January 18, 2022

Wuxi Yushou Medical Appliances Co.,Ltd.
Xiaoling Dai
QA&QC Manager
No.115 Nongxinhe Road, Xishan District, Wuxi City, Jiangsu
Province, China.
Wuxi, Jiangsu 214200
China

Re: K210679
Trade/Device Name: Medical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 9, 2021
Received: January 10, 2022

Dear Xiaoling Dai:

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)*
K210679

Device Name
Medical face mask

Indications for Use *(Describe)*

When properly worn, the medical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate materials. This device is non sterile and for single use only.

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.

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"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

1. Submitter Information

Company Name:Wuxi Yushou Medical Appliances Co.,Ltd.

Address: No.115 Nongxinhe Road, Xishan District, Wuxi City, Jiangsu Province, China.

Phone:+86-510-83777555

Contact Person (including title): Xiaoling Dai (QA&QC Manager)

E-mail : Kiwi-xu@isosh.com

Subject Device Information

Type of 510(k):	Traditional
Common Name:	Surgical face mask
Trade Name:	Medical face mask
Classification Name:	Mask,Surgical
Review Panel:	General Hospital
Product Code:	FXX
Regulation Number:	21 CFR 878.4040
Regulation Class:	2

2. Predicate Device Information

Sponsor:	MEXPO INTERNATIONAL INC.
Common Name:	Surgical Face Mask
Trade Name:	Surgical Face Mask
510(k) number:	K200847
Review Panel:	General Hospital
Product Code:	FXX
Regulation Number:	21 CFR 878.4040
Regulation Class:	Class II

3. Device Description

The medical face masks are single use, 3 layers, flat-pleated style with ear loops and nose piece. The outer layer and inner facing layer of face mask consist of spun-bond polypropylene, and the middle layer consists of melt blown polypropylene filter. Each mask contains ear loops to secure the mask over the user's face and mouth with nose piece to firmly fit over the nose.

4. Intended Use

When properly worn, the medical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate materials. This device is non sterile and for single use only.

5. Test Summary

Medical face mask has been evaluated the safety and performance by lab bench testing according to the following standards:

- ASTM F2299 Standard Test Method for Determining the Initial Efficiency of Materials Used in Surgical face masks to Penetration by Particulates Using Latex Spheres.
- ASTM F1862 Standard test method for resistance of Surgical face masks to penetration by synthetic blood (Horizontal projection of fixed volume at a known velocity)
- ASTM F 2101-19 Standard Test Method For Evaluating The Bacterial Filtration Efficiency (BFE) Of Surgical face mask Materials, Using A Biological Aerosol Of Staphylococcus Aureus.
- 16 CFR Part 1610 STANDARD FOR THE FLAMMABILITY OF CLOTHING TEXTILES
- ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks
- During use, the Non Woven Face Mask will directly contact with user's skin, so we have it tested to demonstrate conformance to the following standards.

  ISO 10993-5, Biological Evaluation Of Medical Devices -- Part 5: Tests For InVitro Cytotoxicity

  ISO 10993-10, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

6. Summary of Comparison and Technological Characteristics

Table 1 - General Comparison

Elements of Comparison		**Subject Device(K210679)**	**Predicate Device(K200847)**	**Comments**
Product Name		Medical face mask	Surgical face mask	--
General Comparison				
Intended Use		When properly worn, the medical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate materials. This device is non sterile and for single use only.	When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and airborne particles. This device is non-sterile and for single use only.	Same
Model		3 Ply, Ear Loops, Flat-Pleated Style	3 Ply, Ear Loops, Flat-Pleated Style	Same
Material	Outer facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Inner facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose piece	Single Galvanize Wire, Coated By PE	Single Galvanize Wire, Coated By PE	Same
	Ear loops	Spandex	not made with natural rubber latex	Same
Color		Blue	White	Different Note 1
Dimension (Width)		9.5cm ± 0.5cm	9.0cm ± 0.5cm	Similar Note 2
Dimension (Length)		17.5cm ± 0.5cm	17.5cm ± 0.5cm	Same
Use		Single Use	Single Use	Same
ASTM F2100 Level		Level 2	Level 2	Same
Fluid Resistance Performance ASTM F 1862		Lot 1: 32 Out of 32 pass at 120 mmHg Lot 2: 32 Out of 32 pass at 120 mmHg Lot 3: 32 Out of 32 pass at 120 mmHg	30 Out of 32 pass at 120 mmHg	Same

