December 22, 2021

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

Re: K210147
Trade/Device Name: Unico High Performance Surgical Mask, Unico High Performance Surgical Mask with Face Shield
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 16, 2021
Received: November 18, 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)*
K210147

Device Name
Unico High Performance Surgical Mask & Unico High Performance Surgical Mask with Face Shield

Indications for Use *(Describe)*
The Unico High Performance Surgical Mask and the Unico High Performance Surgical Mask with Face Shield are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce potential exposure to blood and body fluids. The face masks are single use, disposable device, provided non-sterile.

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

(K210147)

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

Date: Dec 12, 2021

1. Submitter:

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2. Submission Contact Person

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3. Device

- Proprietary Name:
  Unico High Performance Surgical Mask
  Unico High Performance Surgical Mask with Face Shield
- Common Name: Surgical Mask
- Classification Name: Surgical Mask (21 CFR 878.4040)
- Regulatory Class: II
- Product Code: FXX

4. Predicate Device

- Name of Device: 3M™ High Fluid-Resistant Surgical Mask and 3M™ High Fluid-Resistant Procedure Mask (K191355) by 3M Health Care
- Common Name: Surgical Mask

- Classification Name: Surgical Mask (21 CFR 878.4040)
- Regulatory Class: II
- Product Code: FXX

5. Device Description:

The Unico High Performance Surgical Mask and the Unico High Performance Surgical Mask with Face Shield are composed of four layers and are flat-pleated and offers both ear loops and tie strings types. The mask materials consist of outer layer (Polypropylene Spunbond), insertion layer (Polypropylene Spunbond) and inner layer (Polypropylene Spunbond), and middle layer filter (polypropylene melt-blown).
Each mask contains ear loops or tie strings to secure the mask over the user's mouth and face with nose piece to firmly fit over the nose.
The mask may also contain a face shield made from a polyethylene terephthalate film, with an anti-glare strip. The face shield is adhered to the top edge of the mask to cover the upper part of the face to prevent potential exposure to blood and body fluids. The mask(s) are single use, disposable device(s), provided non-sterile.

8. Indications for Use

The Unico High Performance Surgical Mask and the Unico High Performance Surgical Mask with Face Shield are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce potential exposure to blood and body fluids. The face masks are single use, disposable device, provided non-sterile.

9. Comparison of Technological Characteristics with the predicate comparison of Technological Characteristics with the predicate

The subject device is safe and effective as the following predicate device.
3M™ High Fluid-Resistant Surgical Mask and 3M™ High Fluid-Resistant Procedure Mask (K191355) by 3M Health Care.

9.1. Comparison Chart

Item(S)	Subject Device		Predicate Device		Comparison
510k#	K210147		K191355		
Device Name	Unico High Performance Surgical Mask with Face Shield	Unico High Performance Surgical Mask	3M™ High Fluid-Resistant Surgical Mask ASTM Level 3	3M™ High Fluid-Resistant Procedure Mask	
Manufacturer	Unico Global, Inc.		3M Health Care		

ASTM Level	ASTM Level 3		ASTM Level 3	ASTM Level 3	
Indications for use	The Unico High Performance Surgical Mask and the Unico High Performance Surgical Mask with Face Shield are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce potential exposure to blood and body fluids. The face masks are single use, disposable device, provided non-sterile.		3M™ High Fluid-Resistant Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.	3M™ High Fluid-Resistant Procedure Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.	Same
Materials					
Outer Cover	Polypropylene Spunbond, blue	Polypropylene Spunbond, blue	Polypropylene Spunbond, green	Polypropylene Spunbond, green	Same
Insertion	Polypropylene Spunbond, White	Polypropylene Spunbond, White	Polypropylene Spunbond, White	Polypropylene Spunbond, White	Same
Filter	Polypropylene Meltblown, White	Polypropylene Meltblown, White	Polypropylene Meltblown, White	Polypropylene Meltblown, White	Same
Inner Cover	Polypropylene Spunbond, White	Polypropylene Spunbond, White	Polypropylene Thermal, Bonded, White	Polypropylene Thermal, Bonded, White	Different
Nose Wire	PVC Coated Zinc Wire	PVC Coated Zinc Wire	Polyethylene Coated Steel Wire	Polyethylene Coated Steel Wire	Different
Ear Loops	Cotton 50% Spandex 50% cord	Cotton 50% Spandex 50% cord	Not Applicable	Spandex elestic cord (polyurethane core with polyethylene terephtalate /nylon cover)	Different
Tie Strings	Polypropylene Spunbond, White	Polypropylene Spunbond, White	Polypropylene Spunbond, White or polyethylene Terephthalate, white	N/A	Same

