May 19, 2023

Guangzhou Fuzelong Hygiene Material Co., Ltd
% Boyle Wang
Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM. 1801, No. 161 Lujiazui East Rd.,Pudong
Shanghai, Shanghai 200120
China

Re: K222545
Trade/Device Name: Disposable Medical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 1, 2023
Received: April 19, 2023

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,

Katherine D. Kavlock -S

for
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)*
K222545

Device Name
Disposable Medical Mask

Indications for Use *(Describe)*
Disposable Medical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It is 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 as 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

K222545

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

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Contact: Haiyan Zeng
Date of Preparation: Aug.12, 2022

Designated Submission Correspondent

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2.0 Device Information

Trade name:	Disposable Medical Mask
Common name:	Surgical Face Mask
Classification name:	Surgical Face Mask
Model:	Ear loops, Tie-on

3.0 Classification

Production code:	FXX - Mask, Surgical.
Classification Name:	Surgical Apparel (21 CFR part 878.4040)
Classification:	Class II
Panel:	Surgical Apparel

4.0 Predicate Device Information

Manufacturer:	Jiangsu Xingtong Biotechnology Group Co., Ltd.
Device:	Surgical mask
510(k) number:	K211454

5.0 Device Description

The Disposable Medical Mask consists of a mask body, a nose piece, and ear loops or ties.
The mask body is divided into four layers, the inner, second and outer layers are made of polypropylene materials; the middle layer is composed of melt-blown cloth (polypropylene); the nose piece is made of galvanized iron wire, the ear loops are made of polyester and spandex, and the ties are made of polypropylene.
The Medical Surgical Mask will be provided in green. The Disposable Medical Mask is sold as sterile and are intended to be single use, disposable devices.
The size specification of the surgical mask:
- Mask body for ear-loop type: 14.5cm×9cm (S), 17.5cm×9.5cm (M), 18cm×9.3cm (L), 22cm×9.5cm (XL);
- Mask body for Tie-on type: 14.5cm×9cm (S), 17.5cm×9.5cm (M), 18cm×9.3cm (L), 22cm×9.5cm (XL).
The smallest sizes mask (14.5cm×9cm) are for adult population only.

6.0 Indication for Use Statement

Disposable Medical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It is 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 as sterile.

7.0 Comparison to the Predicate Device

Table 1 General Comparison

Item	Subject Device	Predicate Device K211454	Remark
Product Name	Medical Surgical Mask	Surgical 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	Medical Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It is intended for use in infection control practices to reduce the	The surgical 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	Same

		potential exposure to blood and body fluids. This is a single use, disposable device(s), provided as sterile.	reduce the potential exposure to blood and body fluids. This is a single-use, disposable device, provided as sterile.	
Design features		Ear Loops, Tie-on, 4 layers	Ear loops: XT10A1; Tie-on: XT10B1; 3 layers	Different Analysis1
Mask Styles		Flat pleated	Flat pleated	Same
Material	Outer facing layer	Polypropylene	Polypropylene	Same
	Middle layer	1. Polypropylene 2. Melt-blown cloth (polypropylene)	1. Melt-blown cloth (polypropylene)	Similar
	Inner Facing layer	Polypropylene	Polypropylene	Same
	Nose piece	Galvanized iron wire	Polyethylene coated steel wire	Different Analysis 1
	Ear loops, Ties	-Ear loops: Polyester, spandex -Ties: Polypropylene	-Ear loops: Polyester silk & Polyurethane filament -Ties: Polypropylene	Similar Analysis 1
Color		Green	Blue	Different Analysis 2
Dimension		- Mask body for ear-loop type: 14.5cm×9cm (S), 17.5cm×9.5cm (M), 18cm×9.3cm (L), 22cm×9.5cm (XL); - Mask body for Tie-on type: 14.5cm×9cm (S), 17.5cm×9.5cm (M), 18cm×9.3cm (L), 22cm×9.5cm (XL). The smallest sizes mask (14.5cm×9cm) are for adult population only.	Mask body for ear-loop type: 17.5cm×9.5cm & 14.5cm×9.5cm Mask body for Tie-on type: 17.5cm×9.5cm	Different Analysis 3
OTC use		Yes	Yes	Same
Shelf life		2 years	2 years	Same

Single Use	Yes	Yes	Same
Sterility	Sterile	Sterile	Same
Sterilization method and S.A.L.	Sterilized by ethylene oxide gas, SAL=10^{-6}	Sterilized by ethylene oxide gas, SAL=10^{-6}	Same
ASTM F2100 Level	Level 3	Level 3	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 subject device (Green) has different color to the predicate device (Blue), but all proposed devices are conducted the biocompatibility test. The difference does not raise additional questions for safety and effectiveness of device.

Analysis 3: the two devices have some difference in dimensions, the little deviation in dimensions 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	Demonstrate	29 samples out of 32	Pass

Blood Penetration ASTM F1862	resistance to liquid penetration	pass (AQL 4%) Level 3 pass at 160mmHg	32 out of 32 pass at 160 mmHg
Particulate Filtration Efficiency ASTM F2299	Demonstrate particulate filtration	Level 3 pass at ≥98%	Pass Filtration Efficiency (%) ≥ 99.80%
Bacterial Filtration Efficiency ASTM F2101	Demonstrate bacterial filtration	Level 3 pass at ≥98%	Pass Percent BFE (%) ≥ 99.80%
Differential Pressure (Delta P) EN 14683 Annex C	Demonstrate breathability	Level 3 pass at ≤ 6.0 mmH_2O/cm^2	Pass Average 4.2 mm H_2O/cm^2
Flammability 16 CFR 1610	Demonstrate flame resistance	Class I	Pass

Table 4 - Biocompatibility Testing

Item	Subject Device	Result
Cytotoxicity	Under the conditions of the study, the subject device was non-cytotoxic	Pass
Irritation	Under the conditions of the study, the subject device was non-irritating	Pass
Sensitization	Under the conditions of the study, the subject device was 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 K211454.