January 4, 2023

Hubei Woozon Healthcare Co.,Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801, No.161 Lujiazui East Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K222483
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 22, 2022
Received: December 5, 2022

Dear Boyle Wang:

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 -S

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.

510(k) Number *(if known)*
K222483

Device Name
Surgical Face Mask

Indications for Use *(Describe)*
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 is 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.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

Name: Hubei Woozon Healthcare Co.,Ltd.
Address: Nongfeng Road, Nonwoven Fabric Industrial Park, Wangzhou Avenue, Pengchang Town, Xiantao City, Hubei, China.
Tel: +86-728-3280667
Contact: Li Chunlin
Date of Preparation: Aug.8, 2022

Designated Submission Correspondent

Mr. Boyle Wang
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd., Pudong, Shanghai 200120 ,China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device Information

Trade name:	Surgical Face Mask
Common name:	Surgical Face Mask
Classification name:	Surgical Face Mask
Model:	Ear-loop Type

3.0 Classification

Production code:	FXX
Regulation number:	21CFR 878.4040
Classification:	Class II
Panel:	Surgical Apparel

4.0 Predicate Device Information

Manufacturer:	Anhui Tiankang Medical Technology Co., Ltd.
Device:	Surgical Face Mask
510(k) number:	K212368

5.0 Device Description

The Surgical Face Mask is single use, three-layer, flat-pleated style with ear loops and nose piece. The Surgical Face Mask is manufactured with three layers, the inner and outer layers are made of polypropylene, and the middle layer is made of melt blown polypropylene filter. The ear loops are held in place over the users' mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are not made with natural rubber latex. The nose piece in the layers of facemask is to allow the user to fit the facemask around their nose, which is made of Galvanized iron wire. The Surgical Face Mask will be provided in blue. The Surgical Face Mask is sold as non-sterile and are intended to be single use, disposable devices.

6.0 Indication for Use Statement

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 is a single use, disposable device(s), provided non-sterile.

7.0 Comparison to the Predicate Device

Table 1 General Comparison

Item	Subject Device	Predicate Device K212368	Remark
Product Name	Surgical Face Mask	Surgical Face Mask	--
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Intended Use& Indications for use	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 ininfection control practices to reduce the potential exposure to blood and body fluids. This is 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 ininfection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	Same
Design features	Ear Loops,	Ear loop, Tie-On,	Different

		3 layers	3 layers	Analysis 1
Mask Styles		Flat pleated	Flat pleated	Same
Material	Outer facing layer	Polypropylene	Spun-bond polypropylene	Similar Analysis 1
	Middle layer	Melt-blown cloth (polypropylene)	Melt blown polypropylene filter	Same
	Inner Facing layer	Polypropylene	Spun-bond polypropylene	Similar
	Nose piece	Galvanized iron wire	PP coated steel wire	Different Analysis 1
	Ear loops	Plolyester silk & Polyurethane filament	Ear loops: Nylon and spandex; Ties: PP nonwoven	Different Analysis 1
Color		Blue	Blue	Same
Dimension		Length: 175±4mm Width: 95±4mm	Length: 175±5mm Width: 95±2.85mm	Similar Analysis 2
OTC use		Yes	Yes	Same
Single Use		Yes	Yes	Same
Sterility		Non-sterile	Non-sterile	Same
ASTM F2100 Level		Level 1 Level 2 Level 3	Level 1 Level 2 Level 3	Same
Biocompatibility	Cytotoxicity ISO10993-5	Non-cytotoxic under the conditions of the study	Non-cytotoxic under the conditions of the study	Same
	Skin Irritation ISO10993-10	Non-irritating under the conditions of the study	Non-irritating under the conditions of the study	Same
	Skin Sensitization ISO10993-10	Non-sensitizer under the conditions of the study	Non-sensitizer under the conditions of the study	Same

Analysis 1: The two devices have some difference in design features and materials, product materials safety is proved by its biocompatibility, and the difference does not raise additional questions for safety and effectiveness of device.

Analysis 2: The two devices share same dimensions otherwise the tolerance is different, the little deviation in tolerance does not raise additional questions for safety and effectiveness of device.

8.0 Non-Clinical Test Conclusion

The proposed device was tested and conformed to the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Medical face 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);
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	Acceptance Criteria	Results
Synthetic Blood Penetration ASTM F1862	Demonstrate resistance to liquid penetration	29 samples out of 32 pass (AQL 4%) Level 1 pass at 80mmHg	Pass 32 out of 32 pass at 80 mmHg, 3 lots
		29 samples out of 32 pass (AQL 4%) Level 2 pass at 120mmHg	Pass 32 out of 32 pass at 120 mmHg, 3 lots
		29 samples out of 32 pass (AQL 4%) Level 3 pass at 160mmHg	Pass 32 out of 32 pass at 160 mmHg, 3 lots
Particulate Filtration Efficiency ASTM F2299	Demonstrate particulate filtration	Level 1 pass at ≥95%	Pass Average 98.24%
		Level 2 pass at ≥98%	Pass Average 98.75%
		Level 3 pass at ≥98%	Pass Average 99.67%
Bacterial Filtration Efficiency ASTM F2101	Demonstrate bacterial filtration	Level 1 pass at ≥95%	Pass Average 99.18%
		Level 2 pass at ≥98%	Pass Average 99.20%
		Level 3 pass at ≥98%	Pass Average 99.21%
Differential Pressure	Demonstrate breathability	Level 1 pass at ≤ 5.0 mmH_2O/cm^2	Pass Average 3.75 mmH_2O/cm^2

(Delta P) EN 14683 Annex C		Level 2 pass at ≤ 6.0 mmH_2O/cm^2	Pass Average 4.25 mmH_2O/cm^2
		Level 3 pass at ≤ 6.0 mmH_2O/cm^2	Pass Average 4.68 mmH_2O/cm^2
Flammability 16 CFR 1610	Demonstrate flame resistance	Class I	Pass

Table 3 - Biocompatibility Testing

Item	Purpose	Subject Device	Results
Cytotoxicity ISO 10993-5	Demonstrate cytotoxic biocompatibility	Under the conditions of the study, the device is non-cytotoxic.	Pass
Skin Irritation ISO10993-10	Demonstrate non irritability	Under the conditions of the study, the device is non-irritating.	Pass
Skin Sensitization ISO10993-10	Demonstrate non sensitization	Under the conditions of the study, the device is non-sensitizing	Pass

9.0 Clinical Test Conclusion

No clinical study is included in this submission.

10.0 Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device in K212368.