May 13, 2021

United Sewing Automation Inc.
℅ Heather Hatcher
Regulatory Scientist
Womble Bond Dickinson, US LLP
One West Fourth Street
Winston-Salem, North Carolina 27101

Re: K202697
Trade/Device Name: United Sewing High Fluid Resistant Disposable Face Mask, United Sewing High Fluid Resistant Surgical Mask, United Sewing High Fluid Resistant Procedure Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 14, 2020
Received: September 16, 2020

Dear Heather Hatcher:

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 and Part 809); 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.
Acting 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)*
K202697

Device Name
United Sewing High Fluid Resistant Disposable Face Mask
United Sewing High Fluid Resistant Surgical Mask
United Sewing High Fluid Resistant Procedure Mask

Indications for Use *(Describe)*
The United Sewing High Fluid Resistant Disposable Face Mask, United Sewing High Fluid Resistant Surgical Face Mask and United Sewing High Fluid Resistant Procedure Face Mask 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. These face masks are single-use, disposable devices, 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.

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510(K) SUMMARY
K202697

Sponsor Information: United Sewing Automation, Inc.
1772 N. Andy Griffith Parkway
Mount Airy, NC 27030

Contact information: Benjamin Web
Title: CEO
Phone: (336) 710-2404
Email: ben@unitedsewinginc.com

Date of Summary Prepared: May 13, 2021

Common Name: Surgical Mask

Classification Name: Surgical Apparel

Proprietary Name: United Sewing High Fluid Resistant Disposable Face Mask
United Sewing High Fluid Resistant Surgical Face Mask
United Sewing High Fluid Resistant Procedure Face Mask

Review Panel: General and Plastic Surgery

Product Code: FXX

Device Classification: Class II per 21 CFR §878.4040

Predicate Device(s): San-M Package Co., Ltd. Surgical Face Masks (Ear loops and Tie-on) (K160269)

Intended Use/Indications for Use: The United Sewing High Fluid Resistant Disposable Face Mask, United Sewing High Fluid Resistant Surgical Face Mask and United Sewing High Fluid Resistant Procedure Face Mask 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.

These face masks are single-use, disposable devices, provided non-sterile.

Device Description:

The United Sewing High Fluid Resistant Disposable Face Mask is a single use, disposable, nonsterile face mask intended to cover the nose and mouth of the wearer. The subject device consists of 3 layers with the outer and inner layer made with polypropylene spunbound material and middle layer made with polypropylene melt blown material, The device has a bendable nosepiece made with Polyethylene coated single wire, and ear loops made from nylon and spandex material. This device will be provided over the counter under the trade names United Sewing High Fluid Resistant Disposable Face Mask, United Sewing High Fluid Resistant Surgical Face Mask and United Sewing High Fluid Resistant Procedure Face Mask for marketing purpose. This device is not made with natural rubber latex.

Comparison of Technological Characteristics between the subject and predicate devices:

Descriptions and comparisons of the United Sewing High Fluid Resistant Disposable Face Mask, and the same face mask that is marketed as the United Sewing High Fluid Resistant Surgical Face Mask and United Sewing High Fluid Resistant Procedure Face Mask, and predicate device features are presented in the Technological Characteristics Comparison Table.

Item(s)	**Subject Device (K202697)** **United Sewing High Fluid Resistant Disposable Face Mask, also marketed under trade names United Sewing High Fluid Resistant Surgical Face Mask and United Sewing High Fluid Resistant Procedure Face Mask**	**Predicate Device (K160269)** **San-M Package Co., Ltd. Surgical Face Masks (Ear loops and Tie-on)**	**Comparison**
Intended Use/Indications for Use	The United Sewing High Fluid Resistant Disposable Face Mask, also marketed under trade names United Sewing High Fluid Resistant Surgical Face Mask and United Sewing	The surgical face masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate	Similar