Anti-Glare layer	Polypropylene Spunbond, Black	N/A	N/A	N/A	Different
Face Shield	Protective film: Polyethylene 100% Film: Polyethylene terephthalate 100%	N/A	N/A	N/A	Different
Design Features					
Color	Blue (Outer)		Green (Outer)	Green (Outer)	Different
Style	Flat - Pleated		Flat - Pleated	Flat - Pleated	Same
Multiple Layers	Yes		Yes	Yes	Same
Single Use	Yes		Yes	Yes	Same
Sterility					
Sterile	Non-Sterile		Non-Sterile	Non-Sterile	Same
Dimensions					
Length	6.9" ± 0.2"		6.9" ± 0.2"	6.9" ± 0.2"	Same
Width	3.74" ± 0.2"		3.5" ± 0.3"	3.5" ± 0.3"	Different
Technological Characteristics Product Barrier Specifications Per ASTM F2100 – Meets Level 3					
Particulate Filtration Efficiency (PFE)	Passed at ≥98% @ 0.1 micron ASTM F2299		Passed at ≥98% @ 0.1 micron ASTM F2299	Passed at ≥98% @ 0.1 micron ASTM F2299	Same
Fluid Resistance	Passed at 160mm Hg ASTM F1862		Passed at 160mm Hg ASTM F1862	Passed at 160mm Hg ASTM F1862	Same
Bacterial Filtration Efficiency (BFE)	Passed at ≥98% ASTM F2101		Passed at ≥98% ASTM F2101	Passed at ≥98% ASTM F2101	Same
Differential Pressure	Passed at <6 mmH2O/cm^2 MIL-M36954C		Passed at <5 mmH2O/cm^2 MIL-M36954C	Passed at <5 mmH2O/cm^2 MIL-M36954C	Same
Flammability	Passed ≥3 Seconds burn time - Class 1 CFR 16 1610		Passed ≥3 Seconds burn time - Class 1 CFR 16 1610	Passed ≥3 Seconds burn time - Class 1 CFR 16 1610	Same
Biocompatibility					
Result	Non-cytotoxic, Non-sensitizing, Non-irritating		Non-cytotoxic, Non-sensitizing, Non-irritating	Non-cytotoxic, Non-sensitizing, Non-irritating	Same

9.2. Discussion

The subject device and the predicate device have the same indications for Use and has similar design and technological characteristics.
The raw materials of some components are different, but the test results of the non-clinical performance tests and the biocompatibility tests support that the differences do not raise a concern in safety and effectiveness. The subject device also has additional features such as anti-glare layer and face shield, but there are to improve performance. The size of the subject device is little larger especially in width, but the difference is very minor.
We have performed the biocompatibility and performance tests on the subject device and based on the test results we determine that the subject device is safe and effective as the predicate device despite these differences.

10. Performance Tests (Non-clinical)

The following tests were performed on the subject device and the test results support that the subject device is safe and effective as the predicate device.

No	Test	Standard	Test method	Purpose	Acceptance criteria	Test results
1	Particle Filtration Efficiency Latex Particle Challenge	ASTM F2299	Monodispersed polystyrene latex spheres (PSL) were nebulized (atomized), dried, and passed through the test article	Performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article.	-	98.3%
2	Synthetic Blood Penetration for Face Masks (sets of 32), per set	ASTM F1862 and ISO 22609	A test volume of 2 mL of synthetic blood was employed using the targeting plate method.	Procedure was performed to evaluate surgical facemasks and other types of protective.	160mmHg	Not Seen
3	Differential Pressure (Delta P)	EN 14683:2019, Annex C and ASTM F2100-19.	On either side of the test article using a manometer, at a constant flow rate.	The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure.	<60 mm H_2O/cm^2	53
4	Flammability Test, 16 CFR part 1610	16 CFR Part 1610	Article exhibits flame spread and it is less than 3.5 seconds or the test articles exhibit an	This procedure was performed to evaluate the flammability	Class1: Burn time ≥3.5 seconds Class2: Not	Test Article did not ignite

			average flame spread less than 3.5 seconds.	of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread.	applicable to plain surface textile fabrics Class 3: Burn time <3.5 seconds	
5	Bacterial Filtration Efficiency (BFE) only	ASTM F2101-19 and EN 14683:2019, Annex B.	Employ a ratio of The bacterial challenge counts to sample effluent counts, to determine percent bacterial filtration efficiency (%BFE)	BFE is a measurement of a respirator material's resistance to penetration of bacteria.	≥98	99%
6	Cytotoxicity	ISO 10993-5	The amount of test material extracted was based on ANSI/AAMI/ISO and USP surface area or weight recommendations. Test articles and controls were extracted in 1X Minimal Essential Media with 5% bovine serum for 24-25 hours at 37 ± 1°C with agitation.	An extract of the test article was added to cell monolayers and incubated. The cell monolayers were examined and scored based on the degree of cellular destruction.	Score: 0 ~ 4	0 Pass
7	Sensitization	ISO 10993-10	The USP 0.9% Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO) extracts of the test article, Surgical Mask, elicited no reaction at the challenge (0% sensitization), following an induction phase.	Determine the potential allergenic or sensitizing capacity of the test article. The study was used as a procedure for screening of contact allergens in guinea pigs	No allergic or hypersensitivity reaction	The test article sites did not show a significantly greater biological reaction than the sites injected with the control article.
8	Irritation	ISO 10993-10	The USP 0.9% Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO) extracts of the test article,	Determine the potential irritation effects of the test article extract as a result of an	No potential irritant effect	The test article sites did not show a significantly greater biological

			Surgical Mask, were evaluated for their potential to produce irritation after intracutaneous injection in New Zealand White rabbits.	intracutaneous injection in New Zealand White rabbits.		reaction than the sites injected with the control article.

11. Conclusions:

Based on the information provided in this premarket notification, Unicoglobal, Inc. concludes that the Unico High Performance Surgical Mask and the Unico High Performance Surgical Mask with Face Shield are as safe, effective, and perform to the predicate device as described herein in.