation Number**: 21 CFR 880.6850

9. **Device Class**: Class II

10. **Regulation Name**: Sterilization Wrap

11. **Product Code**: FRG

12. **Predicate Device**:
    a. Sterisheet Sterilization Wrap
       i. K200335
       ii. Cleared: 11/12/2020

13. **Reference Device**:
    a. Dukal SMS Sterilization Wrap
       i. K233262
       ii. Cleared: 03/22/2024

14. Device Description: Dukal Crepe Paper One Layer Sterilization Wrap is comprised of a single sheet or one layer.
In accordance with standard hospital practices, two sheets are used to wrap a medical device or a collection of medical devices for sterilization. When wrapping with the Dukal Crepe Paper Sterilization Wrap, two sheets are required. Dukal Crepe Paper Sterilization Wrap allows for the use of the sequential double-wrapping technique and also allows for a sterilized pack to be opened aseptically.

15. Packaging: The packaging material of the inner bag consists of transparent polyethylene (PE).

16. Indications for Use:

The Dukal Crepe Paper sterilization wraps are intended to be used to enclose another medical device that is to be sterilized by a healthcare provider using:

- In 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131˚F / 55˚C and 40-80% relative humidity for 120 minutes.
    - The wrap was validated for aeration times for EO sterilization of 24 hours at 40.0˚C.

Dukal Crepe Paper Sterilization Wraps are intended to allow sterilization of the enclosed medical device(s), and also to maintain sterility of the enclosed device(s) until opened. The devices are intended for over-the-counter use and are single use disposable sterilization wraps.

Dukal Crepe Paper Sterilization Wrap Models	**Intended Loads**	**Maximum Wrapped Package Content Weights Used in Sterility Maintenance Validation Study**	**Descriptions of Loads Used in Sterility Maintenance Validation Study**
Dukal Crepe Paper Sterilization Wrap (60gsm)	Fabric (for example: cloth gowns, towel packs, and similar devices)	6 lbs.	44 huck towels (17”x26”)

	Metal (for example: general use metal medical instruments, delicate sharps, including those with hinges and mated surfaces)	25 lbs.	4 tray liners 20”x25” stacked 10”x10”x2-1/2” tray containing 23 lbs. of metal mass

Note: The loads used in each Sterility Validation Study corresponded to the maximum wrapped package content weights in the above table.

17. Comparison of Technological Characteristics:

Element of Comparison	**Predicate Device-Sterisheet Sterilization Wrap K200335**	**Reference Device-Dukal SMS Sterilization Wrap K233262**	**Subject Device-Dukal Crepe Paper Sterilization Wrap K252823**	**Comparison**
Indications for Use	Sterisheet Sterilization Wraps are single use non-woven sterilization wraps intended to enclose medical devices that are to be sterilized at a healthcare facility. They are used in 3-hour and 6-hour gas exposures at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer.	Dukal SMS sterilization wraps are intended to be used to enclose another medical device that is to be sterilized by a healthcare provider using: In a steam sterilization pre-vacuum cycle at 270˚F / 132˚C for 4 minutes -Models 100, 200 and 300 were validated for	The Dukal Crepe Paper sterilization wraps are intended to be used to enclose another medical device that is to be sterilized by a healthcare provider using:	Subject Device Similar to K233262

		dry times of 20 minutes; models 400, 500 and 600 were validated for dry times of 30 minutes. In 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131˚F / 55˚C and 40-80% relative humidity for 60 minutes. The wrap was validated for aeration times for EO sterilization of 16 hours at 40.0˚C. Dukal SMS sterilization wraps are intended to allow sterilization of the enclosed medical device(s), and also to maintain sterility of the enclosed device(s) until opened. The devices are intended for over-the-counter use and are single use disposable sterilization wraps. Test results validated that the Dukal SMS sterilization wraps allowed sterilization of the enclosed medical device(s) by ethylene oxide sterilization and by pre-vacuum cycles.	• In 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131˚F / 55˚C and 40-80% relative humidity for 120 minutes. • The wrap was validated for aeration times for EO sterilization of 24 hours at 40.0˚C. Dukal Crepe Paper Sterilization Wraps are intended to allow sterilization of the enclosed medical device(s), and also to maintain sterility of the enclosed device(s) until opened. The devices are intended for over-the-counter use and are single use disposable sterilization wraps.	

Materials	Cellulose, synthetic fibers (polypropylene), and synthetic binders	Polypropylene and polyethylene with blue and violet pigments.	Pulp (cellulose fiber), water, papermaking additives	Subject Device similar to K200335
Regulation Classification Product Code	*Regulation Number*: 21 CFR 880.6850 *Classification/Commo n Name*: Sterilization Wrap *Regulatory Class*: II *Product Code*: FRG	Identical	Identical	Identical
Device Design	Cellulose allows EO to pass through the wrap but prevents microorganisms from crossing through the wrap, providing a microbial barrier for the wrapped devices after sterilization; Synthetic fibers increase mechanical resistance. Synthetic binders enhance drapeability, strength, softness, and fluid repellency.	Two sheets of medium blue nonwoven Polypropylene fabric. Each sheet of fabric is composed of three thermally- bonded layers consisting of a Meltblown polypropylene layer surrounded by Spunbond polypropylene layers (SMS).	Cellulose allows EO to pass through the wrap but prevents microorganisms from crossing through the wrap, providing a microbial barrier for the wrapped devices after sterilization; materials used increase mechanical resistance; and enhance drapeability, strength, softness, and fluid repellency.	Subject Device similar to K200335
Wrap Shape	Square or rectangular	Identical	Identical	Identical
Configuration in Load	Double sequential envelope wrap is recommended	Identical	Identical	Identical
Prescription vs OTC	OTC	OTC	OTC	Identical
Single Use vs. Reusable	Single use only	Single use only	Single use only	Identical
Shelf Life	5 years	N/A	8 months	Different
Maintenance of Package Sterility	6 months	6 months	2 months	Similar

