February 20, 2022

Hunan Zhenheyikang Medical Instrument 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: K213724
Trade/Device Name: Medical Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 10, 2022
Received: February 16, 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,

Clarence W. Murray, III, PhD
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)*
K213724

Device Name
Medical Surgical Mask

Indications for Use *(Describe)*
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 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.

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510(k) Summary

K213724

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

1.0 submitter's Information

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Date of Preparation: Nov.12, 2021

Designated Submission Correspondent

Mr. Boyle Wang

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2.0 Device Information

Trade name: Medical Surgical 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: Jiangsu Xingtong Biotechnology Group Co., Ltd.
Device: Surgical mask

510(k) number: K211454

5.0 Device Description

The Medical Surgical Mask is single use, three-layer, flat-pleated style with ear loops and nose piece. The Medical Surgical 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 Medical Surgical Mask will be provided in blue. The Medical Surgical Mask is sold as sterile and are intended to be single use, disposable devices.

6.0 Indication for Use Statement

The 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. 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 as sterile.

7.0 Technological Characteristic Comparison

Table 1 General Comparison

Item	Subject Device K213724	Predicate Device K211454	Comparison
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 potential exposure to blood and body fluids. This is a single use, disposable device(s),	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 reduce the potential exposure to blood and body fluids. This is a single-use,	Same

		provided as sterile.	disposable device, provided as sterile.	
Design features		Ear Loops, 3 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	Melt-blown cloth (polypropylene)	Melt-blown cloth (polypropylene)	Same
	Inner Facing layer	Polypropylene	Polypropylene	Same
	Nose piece	Galvanized iron wire	Polyethylene coated steel wire	Different Analysis1
	Ear loops	78% Polyester + 22% spandex	-Ear loops: Polyester silk & Polyurethane filament	Similar Analysis1
Color		Blue	Blue	Same
Dimension		175mm×95mm±5%	Mask body for ear-loop type: 17.5cm×9.5cm & 14.5cm×9.5cm Mask body for Tie-on type: 17.5cm×9.5cm	Similar Analysis2
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

Bacterial filtration efficiency (BFE) (%)	Lot 1# 31 Out of 32 pass at 160mmHg (21.3 kPa); Lot 2# 31 Out of 32 pass at 160mmHg (21.3 kPa); Lot 3# 32 Out of 32 pass at 160mmHg (21.3 kPa).	Lot 1# pass at 160mmHg; Lot 2# pass at 160mmHg; Lot 3# pass at 160mmHg.	Similar
Different pressure (mmH_2O/cm^2)	Lot1#99.02%-99.58%; Lot2#99.05%-99.59%; Lot3#99.10%-99.68%.	Lot 1# 99.7%-99.9%; Lot 2# 99.7%-99.9%; Lot 3# 99.7%-99.9%.	Similar
Sub-micron particulate filtration efficiency at 0.1 micron, % (PFE)	Lot1#98.8%-99.7%; Lot2#98.7%-99.5%; Lot3#98.9%-99.5%.	Lot 1# 99.2%-99.8%; Lot 2# 99.0%-99.7%; Lot 3# 99.3%-99.7%.	Similar
Resistance to penetration by synthetic blood, Minimum pressure in mmHg for pass result	Lot1#1.66-4.44mmH_20/cm^2 Lot2#1.63-4.24mmH_20/cm^2 Lot3#1.60-4.43mmH_20/cm^2	Lot 1# 2.3-4.6; Lot 2# 2.3-4.5; Lot 3# 2.0-3.9	Similar
Flame spread	Lot 1# Class I; Lot 2# Class I; Lot 3# Class I	Lot 1# Class I; Lot 2# Class I; Lot 3# Class I	Same

Analysis1: the two devices have some difference in design features and materials, product materials safety is proved by its biocompatibility.

Analysis2: the two devices share same dimensions otherwise the tolerance is different.

Analysis 3: The two devices have some little deviation in product performance, but the difference in the performance test result does not raise additional questions for safety and effectiveness since the two device performance results both meet the requirements of ASTM F2100-19, level 3.

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.

Table 2 - Performance Testing

Item	Purpose	Acceptance Criteria	Result
Fluid Resistance Performance ASTM F1862	The purpose of the methodology is to evaluate the Fluid Resistance	29 Out of 32 pass at 120 mmHg (21.3 kPa)	Pass Lot 1# 31 Out of 32 pass at 160mmHg (21.3 kPa) Lot 2# 31 Out of 32 pass at 160mmHg (21.3 kPa) Lot 3# 32 Out of 32 pass at 160mmHg (21.3 kPa)
Particulate Filtration Efficiency ASTM F2299	The purpose of the methodology is to evaluate the Particulate Filtration Efficiency	≥ 98%	Pass Lot1#99.02%-99.58%; Lot2#99.05%-99.59%; Lot3#99.10%-99.68%
Bacterial Filtration Efficiency ASTM F2101	The purpose of the methodology is to evaluate the Bacterial Filtration Efficiency	≥ 98%	Pass Lot1#98.8%-99.7%; Lot2#98.7%-99.5%; Lot3#98.9%-99.5%
Differential Pressure (Delta P) MILM- 36954C	The purpose of the methodology is to evaluate the Differential Pressure (Delta P)	< 6.0 mmH_20/cm^2	Pass Lot1#1.66-4.44mmH_20/cm^2 Lot2#1.63-4.24mmH_20/cm^2 Lot3#1.60-4.43mmH_20/cm^2
Flammability 16 CFR 1610	The purpose of the methodology is to evaluate the Flammability	Class 1	Pass, Class 1

Table 3 - Biocompatibility Testing

Item	Purpose	Result

Cytotoxicity	The purpose of the methodology is to evaluate the Cytotoxicity endpoint.	Pass Under the conditions of the study, the subject device was non-cytotoxic
Irritation	The purpose of the methodology is to evaluate the Irritation endpoint.	Pass Under the conditions of the study, the subject device was non-irritating
Sensitization	The purpose of the methodology is to evaluate the Sensitization endpoint.	Pass Under the conditions of the study, the subject device was non-sensitizing

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.