Elements of Comparison	Subject Device(K210679)	Predicate Device(K200847)	Comments
Particulate Filtration Efficiency ASTM F 2299	Lot 1:98.9％ Lot 2:98.9％ Lot 3: 98.7％	99.9%	Same
Bacterial Filtration Efficiency ASTM F2101	Lot 1: 99.9% Lot 2: 99.9% Lot 3: 99.9%	> 99.9%	Same
Differential Pressure (Delta P) EN 14683:2019+AC：2019	Lot 1: 3.0 mmH_2 0/cm^2 Lot 2: 3.1 mmH_2 0/cm^2 Lot 3: 3.3 mmH_2 0/cm^2	3.0 mmH_2 0/cm^2	Same
Flammability 16CFR 1610	Lot 1: Class 1 Lot 2: Class 1 Lot 3: Class 1	Class 1	Same
Cytotoxicity	Comply with ISO 10993-5 Non cytotoxic	Comply with ISO 10993-5 Non cytotoxic	Same
Irritation	Comply with ISO 10993-10 Non irritating	Comply with ISO 10993- 10 Non irritating	Same
Sensitization	Comply with ISO 10993-10 Non sensitizing	Comply with ISO 10993- 10 Non sensitizing	Same

Table 2 - Performance Testing

Test Methodology	Purpose	Proposed Device	Acceptance Criteria	Result
Fluid Resistance Performance (ASTM F1862)	The test method is used to evaluate the resistance of medical face masks to penetration by the impact of a small volume(~2 mL) of high-velocity stream of synthetic blood. The pass/fail determinations are based on visual detection of synthetic blood penetration.	Lot 1: 32 Out of 32 pass at 120 mmHg Lot 2: 32 Out of 32 pass at 120 mmHg Lot 3: 32 Out of 32 pass at 120 mmHg	29 Out of 32 pass at 120 mmHg	Pass

Particulate Filtration Efficiency (ASTM F2299)	The purpose of this test method is to measure the initial partical filtration efficiency of materials using monodispersed aerosols containing suspended latex spheres particulates of 0.1μm diameter.	Lot 1:98.9% Lot 2:98.9% Lot 3: 98.7%	≥ 98%	Pass
Bacterial Filtration Efficiency (ASTM F2101)	The purpose of this test method is to determine the bacterial filtration efficiency of the mask as specified in ASTM F2101.	Lot 1: 99.9% Lot 2: 99.9% Lot 3: 99.9%	≥ 98%	Pass
Flammability (16 CFR 1610)	The purpose of this test method is to determine the flammability charateristics of the mask as specified in 16 CFR Part 1610. Materials in the construction of medical face masks shall meet the requirements for Class 1, normal flammability specified in 16 CFR Part 1610.	Lot 1: Class 1 Lot 2: Class 1 Lot 3: Class 1	Class 1	Pass
Differential Pressure (EN 14683:2019)	The purpose of this test s to measure the differential pressure between the inside and outside of the mask.	Lot 1: 3.0 mmH_20/cm^2 Lot 2: 3.1 mmH_20/cm^2 Lot 3: 3.3 mmH_20/cm^2	< 6.0 mmH_20/cm^2	Pass

Table 3 - Biocompatibility Testing

Test Methodology	Purpose	Proposed Device	Acceptance Criteria	Result

Cytotoxicity (ISO 10993-5)	The purpose of the test is to determine the biological reactivity of a mammalian cell culture (mouse fibroblast L929cells) in response to the test article.	Non-Cytotoxic	Under the conditions of the study, non-cytotoxicity	Pass
Irritation (ISO 10993-10)	To evaluate the potential skin irritation caused by the extraction of the test article extract contacting with the skin surface of rabbits.	NonSensitizing	Under the conditions of the study, non-irritation	Pass
Sensitization (ISO 10993-10)	To evaluate the potential of test article extracts to cause skin sensitization in the guinea pig according to GPMT method.	Non-Irritating	Under the conditions of the study, non-sensitization	Pass

Note 1: The composition of colorants is pigment blue 15:3 (CAS No.147-14-8), the MSDS of color additive used in our manufacturing process is shown as attachment 4.

Note 2: The width dimension of subject is a little longer than that of predicate device, this difference does not affect the safety and effectiveness.

7. Non-clinical Tests Performed on the Proposed Device

The proposed device was 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 issued on March 5, 2004.

8. Summary of Clinical Testing

There is no clinical study included in this submission.

9. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in this 510(k) submission K210679, the medical face mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K200847.

10. Summary Prepared Date

30 November 2021