March 22, 2024

Dukal LLC
Megan Quevedo
Supervisor of Quality and Regulatory Affairs
2 Fleetwood Court
Ronkonkoma, New York 11779

Re: K233262
Trade/Device Name: Dukal SMS Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: February 23, 2024
Received: February 23, 2024

Dear Megan Quevedo:

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.

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: 2024.03.22 09:06:46 -04'00'

for Christopher Dugard
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233262

Device Name
Dukal SMS Sterilization Wrap

Indications for Use *(Describe)*
The 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
o Models 100, 200 and 300 were validated for 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.
o 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) for 6 months or 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.

These models of the Dukal SMS sterilization wrap have been validated for use with the ethylene oxide and pre-vacuum cycles listed in below 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.

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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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Dukal SMS Sterilization Wrap Recommendations for Use with the Pre-Vacuum Steam or Ethylene Oxide[1]

Dukal SMS Sterilization Wrap Models	Intended Loads	Maximum Wrapped Package Content Weights Used in Sterility Maintenance Validation Study[2]	Descriptions of Loads Used in Sterility Maintenance Validation Study[2]
Model 100	Very Light Weight Package (for example: towel packs or batteries)	3 lbs.	Pre-Vacuum Steam and EO: 20 huck towels (17”x26”)
Model 200	Light Weight Package (for example: standard linen packs or telescope with light cord)	6lbs.	Pre-Vacuum Steam and EO: 2 huck towels (17”x26”) 2 fluid resistant U-drapes (68”x109”) 1 fluid resistant universal bar drape (70”x108”)
Model 300	Light to Moderate Weight Package (for example: general use medical instruments)	9 lbs.	Pre-Vacuum Steam: 15 huck towels (17”x26”) 1 small fluid resistant drape (60”x76”) 5 lbs. of metal mass EO: 16 huck towels 2 fluid resistant large drapes (76”x 100”) 1 fluid resistant small drape (76”x60”) 1 fluid resistant table cover (60” x 90”)
Model 400[3]	Moderate to Heavy Weight Package (for example: general use medical instruments)	13 lbs.	Pre-Vacuum Steam and EO: 4 tray liners 20”x25” stacked 10”x10”x2 1/2” tray containing 11 lbs. of metal mass
Model 500[3]	Heavyweight Package (for example: general use medical instruments)	17 lbs.	Pre-Vacuum Steam and EO: 4 tray liners 20”x25” stacked 10”x10”x2 1/2” tray containing 15 lbs. of metal mass

Model 600[3]	Very Heavy Weight Package (for example: general use medical instruments)	25 lbs.	Pre-Vacuum Steam and EO: 4 tray liners 20”x25” stacked 10”x10”x2 1/2” tray containing 23 lbs. of metal mass

[1] *Individual results may differ due to factors such as variations in handling practices, wrapping techniques, and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap model is most appropriate for each intended use.*

[2] *It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore, it is recommended to not exceed the number, weight, and size of individual content types that were validated for the Sterilization Wraps (i.e.: the number and size of the fluid resistant linens or the weight of the metal mass).*

[3] *The 400, 500 and 600 model wraps were validated for sterilant penetration with 3 lbs. of non-fluid resistant linen, and it is recommended to not exceed 3 lbs. of non-fluid resistant linen in sterilization cycles with these models. It is recommended that the user not include fluid-resistant linens in 400, 500 and 600 model wraps, as use of such fluid resistant materials has not been evaluated with these models.*

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

Note: The trays used for the pre-vacuum studies were not the same as those used for the EO validation. Therefore, different amounts of metal mass were used in each study to achieve the maximum recommended wrapped package content weights for each wrap model.

K233262 510(k) SUMMARY
510(k) Premarket Notification for Dukal SMS Sterilization Wrap

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**: Megan Quevedo
   Quality and Regulatory Affairs Supervisor
   2 Fleetwood Court
   Ronkonkoma NY 11779
   Telephone Number: 631-656-3800 ext. 133
   Fax Number: 631-656-3810

4. **Date Summary Prepared**: February 22, 2024

5. **Name of Device**: Dukal SMS Sterilization Wrap

6. **Trade Name**: Dukal SMS 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**:
    - Kimguard Sterilization wrap, models KC100, KC200, KC300, KC400, KC500 and KC600
      - K082554
      - Cleared: 05/01/2009
    - Kimguard One-Step Sterilization Wrap
      - K143053
      - Cleared: 04/03/2015

13. Device Description: Models 100, 200, 300, 400, 500 and 600
Available in one or two sheets of 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).

