December 10, 2021

Unicoglobal, Inc.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt, STE 200
Irvine, California 92620

Re: K203539
Trade/Device Name: Unico Global level 3 Surgical Gown (Film-reinforced SMS), Unico Global Level 3 Surgical Gown (PP+PE)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FYA
Dated: October 26, 2021
Received: December 1, 2021

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 (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/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 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 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,

For Clarence W. Murray, III, PhD
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203539

Device Name
Unico Global level 3 Surgical Gown (Film-reinforced SMS), Unico Global Level 3 Surgical Gown (PP+PE)

Indications for Use *(Describe)*
The Unico Global Level 3 Surgical Gown (Film-reinforced SMS) and Unico Global Level 3 Surgical Gown (PP+PE) are sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids and particulate matter.
The Unico Global Level 3 Surgical Gowns meets the respective level requirements of ANSI/AAMI PB70:2012 level 3 liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.

The Unico Global Level 3 Surgical Gown (Film-reinforced SMS) and Unico Global Level 3 Surgical Gown (PP+PE) are single use, disposable medical devices; provided sterile or non-sterile. Non-sterile gowns are to be sold to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135-1 prior to marketing to the end users and sterile surgical gowns are to be sold directly to users after EtO sterilization validation to ISO 11135-1.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

(K203539)

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

Date: Dec 7, 2021

1. 510K Applicant / Submitter:

Unicoglobal, Inc.
#904, Woolim Pangyo W-City
9-22, Pangyo-Ro 255bion-Gil
Bundang-gu, Seongnam City
Gyeonggido, 13486
Republic of Korea

2. Submission Contact Person

LK Consulting Group USA, Inc.
1150 Roosevelt, STE 200, Irvine CA 92620
Priscilla Juhee Chung
Phone: 714.202.5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

- Proprietary Name: Unico Global level 3 Surgical Gown (Film-reinforced SMS)
  Unico Global Level 3 Surgical Gown (PP+PE)
- Common Name: Surgical Gown
- Classification: Class II (21 CFR 878.4040)
- Product Code: FYA

4. Predicate Device

Medline Level 2 Surgical Gown (Eclipse Non-Reinforced)
Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced)
Medline Level 3 Surgical Gown (Sirus Non-Reinforced)
Medline Level 3 Surgical Gown (Sirus Fabric Reinforced)
Medline Level 3 Surgical Gown (Aurora Non -Reinforced & Aurora Fabric Rein

(K190950) by Medline Industries, Inc.

5. Description:

The subject device offers the two material models which are Unico Global Level 3 Surgical Gown (Film-reinforced SMS) and Unico Global Level 3 Surgical Gown (PP+PE). The two models use different base materials but use the same PE film layer in addition to the fabric. They have slightly different design elements in neck, body, and belt straps.

The Unico Global Level 3 Surgical Gowns (Film-reinforced SMS and PP+PE) have been tested according to AATCC Test Method 127:2017, ANSI/AAMI PB70:2012, and ISO 811, and meet the AAMI Level 3 barrier level protection for a surgical gown.

The Unico Global Level 3 Surgical Gowns are single use that will be provided in both sterile and non-sterile packaging configurations and offer a variety of sizes ranging from medium to XX-large.

6. Indications for Use

The Unico Global Level 3 Surgical Gown (Film-reinforced SMS) and Unico Global Level 3 Surgical Gown (PP+PE) are sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids and particulate matter.
The Unico Global Level 3 Surgical Gowns meets the respective level requirements of ANSI/AAMI PB70:2012 level 3 liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.

The Unico Global Level 3 Surgical Gown (Film-reinforced SMS) and Unico Global Level 3 Surgical Gown (PP+PE) are single use, disposable medical devices; provided sterile or non-sterile. Non-sterile gowns are to be sold to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135-1 prior to marketing to the end users and sterile surgical gowns are to be sold directly to users after EtO sterilization validation to ISO 11135-1.

7. Comparison of Technological characteristics:

The predicate device is as follows:

K190950 by Medline Industries, Inc.