	High Fluid Resistant Procedure Face Mask, is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. This face mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This face mask is a single-use, disposable devices, provided non-sterile.	material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single-use, disposable device, provided non-sterile.	
Outer Layer	Polypropylene, Spunbound, 99.5%	Polypropylene	Same
Filter (Middle) Layer	Polypropylene, Melt Blown	Polypropylene Spunbond; Polypropylene meltblown	Same
Inner Facing Layer	Polypropylene, Spunbound, 99.5%	Polypropylene thermal-bonded	Same
Nose Piece	Polyethylene Coated Single Wire, 10.16 cm	Polyethylene coated steel wire	Same
Ear Loops	Nylon and Spandex, 12.7 cm each side	Polyester, polyurethane	Different*
Mask Color	White	Variety colors	Different*
Mask Style	Flat pleated	Flat pleated	Same
Multiple Layers	Yes	Yes	Same
Single Use	Yes	Yes	Same
Sterile	Non-sterile	Non-sterile	Same
Length	9.5 cm ± 0.5 cm	90 mm ± 3 mm 92 mm ± 3 mm	Similar
Width	17.5 ± 0.5 cm	175 mm ± 5 mm 180 mm ± 5mm	Similar
Particulate Filtration Efficiency (PFE)	99.76% ASTM F2299	Pass ASTM F2299	Similar
Fluid Resistance	Pass at 160 mm Hg ASTM F1862	Pass at 80-160 mm Hg ASTM F1862	Same
Bacterial Filtration Efficiency (BFE)	99.62% ASTM F2101	Pass at ≥98%	Same

		ASTM F2101	
Differential Pressure	4.8 mm H_2O/cm^2 EN 14683:2019 and ASTM F2101-19	Pass at ≤2.5 H_2O/cm^2 MIL-M36945C	Same
Flammability	Class 1, 16 CFR 1610	Class 1, 16 CFR 1610	Same
Biocompatibility	Non-cytotoxic, non-irritating, and non-sensitizing	Non-cytotoxic, non-sensitizing, non-irritating	Same
*Although the ear loop materials and color subject device are little difference with predicate device, it meets the requirement of essential performance standard ISO 10993 and performance testing. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device			

A Summary of the Non-clinical Testing Conducted:

The United Sewing High Fluid Resistant Disposable Face Mask and United Sewing High Fluid Resistant Surgical Face Mask and United Sewing High Fluid Resistant Procedure Face Mask has met the standards listed in the table below:

Title of Performance Test [*Performance Aspect*]	**Test Method**	**Test Method Acceptance Criteria**	**Results Pass**
Resistance of Medical Face Mask to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) [*Fluid Resistance*]	ASTM F1862M-17	Fluid resistant claimed at 160 mm Hg	32/32 Passed at 160 mmHg
Medical face masks – Requirements and test methods Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus [*Bacterial Filtration Efficiency*]	EN 14683:2019, Annex C ASTM F2101-19*‡	Pass ≥98%	32/32 Passed at 99.62%
Medical face masks – Requirements and test methods (Differential Pressure) – Delta P test [*Air Exchange*]	EN 14683:2019, Annex C ASTM F2101-19*	Pass <6 mm H_2O/cm	32/32 passed at 4.8 mm H_2O/cm^2
Standard for the Flammability of Clothing Textiles [*Flammability*]	16 CFR 1610‡	Class 1	32/32 Passed (≥3.5 seconds] Class 1 Pass
Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres [*Particulate Filtration*]	ASTM F2299	≥ 98%	32/32 Passed at 99.76%

- Biocompatibility Testing

According to ISO 10993-1:2009, the nature of body contact for the subject device is Surface Device category, Skin Contact and duration of contact is A-Limited (≤24h). The following tests for the subject device were conducted to demonstrate that the subject device is biocompatible and safe for its intended use:

1) In vitro Cytotoxicity Test per ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.

2) Skin Sensitization Tests per ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

3) Skin Irritation Tests per ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

A Summary of the Clinical Testing Conducted:

No clinical study is included in this submission

Conclusion:

The conclusion drawn from the nonclinical tests demonstrates that the subject devices in 510(k) submission K202697, the United Sewing High Fluid Resistant Disposable Face Mask and United Sewing High Fluid Resistant Surgical Face Mask and United Sewing High Fluid Resistant Procedure Face Mask are as safe, as effective, and perform as well as or better than the legally marketed predicate devices cleared under K191355.