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

15. Indications for Use:

The 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 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) for 6 months or 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.

These models of the Dukal SMS sterilization wrap have been validated for use with the ethylene oxide and pre-vacuum cycles listed in below table:

Dukal SMS Sterilization Wrap Recommendations for Use with the Pre-Vacuum Steam or Ethylene Oxide[1]

Dukal SMS Sterilization Wrap Models	**Intended Loads**	**Maximum Wrapped Package Content Weights Used in Sterility Maintenance Validation Study**[2]	**Descriptions of Loads Used in Sterility Maintenance Validation Study**[2]
Model 100	Very Light Weight Package (for example: towel packs or batteries)	3 lbs.	Pre-Vacuum Steam and EO: 20 huck towels (17”x26”)
Model 200	Light Weight Package (for example: standard linen packs or telescope with light cord)	6lbs.	Pre-Vacuum Steam and EO: 2 huck towels (17”x26”)

			2 fluid resistant U-drapes (68”x109”) 1 fluid resistant universal bar drape (70”x108”)
Model 300	Light to Moderate Weight Package (for example: general use medical instruments)	9 lbs.	Pre-Vacuum Steam: 15 huck towels (17”x26”) 1 small fluid resistant drape (60”x76”) 5 lbs. of metal mass EO: 16 huck towels 2 fluid resistant large drapes (76”x 100”) 1 fluid resistant small drape (76”x60”) 1 fluid resistant table cover (60” x 90”)
Model 400[3]	Moderate to Heavy Weight Package (for example: general use medical instruments)	13 lbs.	Pre-Vacuum Steam and EO: 4 tray liners 20”x25” stacked 10”x10”x2 1/2” tray containing 11 lbs. of metal mass
Model 500[3]	Heavyweight Package (for example: general use medical instruments)	17 lbs.	Pre-Vacuum Steam and EO: 4 tray liners 20”x25” stacked 10”x10”x2 1/2” tray containing 15 lbs. of metal mass
Model 600[3]	Very Heavy Weight Package (for example: general use medical instruments)	25 lbs.	Pre-Vacuum Steam and EO: 4 tray liners 20”x25” stacked 10”x10”x2 1/2” tray containing 23 lbs. of metal mass

[1] *Individual results may differ due to factors such as variations in handling practices, wrapping techniques, and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap model is most appropriate for each intended use.*

[2] It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore, it is recommended to not exceed the number, weight, and size of individual content types that were validated for the Sterilization Wraps (i.e.: the number and size of the fluid resistant linens or the weight of the metal mass).

[3] The 400, 500 and 600 model wraps were validated for sterilant penetration with 3 lbs. of non-fluid resistant linen, and it is recommended to not exceed 3 lbs. of non-fluid resistant linen in sterilization cycles with these models. It is recommended that the user not include fluid-resistant linens in 400, 500 and 600 model wraps, as use of such fluid resistant materials has not been evaluated with these models.

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

Note: The trays used for the pre-vacuum studies were not the same as those used for the EO validation. Therefore, different amounts of metal mass were used in each study to achieve the maximum recommended wrapped package content weights for each wrap model.