Medline Level 2 Surgical Gown (Eclipse Non-Reinforced)
Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced)
Medline Level 3 Surgical Gown (Sirus Non-Reinforced)
Medline Level 3 Surgical Gown (Sirus Fabric Reinforced)
Medline Level 3 Surgical Gown (Aurora Non -Reinforced & Aurora Fabric Rein)

8. Comparison Chart

Device Characteristic	Subject Device	Predicate Device	Remark
Device Name	Unico Global level 3 Surgical Gown (Film-reinforced SMS) Unico Global Level 3 Surgical Gown (PP+PE)	Medline Level 2 Surgical Gown (Eclipse Non-Reinforced) Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced) Medline Level 3 Surgical Gown (Sirus Non-Reinforced) Medline Level 3 Surgical Gown (Sirus Fabric Reinforced) Medline Level 3 Surgical Gown (Aurora Non - Reinforced & Aurora Fabric Reinforced	-
510K #	K203539	K190950	-
Manufacturer	Unico Global VN Co., Ltd.	Medline Industries, Inc.	-
Product Code	FYA	FYA	Same
Indications for Use	The Unico Global Level 3 Surgical Gown (Film-reinforced SMS) and Unico Global Level 3 Surgical Gown (PP+PE) are sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids and particulate matter. The Unico Global Level 3 Surgical Gowns meets the respective level requirements of ANSI/AAMI PB70:2012 level 3 liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. The Unico Global Level 3 Surgical Gown (Film-reinforced SMS) and Unico Global Level 3 Surgical Gown (PP+PE) are single use, disposable medical devices; provided sterile or non-sterile. Non-sterile gowns are to be sold to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135-1 prior to marketing to the end users and sterile surgical gowns are to be sold directly to users after EtO sterilization validation to ISO 11135-1.	The Medline Level 2 Surgical Gown (Eclipse Non Reinforced) and Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirus Non-Reinforced & Sirus Fabric Reinforced), Medline Level 3 Surgical Gown (Aurora Non- Reinforced & Aurora Fabric Reinforced) are sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter. The Medline Level 2 Surgical Gown and the Medline Level 3 Surgical Gowns meet the respective level requirements of ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities. The Medline Level 2 Surgical Gown and the Medline Level 3 Surgical Gowns have been validated using an ethylene oxide (EtO) sterilization process. The Medline Level 2 Surgical Gown and the Medline Level 3 Surgical Gowns are also sold as bulk single-use, non-sterile, to repackager/relabeler establishments for further packaging and sterilization using the validated EtO sterilization method according to ISO 11135-1 prior to being provided to the end user.	Same

Color	Blue		Blue	Same
Design Feature	Film-reinforced SMS	PP+PE	Available in Fabric Reinforced and Non Reinforced Velco hook and loop for neck closure Single Use Belt Straps Knit Cuffs Transfer Tab Raglan or Set-in/Standard Sleeves	Similar
	Velcro hook and loop with neck straps at neck Single use Belt Straps Knit Cuffs Transfer Tab Set-in Sleeves	Neck straps Single use Belt straps Knit cuffs Set-in Sleeves		
Size	Medium to XX-Large		Small to XXXX-Large	Similar
Materials	Film (PE) Reinforced Nonwoven SMS Polypropylene/Polyethylene		Nonwoven SMS Polypropylene/Polyolefin	Different
Performance Specifications	Level 3 PB70 Barrier Protection		Level 2 PB70 Barrier Protection Level 3 PB70 Barrier Protection	Same
Prescription vs. OTC	OTC		OTC	Same
Contact Durations	Surface, Intact, < 24 hours		Surface, Intact, < 24 hours	Same
Sterile vs Non-Sterile	Non-sterile Sterile		Sterile	Similar
Single Use vs. Reusable	Single Use		Single Use	Same
Biocompatibility	Under the test conditions, the subject device was shown to be non-systemic toxic, non-irritating and non-sensitizing per ISO 10993-11 & ISO 10993-10		Under the test conditions, the subject device was shown to be non-cytotoxic, non-irritating and non-sensitizing per ISO 10993-5 & ISO 10993-10.	Similar
Flammability	Meets requirements of Flame Resistant CPSC 1610 Class 1		Meets requirements of Flame Resistant CPSC 1610 Class 1	Same
Sterilization Method	Ethylene Oxide (EtO)		Ethylene Oxide (EtO)	Same

