September 18, 2024

KM Corp.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Kannan Ave. STE 160
Irvine, California 92612

Re: K241123
Trade/Device Name: Perpak™ Sterilization Tyvek Pouch
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: September 2, 2024
Received: September 3, 2024

Dear Priscilla Chung:

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,

Christopher K. Dugard
-S

Christopher K. Dugard, M.S.
Assistant Director
THT4C1: Sterility Devices Team
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)*
K241123

Device Name
Perpak™ Sterilization Tyvek Pouch

Indications for Use *(Describe)*
The Perpak™ Sterilization Tyvek Pouch is intended to provide health care workers with an effective method to enclose devices intended for sterilization in the LOWTEM Crystal 120 Sterilizer. The device is intended to allow sterilization of enclosed devices and also to maintain sterility of the enclosed devices until used up to 3 years post sterilization.

Specifications

Type	Model name	Dimensions	Max load (Each material)	
			Metal (g)	Plastic (g)
Sterilization Pouch Flat	AOB00402	150mm×600mm	170	360
	AOB00164	100mm×350mm	70	10
	AOB00163	150mm×700mm	190	370
	AOB00162	150mm×550mm	130	300
	AOB00161	150mm×450mm	80	160
Sterilization Roll Flat	AOA00017	400mm×200M	155	355
	AOA00016	300mm×200M	140	340
	AOA00015	250mm×200M	100	330
	AOA00014	200mm×200M	100	310
	AOA00013	150mm×200M	80	160
	AOA00012	100mm×200M	70	10
	AOA00011	75mm×200M	50	10

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

(K241123)

This summary of 510(K) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 09/2/2024

1. Submitter/Applicant

KM Corp.
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2. U.S Agent/Contact Person

Priscilla Chung
LK Consulting Group USA, Inc.
18881 Von Karman Ave STE 160, Irvine CA 92612
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

Trade Name: Perpak™ Sterilization Tyvek Pouch
Common Name: Sterilization Wrap
Classification: Class II
Classification regulation: 21 CFR 880.6850
Product Code: FRG

4. Predicate Devices:

Sterilization Pouch/Roll Made with Tyvek® by SIGMA Medical Supplies Corp.(K180672)

5. Device Description:

The Perpak™ Sterilization Tyvek Pouch is intended to be used to contain medical devices to be terminally sterilized in the LOWTEM Crystal 120 Sterilization System. The medical devices are inserted into the Pouch/Roll, sealed, and then sterilized in the LOWTEM Crystal 120 Sterilization System. After completion of the sterilization process, the Pouch/Roll maintains sterility of the enclosed medical devices until the seal is opened up to 3 years post sterilization.

6. Indication for use:

The Perpak™ Sterilization Tyvek Pouch is intended to provide health care workers with an effective method to enclose devices intended for sterilization in the LOWTEM Crystal 120 Sterilizer. The device is intended to allow sterilization of enclosed devices and also to maintain sterility of the enclosed devices until used up to 3 years post sterilization.

Specifications

Type	Model name	Dimensions	Max load (Each material)	
			Metal (g)	Plastic (g)
Sterilization Pouch Flat	AOB00402	150mm×600mm	170	360
	AOB00164	100mm×350mm	70	10
	AOB00163	150mm×700mm	190	370
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	AOA00013	150mm×200M	80	160
	AOA00012	100mm×200M	70	10
	AOA00011	75mm×200M	50	10

7. Performance Tests

The following performance and shelf-life tests were performed and the test results passed the pre-set criteria, supporting the substantial equivalence to the predicate devices.

Test Method	Purpose	Acceptance Criteria	Results
ASTM F 1929; ISO 11607-1	Dye penetration Test (Seal Integrity Test)	No leaks	Pass
ASTM F88/F88M; ISO 11607-1	Seal Peel Test	> 0.6kg.f	Pass
ASTM F 2251	Thickness Variations	Film : 70 ± 10II ㎛ (0.07 ± 0.01mm) Tyvek : 89~282 ㎛ (0.089 ~ 0.282 mm)	Pass
ASTM D 503	Tensile strength of Tyvek®	Tensile strength: Spec > 117 N Elongation : Spec > 10%	Pass
ASTM D882	Tensile strength of plastic film	1) Spec > 300 kg·f/cm^2 2) Elongation : Spec > 50 %	Pass
ASTM F1140	Burst Strength	> 1kg·f/ cm^2	Pass

