November 16, 2021

Xiantao Dingcheng Non-woven Product Co., Ltd
Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai
China

Re: K212344
Trade/Device Name: Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 30, 2021
Received: October 18, 2021

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,

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)*
K212344

Device Name
Surgical Mask

Indications for Use *(Describe)*
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 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 SMDA 1990 and 21 CFR 807.92.

1.0 Submitter's information

Name: Xiantao Dingcheng Non-woven Product Co., Ltd
Address: Liukou Industrial Park, Xiantao City, Hubei Province, CHINA
Phone Number: +86-18007229722
Contact: Ms. Cheng Qin
Date of Preparation: 21/07/2021

Designated Submission Correspondent

Mr. Boyle Wang
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Room 608, No. 738 Shangcheng Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device information

Trade name: Surgical Mask
Common name: Surgical Mask
Classification name: Mask, Surgical
Model(s): ear strap, 175×95mm

3.0 Classification

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

4.0 Predicate device information

Manufacturer: Wuhan Dymex Healthcare Co., Ltd
Device: Surgical Face Mask
510(k) number: K182515
This device has not been subject to a design-related recall.

5.0 Device description

The Surgical Mask is single use, three-layer, flat-pleated style with ear straps and nose piece. The mask is manufactured with three layers, the inner and outer layers are made of nonwoven fabrics, and the middle layer is made of melt blown fabrics. The ear straps are held in place over the users' mouth and nose by two elastic ear straps welded to the facemask. The elastic ear straps are not made with natural rubber latex. The nose piece on the layers of facemask is to allow the user to fit the facemask around their nose, which is made of Polypropylene+Galvanize d-iron dual core. The Surgical Mask will be provided in blue. The masks are sold non-sterile and are intended to be single use, disposable devices.

6.0 Indication for Use Statement

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 non sterile.

7.0 Comparison of Technological Characteristics

Table 1 Technological Characteristic Comparison Table

Item		Proposed device	Predicated device	Remark
Product Code		FXX	FXX	Same
Regulation No.		21 CFR 878.4040	21 CFR 878.4040	Same
Class		II	II	Same
Product name		Surgical Mask	Surgical Face Mask	-
510(k) No.		K212344	K182515	-
Models		ear strap, 175×95mm	ear strap	-
Intended Use		The 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 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 is a single use, disposable device(s), provided non-sterile.	Same
OTC use		Yes	Yes	Same
Composite		Flat Pleated, 3 layers	Flat Pleated, 3 layers	Same
	Internal layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene	Melt blown polypropylene	Same

Material	External layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose piece	Polypropylene+Galvanized-iron dual core	Malleable polyethylene wire	* Different 1
	ear strap	Polyester, spandex	spandex	* Different 2
Color		Blue	Yellow	* Different 3
Dimension (Length)		17.5cm±0.5cm	17.5cm±0.2cm	* Different 4
Dimension (Width)		9.5cm±0.5cm	9.5cm±0.2cm	* Different 5
Sterility		Non-Sterile	Non-Sterile	Same
Single Use		Yes	Yes	Same
Sterile		No	No	Same
ASTM F2100 Level		Level 3	Level 2	* Different 6

* Different analysis:

Different 1-3: the two devices have some difference in materials and product color, product materials safety is proved by its biocompatibility, and the difference does not raise additional questions for safety and effectivenessof device.

Different 4-5: 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.

Different 6: the two devices in different levels, the difference 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: Surgical Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004.

Following standards are applicable for the device of Surgical Mask:

- ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- ASTM F1862-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- ASTM F2299− 03 (Reapproved 2017) Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- EN 14683-2019 Medical Face Masks – Requirements and Test Methods
- 16 CFR Part 1610(a) Standard for The Flammability of Clothing Textiles
- ISO 10993-1:2018 Biological evaluation of medical devices -- Part 1: Evaluation and testing
- ISO 10993-5 Third edition 2009-06-01, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity.
- ISO 10993-10 Third Edition 2010-08-01, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

Table 2 Summary of Non-Clinical Performance Testing

No.	Name of the Test Methodology / Standard	Purpose	Acceptance Criteria	Results
1	ISO 10993-10:2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin	This part of ISO 10993 assesses possible contact hazards from chemicals released from medical devices, which may	Skin Sensitization Test: provided grades less than 1, otherwise sensitization.	All grades are 0. All animals were survived and no abnormal signs were observed during the study.

2	Sensitization.	produce skin and mucosal irritation, eye irritation or skin sensitization.	Skin Irritation Test: If the primary irritation index is 0-0,4, the response category is Negligible. 0,5-1,9 means slight 2-4,9 means moderate 5-8 means severe	The primary irritation index is 0. The response of the proposed device was categorized as negligible under the test condition
3	ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity	This part of ISO 10993 describes test methods to assess the in vitro cytotoxicity of medical devices.	The viab.% of the 100% extract of the test article is the final result, and if viability is reduced to <70% of the blank, it has cytotoxic potential.	Viab.% of 100% test article extract is 90.4% It means the proposed device have no potential toxicity to L-929 in the MTT method
4	Bacterial filtration efficiency (BFE) (%) ASTM F2101-19	The purpose of the test is to evaluate the Bacterial filtration efficiency (BFE) (%)	≥98	Average Lot 1: 99.3% Average Lot 2: 99.2% Average Lot 3: 99.3% Pass
5	Differential pressure (mmH_2O/cm^2) EN 14683	The purpose of the test is to evaluate the Different pressure (mmH_2O/cm^2)	<6.0 mmH_2O/cm^2	Average Lot 1: 4.4 mmH_2O/cm^2 Average Lot 2: 4.6 mmH_2O/cm^2 Average Lot 3: 4.6 mmH_2O/cm^2 Pass

6	Sub-micron particulate filtration efficiency at 0.1 micron, % (PFE)	The purpose of the test is to evaluate the Sub-micron particulate filtration efficiency at 0.1 micron, % (PFE)	≥98	Average Lot 1: 98.44% Average Lot 2: 98.26% Average Lot 3: 98.30% Pass
7	Resistance to penetration by synthetic blood, Minimum pressure in mmHg for pass result	The purpose of the test is to evaluate the Resistance to penetration by synthetic blood, Minimum pressure in mmHg for pass result	29 of 32 test articles passed at 160mmHg	Lot 1: 31 of 32 test articles passed at 160mmHg; Lot 2: 32 of 32 test articles passed at 160mmHg; Lot 3: 32 of 32 test articles passed at 160mmHg Pass
8	Flammability	The purpose of the test is to evaluate the Flammability	Class 1	Class 1, Non Flammable Pass
9	Tensile strength of Ear Straps	to evaluate the tensile strength	>10 N	Average Lot 1: Left: 14.3 N Right: 14.4N Average Lot 2: Left: 14.1 N Right: 14.7N Average Lot 3: Left: 14.6 N Right: 13.9N Pass
10	Product dimensions	to evaluate the	Length:	Average Lot 1:

		Product dimensions	17.5cm±0.5cm Width: 9.5cm±0.5cm	(Length): 17.7 cm (Width): 9.8 cm Average Lot 2: (Length): 17.8 cm (Width): 9.6 cm Average Lot 3: (Length): 17.4 cm (Width): 9.6 cm

8.0 Clinical Test Conclusion

No clinical study implemented for the Surgical Mask.

9.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better the legally marketed device..