The subject device and the predicate device have the same indications for Use and has similar technological characteristics.
The major differences are materials and design. The predicate device uses a traditional nonwoven SMS (3-layer) fabric, whereas the subject device uses a traditional non-woven SMS (3-layers) plus an extra film layer. The subject device has an additional material model which was made with PP+PE which is spunbond (PP) fabric with a PE Film-reinforced layer.
For the design of the gowns, both the subject device and the predicate device have a Velcro hook and loop at neck (only for the subject SMS model), belt straps, knitted cuff, transfer tab, and set-in sleeve features.
The major design difference is that the subject SMS gowns has an additional neck strap at the neck in addition to the Velcro hook and loop. The subject PP+PE gowns have a neck strap only.

Other than this, both the devices share the same design features.

We have performed the biocompatibility and performance tests on the subject device and based on the test results we determine that these differences do not affect the safety and effectiveness of the device.

9. Summary of Non-Clinic Performance Tests

The following tests were performed on the subject device and the test results support that the subject device met the requirement for each test. Especially the performance test results support that the subject device satisfied the requirement of level 3 surgical gown.

Test Item	Test Standard	Acceptance Criteria	Results
Sterilization Validation	ISO 11135-1:2014	Sterility Assurance Level: 10^{-6}	Pass
Shelf-Life Validation	ASTM F1980, ASTM F88, ASTM F1929, ISO 10993-7, ISO 11737-2	▪ Bioburden test: ISO 11737-1'Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products' ▪ Sterility test: No microbial growth ▪ Seal Strength Test (Blister): Maximum seal strength (N/15mm) -> >1.2 ▪ Dye Penetration test: No leakage	Pass
Acute systemic toxicity	ISO 10993-11	Adverse no effects occurring at any time within 72h after single, multiple or continuous exposures of a test sample for 24h.	Pass
Sensitization & Irritation Tests	ISO 10993-10	▪ Sensitization test: The observations are scored between 0 (no visible change) to 3 (intense erythema and swelling). More than grade 0 indicates sensitization. ▪ Irritation tests: The test result obtained is a score between 0 and 8 calculated from the various observations, considered as negligible (0-0.4), slight (0.5-1.9), moderate (2-4.9), or severe (5-8).	Pass
Water Resistance: Impact Penetration	AATCC Test Method 42 and is in accordance with ANSI/AAMI PB70	Visual Penetration: None seen Amount of Penetration (g) : ≤ 1.0 g	Pass
Water Resistance: Hydrostatic Pressure	AATCC Test Method 127:2017, ANSI/AAMI PB70:2012, and ISO 811:2018	Pressure: ≥ 50 cm	Pass
Tear Resistance	ASTM D5587	No acceptance criteria currently exist for this test.	Pass
Basis Weight	ASTM D3776	Test articles should be weighed, and the basis weight should be calculated as the mass divided by the area. all should weigh the same.	Pass

Sterilant Gas Residue Analysis	ANSI/AAMI/ISO 10993-7	Maximum levels of sterilant residuals: ETO < 25ppm/device, ECH < 25ppm/device (ISO 10993-7)	Pass
Tensile Testing	SFDA (21 CFR Parts 58, 210, 211, and 820) Regulations	No acceptance criteria currently exist for this test.	Pass
Flammability	16 CFR part 1610	Class Plain Surface Textile Fabric: Burn time ≥3.5 seconds	Pass
Seam Strength test	ASTM D1683/D1683M	No acceptance criteria currently exist for this test.	Pass

10. Conclusions:

The conclusion drawn from the non-clinical tests demonstrates that the subject device in 510(K) submission K203539, the Unico Global Level 3 Surgical Gown (Film-reinforced SMS) and Unico Global Level 3 Surgical Gown (PP+PE) are as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K190950.