ASTM D1922	Tear Resistance of Tyvek	MD: Spec > 3,400m N TD: Spec > 2,000mN	Pass
ASTM D1922	Tear Resistance of plastic film	MD: Spec > 260m N TD: Spec > 170mN	Pass
ASTM F1608	Microbial Barrier	Log Reduction Value ≥4, ≥99.99%	Pass
Sterilant penetration test	Sterilant penetration test of the Perpak Sterilization Tyvek Pouch. Roll using the half-cycle validation of the LOWTEM Crystal 120 Sterilizer	All Negative	Pass
Microbial Barrier, Packaging Integrity	Microbial Barrier, Packaging Integrity performance of the Perpak Sterilization Tyvek Pouch, Roll	All processed Cycle tapes, CI strips and SCBI exhibited complete color change and all processed SCBIs were negative for growth.	Pass
Sterility test	Sterility test for medical devices packaged with KM Perpak pouch-LOWTEM	Medical devices packaged in KM Perpak TM sterilization pouches after LOWTEM Crystal 120 sterilization cycle have been verified to maintain the sterility	Pass

8. Comparison of Subject Device to Predicate Device

Comparison Chart

<table>
<tr><th>Comparison criteria</th><th>Subject Device</th><th>Predicate Device</th></tr>
<tr><td>Company</td><td>KM Corp.</td><td>SIGMA Medical Supplies Corp.</td></tr>
<tr><td>Device Name</td><td>Perpak™ Sterilization Tyvek Pouch</td><td>Sterilization Pouch/Roll Made with Tyvek®</td></tr>
<tr><td>Common name</td><td>Sterilization Wrap</td><td>Sterilization Wrap</td></tr>
<tr><td>Classification Regulation</td><td>21 CFR 880.6850</td><td>21 CFR 880.6850</td></tr>
<tr><td>Product Code</td><td>FRG</td><td>FRG, JOJ</td></tr>
<tr><td>510(k) Number</td><td>K241123</td><td>K180672</td></tr>
<tr><td>Indication for use</td><td>The Perpak™ Sterilization Tyvek Pouch is intended to provide health care workers with an effective method to enclose devices intended for sterilization in the LOWTEM Crystal 120 Sterilizer. The device is intended to allow sterilization of enclosed devices and also to maintain sterility of the enclosed devices until used up to 3 years post sterilization.
Specifications
<table>
<tr><th rowspan="2">Type</th><th rowspan="2">Model name</th><th rowspan="2">Dimensions</th><th colspan="2">Max load (Each material)</th></tr>
<tr><th>Metal (g)</th><th>Plastic (g)</th></tr>
<tr><td rowspan="2"></td><td>AOB00402</td><td>150mm×600mm</td><td>170</td><td>360</td></tr>
<tr><td>AOB00164</td><td>100mm×350mm</td><td>70</td><td>10</td></tr>
</table></td><td>The Sterilization Pouch/Roll Made with Tyvek® are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERRAD® 100S Sterilizer. The device is intended to allow sterilization of enclosed devices and also to maintain sterility of the enclosed devices until used up to 3 years post sterilization. The pouches and rolls are printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to blue (or lighter)</td></tr>
</table>