16. Comparison of Technological Characteristics with the Predicate Devices:

Element of Comparison	**Predicate Device-K082554 Kimguard Sterilization wrap**	**Predicate Device-K143053 Kimguard One-Step Sterilization Wrap**	**Subject Device-Dukal SMS Sterilization Wrap**	**Comparison**
Indications for Use	KIMGUARD Sterilization Wrap is intended to be used to enclose another medical device that is to be sterilized by a healthcare provider by pre-vacuum steam at 270˚F / 132˚C for 4 minutes or by 100% ethylene oxide (EtO) with a concentration of 725-735 mg/L at 131˚F / 55˚C and 40-80% relative humidity for 60 minutes. The wrap is intended to allow sterilization of the enclosed medical device(s), and also to maintain sterility of the enclosed device(s)	KIMGUARD One-Step Sterilization Wrap (KC100, KC200) are intended to be used to enclose another medical device that is to be sterilized by a healthcare provider using: -Pre-vacuum steam at 270˚F / 132˚C for 4 minutes. The wrap was validated for dry times of 20 minutes for Models KC100, and KC200. -100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131˚F /	The 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 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.	Similar

	until opened. The wrap was validated for aeration times for EtO sterilization of 8 hours at 55˚C or 12 hours at 43.3˚C. The wrap was validated for dry times of 20 minutes for Models 100, 200, and 300 and for dry times of 30 minutes for models 400, 500, and 600. KIMGUARD Sterilization Wrap is not indicated for use for gravity steam sterilization.	55˚C and 40-80% relative humidity for 60 minutes. The wrap was validated for aeration times for EtO sterilization of 8 hours at 55˚C or 12 hours at 43.3˚C for Models KC100, and KC200. KIMGUARD One-Step Sterilization Wrap (KC100, KC200) are intended to allow sterilization of the enclosed medical device(s), and also to maintain sterility of the enclosed device(s) until opened. Test results validated that the KIMGUARD One-Step Sterilization Wraps (KC100,KC200) allowed sterilization of the enclosed devices by ethylene oxide sterilization and by pre-vacuum cycles.	-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.	
Regulation, Classification, Product Code	*Regulation Number*: 21 CFR 880.6850 *Classification/Common Name*: Sterilization Wrap *Regulatory Class*: II *Product Code*: FRG	*Regulation Number*: 21 CFR 880.6850 *Classification/Common Name*: Sterilization Wrap *Regulatory Class*: II *Product Code*: FRG	*Regulation Number*: 21 CFR 880.6850 *Classification/Common Name*: Sterilization Wrap *Regulatory Class*: II *Product Code*: FRG	Same
Device Design	Two sheets of medium blue nonwoven Polypropylene fabric. Each sheet of fabric is composed of three thermally- bonded layers consisting of a Meltblown	Two sheets of medium blue nonwoven Polypropylene fabric. Each sheet of fabric is composed of three thermally- bonded layers consisting of a Meltblown	Available in one or two sheets of blue nonwoven Polypropylene fabric. Each sheet of fabric is composed of three thermally-bonded layers consisting of a Meltblown polypropylene layer surrounded by Spunbond	Similar

	polypropylene layer surrounded by Spunbond polypropylene layers (SMS).	polypropylene layer surrounded by Spunbond polypropylene layers (SMS).	polypropylene layers (SMS).	
Method for bonding SMS layers	Thermal bonding with round pin, hexagonal, triangle bond pattern ("daisy" pattern)	Thermal bonding with round pin, hexagonal, triangle bond pattern ("daisy" pattern)	Thermal bonding with line of one square inch pattern	Similar
Materials	Polypropylene with blue and white pigments and antistatic treatment	Polypropylene with blue and white pigments and antistatic treatment	Polypropylene and polyethylene with blue and violet pigments.	Similar
Models	6 basis weights models- Models KC100, KC200, KC300, KC400, KC500 and KC600	2 basis weights models- Models KC100 and KC200. KIMGUARD ONE-STEP Sterilization Wrap is comprised of two sheets of KIMGUARD Sterilization Wrap ultrasonically seamed on two edges. This allows for convenient wrapping with two sheets simultaneously.	6 basis weights models- Models 100, 200, 300, 400, 500 and 600 Dukal One-Step SMS Sterilization Wrap is comprised of two sheets of Dukal SMS Sterilization Wrap ultrasonically seamed on two edges. This allows for convenient wrapping with two sheets simultaneously.	Similar
Product Color and Sizes	Blue and white fabric, 9x9", 12x12", 15x15", 18x18", 20x20", 24x24", 30x30", 36x36", 40x40", 45x45", 48x48", 54x54", 54x72", 60x60"	Blue and white fabric, 9x9", 12x12", 15x15", 18x18", 20x20", 24x24", 30x30", 36x36", 40x40", 45x45", 48x48", 54x54", 54x72", 60x60"	Blue fabric, 9x9", 12x12", 15x15", 18x18", 20x20", 24x24", 30x30", 36x36", 40x40", 45x45", 48x48", 54x54", 54x72", 54x90", 60x60"	Similar
Prescription vs OTC	OTC	OTC	OTC	Same
Single Use vs. Reusable	Single use only	Single use only	Single use only	Same
Biocompatibility	Applicable parts of ISO 10993 – Biological evaluation of medical devices	Applicable parts of ISO 10993 – Biological evaluation of medical devices	Applicable parts of ISO 10993 - Biological evaluation of medical devices	Same

