May 13, 2022

Unimax Medical Products Co., Ltd.
% Jarvis Wu
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai 200122
China

Re: K220749
Trade/Device Name: Surgical Face Mask, Model Number-17.5X9.5CM EAR-LOOP
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: March 14, 2022
Received: March 14, 2022

Dear Jarvis Wu:

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,

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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.

Submission Number *(if known)*

K220749

Device Name

Surgical Face Mask (17.5X9.5CM EAR-LOOP)

Indications for Use *(Describe)*

The Surgical Face 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 the potential exposure to blood and body fluids. This a single use, disposable device(s), 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.

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."

Unimax Medical Products Co., Ltd.
No.1 Liansai Road, Changshangkou Town, Xiantao City, Hubei Province, P.R. China.

510(k) Summary

Document Date Prepared:2022/3/5

A. Applicant:

Name: Unimax Medical Products Co., Ltd.

Address: No.1 Liansai Road, Changshangkou Town, Xiantao City, Hubei Province, P.R. China.

Contact Person: Ning Haibo

Tel: +86-027 82213162

Mail: sales@unimaxmedical.com

Submission Correspondent:

Primary contact: Mr. Jarvis Wu

Shanghai SUNGO Management Consulting Co., Ltd.

14th floor, 1500# Century Ave., Shanghai 200122, China

Tel: +86-21-58817802

Email: haiyu.wang@sungoglobal.com

Secondary contact: Mr. Raymond Luo

14th floor, 1500# Century Ave., Shanghai 200122, China

Tel: +86-21-68828050

Email: fda.sungo@gmail.com

B. Device:

Proprietary Name: Surgical Face Mask

Common Name: Surgical Face Mask

Model(s): 17.5X9.5CM EAR-LOOP

Regulatory Information

Classification Name: Surgical Face Mask

Classification: Class II

Product code: FXX

Regulation Number: 878.4040

Review Panel: Surgical Apparel

C. Predicate device:

510K	Device name	ASTM F2100-19 level	Manufacturer
K203426	Surgical Face Mask（non - sterile）	Level 2	Nantong Taiweishi Medical Technology Co., Ltd.

(Note: Predicate device has NOT been subject to any Medical Device Recalls, including design-related recall.)

D. Indications use of the device:

The Surgical Face 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 the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

E. Device Description:

Surgical Face Mask is composed of Nylon and Spandex ear loops, Iron-plastic nose clip, Inner layer Spun-bond polypropylene, Middle Melt-blown polypropylene and outer Spun-bond polypropylene. The melt-blown polypropylene material acts as the filter that stops microbes from entering or exiting the mask. Surgical Face Masks feature pleats or folds. Three pleats are used to allow the user to expand the mask such that it covers the area from the nose to the chin. The type is ear-loop, where a string-like material is attached to the mask and placed behind the ears. The proposed device(s) are sold non-sterile and are intended to be single use, disposable device.

F. Comparison with predicate device

Table 1 General Comparison

Device	**Proposed Device**	**Predicate device**	**Comparison**
Manufacturer	Unimax Medical Products Co., Ltd.	Nantong Taiweishi Medical Technology Co., Ltd.	-
510K number		K203426	-
Device name	Surgical Face Mask	Surgical Face Mask（non-sterile）	-
Classification	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same

Indications for use		The Surgical Face 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 the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	The Disposable Surgical Face Masks 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 the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	Same
Material	**Outer layer**	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt-blown polypropylene	Melt blown polypropylene filter	Same
	Inner layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose clip	Iron-plastic strip	Polyethylene	Different
	Ear loops	Nylon and Spandex	Nylon and Spandex	Same
Color		Blue	Blue	Same
Dimension (length)		175mm ±5mm	175mm+/-5%	Similar
Dimension (Width)		95mm±5mm	95mm+/-5%	Similar
OTC use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
Use		Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100-19 level		Level 2	Level 2	Same
Biocompatibility		Meet ISO10993 ,proved non-cytotoxicity, non-irritating and	Meet ISO10993 ,proved non-cytotoxicity, non-irritating and	Same

	non-sensitizing	non-sensitizing	

From the comparison we found the material of proposed device's nose clip was different from the predicate device. The biocompatibility tests were conducted to both components to ensure their compliance to the ISO10993-5 and ISO10993-10. There is no new risk generated from the difference of the material.

G. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was similar to the predicate device. The test results demonstrated that the proposed device complies with the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004:

- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- ASTM F2100, Standard Specification for Performance of Materials Used In Medical Face Masks
- ASTM F1862, Standard Test Method for Resistance of Medical Face Masks To Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume At A Known Velocity);
- EN 14683, Medical Face Masks—Requirements and Test Methods;
- ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using A Biological Aerosol of Staphylococcus Aureus;
- ASTM F2299, Stand test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres;
- 16 CFR 1610, Standard for the Flammability of clothing textiles;

Table 2 - Performance Testing

Item	Purpose	Proposed device	Acceptance Criteria	Result
Fluid Resistance Performance ASTM F1862	Assess the performance of a mask to resistance to a synthetic blood preparation	3 non-consecutive lots tested, using a sample size of 32/lot. 32 out of 32 pass at	29 out of 32 pass at 120 mmHg for level 2	PASS

	targeted toward the mask at a set pressure	120 mmHg		
Particulate Filtration Efficiency ASTM F2299	Assess the performance of a mask to penetration by sub-micron polystyrene latex particles of 0.1 micron	3 non-consecutive lots tested, using a sample size of 32/lot. Lot1: 99.17% Lot2: 99.49% Lot3: 98.90%	≥ 98%	PASS
Bacterial Filtration Efficiency ASTM F2101	Assess the performance of a mask to penetration by a prepared solution with known concentration of an indicator bacterial organism	3 non-consecutive lots tested, using a sample size of 32/lot. Lot1: 99.87% Lot2: 99.9% Lot3: 99.84%	≥ 98%	PASS
Differential Pressure (Delta P) EN 14683 Annex C	Assess the performance of a mask for resistance to air movement through the materials of the face of the mask	3 non-consecutive lots tested, using a sample size of 32/lot. Lot1: 2.08 mmH_2O/cm^2 Lot2: 2.08 mmH_2O/cm^2 Lot3: 2.07 mmH_2O/cm^2	< 6.0mmH_2O/cm^2	PASS
Flammability 16 CFR 1610	Assess the resistance of a mask to ignition	3 non-consecutive lots tested, using a sample size of 32/lot. Class 1	Class 1	PASS

Table 3 – Biocompatibility Testing

Test Method	Purpose	Acceptance Criteria	Result
Cytotoxicity	Assess the potential risk of Cytotoxicity of mask material	Non-Cytotoxic	PASS Under the conditions of the study, the device is non-cytotoxic.
Irritation	Assess the potential risk of Irritation of mask material	Non-Irritating	PASS Under the conditions of the study, the device is non-irritating.
Sensitization	Assess the potential risk of Sensitization of mask material	Non-Sensitizing	PASS Under the conditions of the study, the device is non-sensitizing

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Surgical Face Mask (Model: 17.5X9.5CM EAR-LOOP) is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K203426.