<table>
<tr><td></td><td>
<table>
<tr><td rowspan="3">Sterilization Pouch Flat</td><td>AOB00163</td><td>150mm×700mm</td><td>190</td><td>370</td></tr>
<tr><td>AOB00162</td><td>150mm×550mm</td><td>130</td><td>300</td></tr>
<tr><td>AOB00161</td><td>150mm×450mm</td><td>80</td><td>160</td></tr>
<tr><td rowspan="8">Sterilization Roll Flat</td><td>AOA00017</td><td>400mm×200M</td><td>155</td><td>355</td></tr>
<tr><td>AOA00016</td><td>300mm×200M</td><td>140</td><td>340</td></tr>
<tr><td>AOA00015</td><td>250mm×200M</td><td>100</td><td>330</td></tr>
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<tr><td>AOA00012</td><td>100mm×200M</td><td>70</td><td>10</td></tr>
<tr><td>AOA00011</td><td>75mm×200M</td><td>50</td><td>10</td></tr>
</table>
</td><td>when exposed to hydrogen peroxide vapor during processing in the STERRAD® 100S Sterilizer.</td></tr>
<tr><td>Material Composition</td><td>Tyvek®, Ethylene Polymer, Polyethene(PE), Polyethylene Terephthalate(PET), Bisphenol A-Epichlorohydrin Resin, Polyester polyol, Toluene diisocyanate, Methanol</td><td>Tyvek®, PET, PE, Water, CH3COOH, Alcohol, n-Heptane adhesive, Hydrogen peroxide vapor Process Indicator Print Ink</td></tr>
<tr><td>Sterilization Cycles</td><td>The Crystal 120 sterilizer's Standard cycle
The recommended Hydrogen Peroxide Sterilization Cycle parameters are exposure time : 16 minutes (Hydrogen Peroxide 59%, 2.5g is injected for each of the 4 sterilization injections), exposure Temperature : 55 ± 5℃, Total cycle time : 53 minutes</td><td>STERRAD® 100S Cycle
The recommended Gas Plasma Sterilization Cycle parameters are exposure time: 6 minutes (Injection volume: 2880μL), exposure Temperature: 50°C, Plasma Stage – Delivered power: 400 Watt.</td></tr>
<tr><td>Configuration/ Dimension</td><td>Various Size
• Sterilization pouch, Flat
• Sterilization roll, Flat</td><td>Various Size
• Self-sealing sterilization pouches
• Sterilization pouches, Flat
• Sterilization pouches, Gusseted
• Sterilization rolls, Flat
• Sterilization rolls, Gusseted</td></tr>
<tr><td>Microbial Barrier Properties (Packaging Integrity)</td><td>Tests conducted on unaged and aged (3 years accelerated aging) devices, before and after sterilization.
<table>
<tr><td>Thickness Variations
ASTM F 2251</td><td>Pass</td></tr>
<tr><td>Tensile strength of plastic film
*ASTM D822</td><td>Pass</td></tr>
<tr><td>Tensile strength of Tyvek®
*ASTM D5035</td><td>Pass</td></tr>
<tr><td>Tear Resistance
*ASTM D1922</td><td>Pass</td></tr>
<tr><td>Burst Strength
ASTM F1140</td><td>Pass</td></tr>
<tr><td>Seal Peel Test
ASTM F88/F88M; ISO 11607-1</td><td>Pass</td></tr>
<tr><td>Dye penetration Test
(Seal Integrity Test)
ASTM F1929; ISO 11607-1</td><td>Pass</td></tr>
<tr><td>Microbial Barrier Test
*ASTM F1608</td><td>Pass</td></tr>
</table>
*The test items were performed on materials of the products; therefore, there is no specification requirements.</td><td>Tests conducted on unaged and aged (3 years accelerated aging) devices, before and after sterilization.
<table>
<tr><td>Thickness Variations
ASTM F 2251</td><td>Pass</td></tr>
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ASTM F1140</td><td>Pass</td></tr>
<tr><td>Seal Peel Test
ASTM F88/F88M; ISO 11607-1</td><td>Pass</td></tr>
<tr><td>Dye penetration Test
(Seal Integrity Test)
ASTM F1929; ISO 11607-1</td><td>Pass</td></tr>
<tr><td>Microbial Barrier Test
*DIN 58953-6</td><td>Pass</td></tr>
</table>
*The test items were performed on materials of the products; therefore, there is no specification requirements.</td></tr>
<tr><td>Sterilant Penetration</td><td>• Half-Cycle Efficacy
: Showed a 6 log reduction of Geobacillus stearothermophilus</td><td>• Half-Cycle Efficacy
: Showed a 6 log reduction of Geobacillus stearothermophilus
• Chemical Indicator (CI) Functionality and Endpoint
: The sterilant penetrated through the pouch configuration and affected the CI color change to the endpoint color</td></tr>
</table>

Technological Comparison Discussion

The subject device is the same as the predicate device in the intended use, design, and technological characteristics. The difference is that the subject device does not include chemical indicator as the sterilizer which is used with the subject device uses a 510k cleared chemical indicator. Another difference is that the material compositions and we performed various performance tests to support the subject device performance.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device in 510(k) submission K241123, the Perpak™ Sterilization Tyvek Pouch, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared in K180672.