Maintenance of Package Sterility	Real-time testing following sterilization using pre-vacuum steam or Ethylene Oxide supports maintenance of package sterility for 30 days.	Real-time testing following sterilization using pre-vacuum steam or Ethylene Oxide supports maintenance of package sterility for 365 days.	Accelerated aging testing following sterilization using pre-vacuum steam or Ethylene Oxide supports maintenance of package sterility for 6 months.	Similar

Comparison Summary of Non-Clinical Testing Results

Test	**Predicate Device-K082554 Kimguard Sterilization wrap**	**Predicate Device-K143053 Kimguard One-Step Sterilization Wrap**	**Subject Device-Dukal SMS Sterilization Wrap**	**Comparison**
Material Compability, ISO 11607) & Premarket Noficaon 510(k) Submissions for Medical Sterilizaon Packaging Systems in Health Care Facilies; Dra Guidance for Industry and FDA, - - Basis weight, ASTM D3776/D3776M - Air permeability, ASTM D737 Compable - Material burst strength, ASTM D3786 - Grab Tensile strength, ASTM D5034 - Trapezoidal Tear strength, ASTM D5587	Compatible	Compatible	Compatible	Same

- Hydrostaðc Pressure, AATC127				
Sterilant Penetraðon (BI incubation)	BI result: Negative	BI result: Negative	BI result: Negative	Same
Maintenance of Package Sterility (ASTM F1608 & USP <71>)	No growth Real-time testing following sterilization using pre-vacuum steam or Ethylene Oxide supports maintenance of package sterility for 30 days.	No growth Real-time testing following sterilization using pre-vacuum steam or Ethylene Oxide supports maintenance of package sterility for 365 days.	No growth Accelerated aging testing following sterilization using pre-vacuum steam or Ethylene Oxide supports maintenance of package sterility for 6 months.	Similar
Biocompatibility-Cytotoxicity (ISO 10993-5), Irritation & Sensitization (ISO 10993-10)	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.	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.	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.	Same
EO Sterilization Residual (ISO 10993-7)	Meet requirements of ISO 10993-7	Meet requirements of ISO 10993-7	Meet requirements of ISO 10993-7	Same

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 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 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
- ASTM D3776/D3776M-20 Standard Test Method for Mass Per Unit Area (Weight) of Fabric
- ASTM D1683/D1683M-22 Standard Test Method for Failure in Sewn Seams of Woven Fabrics
- ASTM D5034-21 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
- ASTM D5587-15(2019) Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure
- ASTM D257-14 (Reapproved 2021) Standard Test Methods for DC Resistance or Conductance of Insulating Materials
- ASTM D3786/D3786M-18 Standard Test Method for Bursting Strength of Textile Fabrics-Diaphragm Bursting Strength Tester Method
- ISO 9073-10:2003 Textiles-Test methods for nonwovens -Part 10 Lint and other particles generation in the dry state
- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles
- AATCC TM193(2017) Test Method for Aqueous Liquid Repellency: Water/Alcohol Solution Resistance
- 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
- AATCC Test Method 127-2018 Water Resistance: Hydrostatic Pressure Test
- ASTM D737-18 Standard Test Method for Air Permeability of Textile Fabrics
- ASTM D4966-22 Standard Test Method for Abrasion Resistance of Textile Fabrics (Martindale Abrasion Tester Method)

- USP-NF 2022 <71> Sterility test
- ASTM F1608-21 Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)

