



June 28, 2022

Shandong Xingyu Gloves Co., Ltd.  
% Jarvis Wu  
Consultant  
Shanghai Sungo Management Consulting Company Limited  
14th Floor, 1500# Central Avenue  
Shanghai, Shanghai 200122  
China

Re: K221272

Trade/Device Name: Medical Face Mask  
Regulation Number: 21 CFR 878.4040  
Regulation Name: Surgical Apparel  
Regulatory Class: Class II  
Product Code: FXX  
Dated: May 2, 2022  
Received: May 2, 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](mailto: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

## Indications for Use

Submission Number (if known)

K221272

Device Name

Medical Face Mask

Indications for Use (Describe)

The Medical 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.**

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## 510(k) Summary

### K221272

*Document Date Prepared: 2022/6/27*

#### **A. Applicant:**

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#### **B. Device:**

Proprietary Name: Medical Face Mask

Common Name: Surgical Face Mask

Model(s): M001, M2002, M3001, M3002

#### 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
K211631	Surgical Face Mask	Level 2 & 3	Macheng thimble Technology Investment 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 Medical 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.

**E. Device Description:**

The Proposed Device Medical Face Mask (Model: M001, M2002, M3001, M3002) are available in blue and black colors, and flat pleated type mask, utilizing ear loops way for wearing, and it has Nose clips design for fitting the face mask around the nose.

The proposed device(s) submitted meet both the performance requirements of level 2 and 3 specified in ASTM F2100-19.

Level 2 blue mask is model number M2001; Level 2 black mask is model number M2002;

Level 3 blue mask is model number M3001; Level 3 black mask is model number M3002;

The proposed device is manufactured with three layers, the inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter. The model of proposed device, ear loops, is held in place over the user’s mouth and nose by two elastic ear loops welded to the face mask. The elastic ear loops are made of Polyester and Spandex. The nose piece contained in the proposed device is in the layers of face mask to allow the user to fit the face mask around their nose, which is made of Metal Core Plastic (Iron wire & Polypropylene). 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
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<b>Manufacturer</b>	Shandong Xingyu Gloves Co., Ltd.	Macheng thimble Technology Investment Co., Ltd	-	
<b>510K number</b>	K221272	K211631	-	
<b>Device name</b>	Medical Face Mask	Surgical Face Mask	-	
<b>Classification</b>	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same	
<b>Indications for use</b>	The Medical 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.	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 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.	Same	
<b>Material</b>	<b>Outer layer</b>	Non-woven fabric	Spun-bond polypropylene	Same
	<b>Middle layer</b>	Melt-blown Non-woven fabric	Melt blown polypropylene filter	Same
	<b>Inner layer</b>	Non-woven fabric	Spun-bond polypropylene	Same
	<b>Nose clip</b>	Metal Core Plastic (Iron wire & Polypropylene)	Malleable aluminum wire	substantially equivalent
	<b>Ear loops</b>	Polyester and Spandex	Polyester	substantially equivalent
<b>Color</b>	Blue, Black	Blue	substantially equivalent	
<b>Dimension</b>		17.5cm+/-0.5cm		

<b>(length)</b>	175mm+/-5mm		Same
<b>Dimension (Width)</b>	95mm+/-5mm	9.5cm+/-0.5cm	Same
<b>OTC use</b>	Yes	Yes	Same
<b>Sterility</b>	Non-Sterile	Non-Sterile	Same
<b>Use</b>	Single Use, Disposable	Single Use, Disposable	Same
<b>ASTM F2100-19 level</b>	Level 2 & 3	Level 2 & 3	Same
<b>Biocompatibility</b>	Meet ISO10993 ,proved non-cytotoxicity, non-irritating and non-sensitizing	Meet ISO10993 ,proved non-cytotoxicity, non-irritating and non-sensitizing	Same

From the comparison we found the material of proposed device's nose clip and Ear loops, as well as its color, are 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

<b>Item</b>	<b>Proposed device</b>	<b>Proposed device</b>	<b>Acceptance Criteria</b>	<b>Result</b>
<b>Fluid Resistance Performance ASTM F1862</b>	Assess the performance of a mask to resistance to a synthetic blood preparation targeted toward the mask at a set pressure	32 out of 32 per lot pass at 120 mmHg for 3 non-consecutive lots tested;  32 out of 32 per lot pass at 160 mmHg for 3 non-consecutive lots tested;	29 out of 32 pass at 120 mmHg for Level 2  29 out of 32 pass at 160 mmHg for Level 3	PASS
<b>Particulate Filtration Efficiency ASTM F2299</b>	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.  Average Result- Level 2 : 99.2% Level 3 : 99.5%	≥ 98%	PASS
<b>Bacterial Filtration Efficiency ASTM F2101</b>	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.  Average Result- Level 2 : 99.3% Level 3 : 99.3%	≥ 98%	PASS



<b>Differential Pressure (Delta P)</b> <b>EN 14683 Annex C</b>	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. Average Result- Level 2 : 5.0 mmH <sub>2</sub> O/cm <sup>2</sup> Level 3 : 4.4 mmH <sub>2</sub> O/cm <sup>2</sup>	< 6.0mmH <sub>2</sub> O/cm <sup>2</sup>	PASS
<b>Flammability 16</b> <b>CFR 1610</b>	Assess the resistance of a mask to ignition	3 non-consecutive lots tested, using a sample size of 32/lot. Average Result- Level 2 : Class 1 Level 3 : Class 1	Class 1	PASS

Table 3 – Biocompatibility Testing

<b>Test Method</b>	<b>Purpose</b>	<b>Acceptance Criteria</b>	<b>Result</b>
<b>Cytotoxicity</b>	Assess the potential risk of Cytotoxicity of mask material	Non-Cytotoxic	PASS Under the conditions of the study, the device is non-cytotoxic.
<b>Irritation</b>	Assess the potential risk of Irritation of mask material	Non-Irritating	PASS Under the conditions of the study, the device is non-irritating.
<b>Sensitization</b>	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 Medical Face Mask (Model: M001, M2002, M3001, M3002) is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K211631.