18. Summary of Non-Clinical Testing Results

Summary of bench tests performed to demonstrate safety and effectiveness of Dukal Crepe Paper Sterilization Wraps

Test	Purpose	Acceptance Criteria	Results
Physical and Chemical Properties	To evaluate the package integrity after EO sterilization	Various standards for various properties. For example, ISO 536 for Substance, ISO 5636-3 for Permeability, EN 868-2 for Fluorescence and Water repellency	There was no effect on the physical and chemical properties after EO sterilization.
Bacterial Filtration Efficiency and Germ Proofness dry challenge test	To demonstrate that the sterilization wrap provides a microbial barrier property	Bacterial Filtration Efficiency (ASTM F2101) Germ Proofness dry challenge test (DIN 58953-6)	Passed.
Material Compatibility	To demonstrate sterilization wrap is suitable for use in EO sterilization	The physical, chemical, and microbial barrier properties of sterilization wrap are compatible for intended use in EO sterilization per ISO 10993	The ability of the wraps to act as a microbial barrier was unaffected, and the contents of the packs remained sterile after EO sterilization.
Biocompatibility	To demonstrate that sterilization wrap provides reasonable assurance for safety	Biological evaluation (Cytotoxicity, Sensitization and Irritation Test) per ISO 10993	Under the conditions of the study, the device did not show cytotoxicity potential. Under the conditions of the study, the irritation response category of the device was classified as negligible. Under the conditions of the study, the device showed no significant evidence of causing delayed dermal contact sensitization.

EO/ECH Sterilization Residuals	To demonstrate that the EO/ECH residuals meet the requirements of ISO 10993-7.	EO/ECH evaluation per ISO 10993-7	Meets ISO 10993-7 requirements.
Sterilant Penetration	To demonstrate sterilization wrap allows sterilization of the wrapped devices in half cycle testing	Inactivation of 6-Log biological indicators at the worst-case location in the device load wrapped in the sterilization wrap for all the testing performed	Passed.
Maintenance of Package Sterility	To demonstrate sterilization wrap maintains sterility of the medical device	The sterilized devices wrapped in sterilization wrap remain sterile	Sterility was maintained for 2 months for wrapped devices after sterilization.

Non-Clinical Test Results:

The subject sterilization wraps were tested and found conformance with the following standards:

- ISO 10993-7:2008 - Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals
- ISO 10993-5:2009/(R)2014 - Biological Evaluation of Medical Devices-Part 5: Tests for in vitro Cytotoxicity
- ISO 10993-10:2021 - Biological Evaluation of Medical Devices-Part 10: Tests for Skin Sensitization
- ISO 10993-23: 2021 - Biological Evaluation of Medical Devices-Part 23: Tests for Irritation
- ISO 6588-2:2021 Paper, board and pulps—Determination of pH of Aqueous Extracts—Part 2: Hot Extraction
- ASTM F1980: 2021 - Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
- ISO 11607-1: 2019 - Packaging for Terminally Sterilized Medical Devices Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems
- AAMI TIR12:2020 (R2023) - Designing, Testing, and Labeling Medical Devices Intended For Processing By Health Care Facilities: A Guide for Device Manufacturers
- ANSI/AAMI ST79:2017/(R)2022 - Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities

- ISO 1974: 2012 - Paper-Determination of tearing resistance - Elmendorf method
- ISO 1924-3: 2005 -Paper and board-Determination of tensile properties, Part 3 Constant rate of elongation method (100 mm/min)
- ISO 534: 2011 - Paper and board-Determination of thickness, density, and specific volume
- ISO 536: 2019 - Paper and board-Determination of grammage
- ISO 2758: 2014 - Paper-Determination of bursting strength
- ASTM F2101-23 - Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- ASTM F1608-21 - Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)
- ISO 5636-5:2013 - Paper and board - Determination of air permeance and air resistance (medium range) - Part 5: Gurley method
- EN 868-2: 2017 - Packaging for terminally sterilized medical devices. Part 2: Sterilization wrap - Requirements and test methods
- ISO 2493-1: 2010 - Paper and board-Determination of bending resistance-Part 1: Constant rate of deflection
- ASTM D257-14 (Reapproved 2021) - Standard Test Methods for DC Resistance or Conductance of Insulating Materials
- 16 CFR Part 1610 - Standard for the Flammability of Clothing Textiles
- AATCC TM193(2017) - Test Method for Aqueous Liquid Repellency: Water/Alcohol Solution Resistance
- USP-NF 2022 <71> - Sterility test

19. Summary for Clinical Testing: Not Applicable

20. Conclusion:

The conclusion drawn from the nonclinical tests demonstrates that the subject device, Dukal Crepe Paper sterilization wrap, included in this 510(k) submission, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K200335.