Summary for Non-Clinical Testing:

Test Item	Test Standard Methods	Test Requirements	Test Results of Subject Device-Dukal SMS Sterilization Wrap	Remark
Basis Weight	ASTM D3776/ D3776M-20	100: 35gsm(±2gsm) 200: 45gsm (±2gsm) 300: 52gsm(±2gsm) 400: 60gsm(±2gsm) 500 70gsm(±2gsm) 600:75gsm(±2gsm)	100: 35gsm(±2gsm) 200: 45gsm (±2gsm) 300: 52gsm(±2gsm) 400: 60gsm(±2gsm) 500 70gsm(±2gsm) 600:75gsm(±2gsm)	Meets requirement
Seam Strength	ASTM D1683/D1683M-22	≥20N	≥20N	Meets requirement
Breaking Strength and Elongation	ASTM D5034-21	Breaking Strength MD≥45N CD≥30N Elongation MD≥20% CD≥20%	Breaking Strength MD≥45N CD≥30N Elongation MD≥20% CD≥20%	Meets requirement
Tearing Strength	ASTM D5587-15(2019)	MD≥10N CD≥7N	MD≥10N CD≥7N	Meets requirement
Surface Resistance	ASTM D257-14 (Reapproved 2021)	≤ 2*10^12 Ω	≤ 2*10^12 Ω	Meets requirement
Bursting Strength	ASTM D3786/D3786M-18	≥80 kPa	≥80 kPa	Meets requirement
Lint Generation	ISO 9073-10:2003	1.0~4.0 (Log 10)	1.0~4.0 (Log 10)	Meets requirement
Flammability	16 CFR Part 1610	Class 1	Class 1	Meets requirement

Aqueous Liquid Repellency	AATCC TM193(2017)	Grade 3 or above	Grade 3 or above	Meets requirement
Bacterial Filtration Efficiency (BFE)	ASTM F2101-23	≥50%	≥50%	Meets requirement
Hydrostatic Pressure	AATCC Test Method 127-2018	≥20 cmH2O	≥20 cmH2O	Meets requirement
Air Permeability	ASTM D737-18	≥20 ft^3/min/ ft^2	≥20 ft^3/min/ ft^2	Meets requirement
Abrasion Resistance	ASTM D4966-22	Grade 3 or above	Grade 3 or above	Meets requirement
Sterilant penetra&#65533;on-BI incubation	BI incubation	BI result: Negative	BI result: Negative	Meets requirement
Maintenance of Package Sterility-Sterility Test	USP-NF 2022 <71>	No growth	No growth	Meets requirement
Maintenance of Package Sterility-Microbial Aerosol Challenge	ASTM F1608-21	Average Spore Retained: ≥60%	Average Spore Retained: ≥60%	Meets requirement
Biocompatibility-Cytotoxicity, Irritation and Sensitization	ISO 10993-5:2009, ISO 10993-23: 2021, ISO 10993-10:2021	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	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.	Meets requirement

		dermal contact sensitization.		
EO Sterilization Residual	ISO 10993-7:2008	Meet requirements of ISO 10993-7	Meet requirements of ISO 10993-7	Meets requirement
pH Value	ISO 6588-2:2021	Non-Aged - Extract Appearance: Neither of the extracts shows blue color - pH: Meets acceptance criteria Aged 30 days - Extract Appearance: Neither of the extracts shows blue color - pH: Meets acceptance criteria	Non-Aged - Extract Appearance: Neither of the extracts shows blue color - pH: Meets acceptance criteria Aged 30 days - Extract Appearance: Neither of the extracts shows blue color - pH: Meets acceptance criteria	Meets requirement

Summary for Clinical Testing: Not Applicable

Conclusions: The conclusion drawn from the 510(k) from the nonclinical tests shall demonstrate that the subject devices included in the 510(k) submission, Dukal SMS sterilization wraps, are as safe, as effective, and perform as well as or better than the legally marketed predicate device cleared under K082554 (Kimguard Sterilization wrap, models KC100, KC200, KC300, KC400, KC500 and KC600) and K143053 (Kimguard One-Step Sterilization Wrap).