September 29, 2021

Universal Incorporation
℅ Tyra Chiu
Regulatory Consultant
VOLER Biotech Consulting Co., Ltd.
1 Ft, No 3-1, Ln. 58, Hejiang St., Zhongshan Dist.
Taipei, 72548
Taiwan

Re: K210513
Trade/Device Name: UNIWEB Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 13, 2021
Received: August 31, 2021

Dear Tyra Chiu:

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, Ph.D.
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)*
K210513

Device Name
UNIWEB Surgical Mask

Indications for Use *(Describe)*
The Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. This device is intended for Adult use Only. The UNIWEB Surgical 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

Date September 29, 2021

Manufacturer/ 510(k) Owner UNIVERSAL INCORPORATION
10F., No.372 Linsen N. Rd.,Zhongshan Dist.,Taipei City 10446,Taiwan

Contact Person Mei-Hui Huang
Phone: +886-2-25119161
E-mail: uk@uk.com.tw

Device Trade Name UNIWEB Surgical Mask
Common Name Surgical Masks
Classification Name Masks, Surgical
Device Class II
Classification Panel General & Plastic Surgery
Regelation Number 878.4040
Product Code FXX

Device Description and Technology Characteristics UNIWEB SURGICAL MASK are 3-layer surgical masks that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials. This device is non-sterile and for single use only. The mask is constructed of nonwoven fabric, including the bottom layer, surface layer and middle layer, and is provided with ear loops and nose wire for individualized fit.

Models ASTM Level 1, ASTM Level 2

Indications for Use The Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. This device is intended for adult use Only. The UNIWEB Surgical Masks are single use, disposable device, provided non-sterile.

Predicate Device(s) K141085 WestTec Procedure Facemask, WestTec Surgical Facemask/ WESTTEC, LLC

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Proposed Device	Predicate Device	Comparison
Device Name	UNIWEB Surgical Mask	WestTec Procedure Facemask, WestTec Surgical Facemask	-
510(k) #	K210513	K141085	-
Applicant	Universal Incorporation	WESTTEC, LLC	-
Product code	FXX (21 CFR 878.4040)	FXX (21 CFR 878.4040)	Same
Classification	II	II	Same
OTC use	YES	YES	Same

Intended Use	The Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. This device is intended for adult use Only. The UNIWEB Surgical Masks are single use, disposable device, provided non-sterile.	WestTec Procedure and Surgical facemasks are intended to be worn by healthcare workers to protect the user and patient against transfer of microorganisms, blood and body fluids, and airborne particulates. The WestTec Procedure and Surgical facemasks are single use, disposable devices provided non-sterile.	Same
Dimensions	175 mm x 95 mm	175 mm x 90 mm	Similar
Layers	Three	Three	Same
Mask Style	Flat-pleated	Flat-pleated	Same
Design Feature	Ear loops	Ear loops	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use	Single Use	Same
Material:	Surface Layer: Polypropylene Spunbond Middle Layer: Polypropylene Meltblown Bottom Layer: Polypropylene Spunbond Nose Wire: galvanized iron wire covered with polyethylene Ear Loops: Nylon and Spandex	Outer Layer: spunbond polypropylene. Middle Layer: meltblown polypropylene filter media. Inner Layer: spunbond polypropylene. Earloops are soft non natural rubber latex,elastic loops. Nose Band: steel wires encased in polyethylene	similar
Fluid Resistance (ASTM F1862)	Pass at 80 mmHg, Pass 120 mmHg	Pass at 120 mmHg	Same
Bacterial Filtration Efficiency (ASTM F2101)	≥ 99.8 %	99.7 %	Same. Meet Level 2 requirement
Differential Pressure (Mil-M-36954C)	3.6~4.2 mmH_2O/cm^2	3.3~3.6 mmH_2O/cm^2	Same. Meet Level 2 requirement
Particle Filtration Efficiency (ASTM F2299)	99.74~99.95 % (at 0.1 microgram)	98 %	Same. Meet Level 2 requirement
Flammability (16 CFR 1610)	Class I	Class I	Same
Biocompatibility (ISO 10993-5, -10)	Non-Cytotoxic, Non-Sensitizing, Non-Irritating	Non-Cytotoxic, Non-Sensitizing, Non-Irritating	Same

Discussion on Performance Data Non-Clinical Tests

The proposed devices were tested and conformed to the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission.

Non-Clinical Testing Summary:

Test Methodology	Purpose of the test	F2100-19 Level 1 Requirement	F2100-19 Level 2 Requirement	**UNIWEB Surgical Mask Test Result Level 1**	**UNIWEB Surgical Mask Test Result Level 2**
Bacteria Filtration Efficiency	Determine the bacterial filtration efficiency as directed in Test Method ASTM F2101.	≥ 95 %	≥ 98 %	96/96 (3 lots) passed at ≥ 99%	96/96 (3 lots) passed at ≥ 99%
Particle Filtration Efficiency	Determine particulate filtration efficiency as directed in Test Method F2299.	≥ 95 %	≥ 98 %	96/96 (3 lots) passed at ≥ 99%	96/96 (3 lots) passed at ≥ 99%
Differential Pressure (Delta-P)	Determine breathing resistance or differential pressure as directed in EN 14683:2019, Annex C.	<5.0 mmH_2O/cm^2	<6.0 mmH_2O/cm^2	96/96 (3 lots) show 3.6~4.2 H_2O/cm^2 , pass at <5.0 H_2O/cm^2	96/96 (3 lots) show 3.6~4.2 H_2O/cm^2, pass at <6.0 H_2O/cm^2
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	Determine synthetic blood penetration resistance as specified in Test Method F1862	80 mmHg (≥ 29/32 show passing results per lot)	120 mmHg (≥ 29/32 show passing results per lot)	96/96 (3 lots) passed at 80 mmHg	95/96 (3 lots) passed at 120 mmHg
Flammability	Determine flammability as specified in 16 CFR Part 1610	Class I (Burn time ≥3.5 s, IBE, or DNI)	Class I (Burn time ≥3.5 s, IBE, or DNI)	96/96 (3 lots) show IBE, passed at class I	96/96 (3 lots) show IBE, passed at class I

Biocompatibility Testing Summary:

Test Methodology	Purpose of the test	Acceptance Criteria	Test Results
In vitro Cytotoxicity test	Determine the effects on cells following ISO 10993-5	Cell viability of 100% test article extract is ≥ 70% of control group	Passed.
Skin sensitization Test	Estimate the potential for contact sensitization following ISO 10993-10	Grades =0	Passed.
Skin Irritation Test	Estimate the irritation potential of medical device following ISO 10993-10	Mean score 0~0.4 (Negligible)	Passed.

A shelf-life evaluation was conducted, and the test results demonstrate that the device maintain its performance in its claimed 3-year shelf life.

Discussion on Clinical Test Performed

Not applicable

The subject device has same indications for use, technology,

operation principle and technical characteristics with the predicate device(s). Verification activities were performed on subject device and all tests were verified to meet the required acceptance criteria. The non-clinical tests demonstrate that the differences in the devices do not affect the indications for use of the device or raise any unsolved issues. There are no significant differences between subject device and the predicate device(s) that would adversely affect the use of the product.

Conclusion The conclusions drawn from the non-clinical tests demonstrate that the subject device, UNIWEB Surgical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device, K141085, WestTec procedure facemask.