January 28, 2022

Hubei Xinxin Non-woven Co.,Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K212120
Trade/Device Name: Surgical Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 20, 2021
Received: December 27, 2021

Dear Diana Hong:

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)*
K212120

Device Name
Surgical Masks

Indications for Use *(Describe)*
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 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, provided non-sterile.

XX0009 Ear loop Level: Level 1, Level 2 and Level 3
XX0008 Tie-on Level: Level 1, Level 2 and Level 3
XX0006 Tie-on with shield Level: Level 1, Level 2 and Level 3
XX0005 Ear loop with shield Level: Level 1, Level 2 and Level 3

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 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K212120

1. Date of Preparation: 01/27/2022

2. Sponsor Identification

Hubei Xinxin Non-woven Co., Ltd.
Taizihu Industrial Park, Pengchang Town, Xiantao, Hubei, 433018, China

Establishment Registration Number: 3011547453.

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jinlei Tang (Alternative Contact Person)

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P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Surgical Masks
Common Name: Surgical Face Mask

Regulatory Information
Classification Name: Mask, Surgical
Classification: II;
Product Code: FXX;
Regulation Number: 21CFR 878.4040
Review Panel: General Hospital

Indication for use:
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 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, provided non-sterile.
XX0009 Ear loop Level: Level 1, Level 2 and Level 3
XX0008 Tie-on Level: Level 1, Level 2 and Level 3
XX0006 Tie-on with shield Level: Level 1, Level 2 and Level 3
XX0005 Ear loop with shield Level: Level 1, Level 2 and Level 3

Device Description:
The surgical masks are single use, flat-pleated masks that are provided in blue. The outer and inner layers of the mask are made of spunbond polypropylene. The middle filter is made of one layer of meltblown polypropylene filter. The Surgical Masks are available in four types due to different configurations, including ear loop, tie-on, ear loop with shield and tie-on with shield. Detail configurations of them are presented in Table 1 Surgical Masks Description. The ties are made of spunbond polypropylene and the ear loops are made of spandex. The shield is made of PET. The nose piece is made of iron wire and polypropylene. Users can adjust the nose piece according to the shape of the bridge of the nose, and fix the mask on the bridge of the nose to prevent the mask from falling off. The proposed devices are provided in non-sterile. The proposed devices contain four (4) types of masks: XX0009, XX008, XX0006 and XX0005. Each of these types have three different levels, level 1, level 2, and level 3. Therefore, the proposed devices have 12 models *in toto*, and detailed model information is provided in Table 1.

Table 1. Surgical Masks Description

Product Model	Ear loop	Tie-on	Shield	ASTM F2100 Level
XX0009	√	NA	NA	Level 1, Level 2 and Level 3
XX0008	NA	√	NA	Level 1, Level 2 and Level 3

XX0006	NA	√	√	Level 1, Level 2 and Level 3
XX0005	√	NA	√	Level 1, Level 2 and Level 3

5. Identification of Predicate Device

510(k) Number: K160269
Product Name: Surgical Face Masks (Ear loops and Tie-on)

6. Summary of Technological characteristics

Table 1. Comparison of Surgical Masks

ITEM	Proposed Device K212120	Predicate Device K160269	Remark
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Indication for Use	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 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, provided non-sterile. XX0009 Ear loop Level: Level 1, Level 2 and Level 3 XX0008 Tie-on Level: Level 1, Level 2 and Level 3 XX0006 Tie-on with shield Level: Level 1, Level 2 and Level 3 XX0005 Ear loop with shield Level: Level 1, Level 2 and Level 3	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, provided non-sterile.	Same
Mask style	Flat-pleated	Flat-pleated	Same
Configurations	Ear loop; Tie-on; Ear loop with shield; Tie-on with shield	Ear loop; Tie-on; Ear loop with visor; Tie-on with visor	Same
Color	Blue	Blue, White	Different
Dimension	Mask:	Length: 90±3mm;	Different

	Length: 175±5mm; Width: 95±5mm; Nose piece: Length:115mm±10mm; Ear loop: Natural length: 165±10mm; Stretched length: 420±10mm; Ties: Length: 400±10mm; Shield: Length: 295±5mm; Width: 122±5mm			Width: 175±5mm; Or Length:90±3mm; Width: 180±5mm			
Sterility	Non-Sterile			Non-Sterile			Same
Use	Single Use, Disposable			Single Use, Disposable			Same
ASTM F2100 Level	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	Same
Particulate filtration efficiency	Pass at 96.17%	Pass at 98.95%	Pass at 99.06%	Pass at 99.6%	Pass at 99.6%	Pass at 99.7%	Different
Bacterial filtration efficiency	Pass at 96.80%	Pass at 98.90%	Pass at 99.04%	Pass at >98%	Pass at >98%	Pass at >99%	Different
Differential pressure	Pass at 4.0 mmH_2O/cm^2	Pass at 5.1 mmH_2O/cm^2	Pass at 5.2 mmH_2O/cm^2	Pass at 2.0 mmH_2O/cm^2	Pass at 1.6 mmH_2O/cm^2	Pass at 2.5 mmH_2O/cm^2	Different
Flammability	Class 1	Class 1	Class 1	Class 1	Class 1	Class 1	Same
Fluid resistance	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Same
Label/Labeling	Complied with 21 CFR part 801			Complied with 21 CFR part 801			Same
Patient Contacting Material							
Outer facing layer	Spunbond Polypropylene			Polypropylene			Different
Middle layer	Meltblown Polypropylene Filter			Meltblown Polypropylene Filter; Spunbond Polypropylene Filter			
Inner facing layer	Spunbond Polypropylene			Polypropylene			
Nose piece	Iron wire and Polypropylene			Polyethylene coated steel wire			
Ear loop	Spandex			Polyester, Polyurethane Side tapes: Polyester spunbond (ear loops mask only)			
Ties	Spunbond Polypropylene			Polypropylene spunbond or polyester			

		spunbond	
Shield	PET	Polyester	
Biocompatibility			
Cytotoxicity	Under the conditions of the study, the proposed device was non-cytotoxic.	Under the conditions of the study, the subject device was non-cytotoxic.	Same
Irritation	Under the conditions of the study, the proposed device was non-irritating.	Under the conditions of the study, the subject device was non-irritating.	
Sensitization	Under the conditions of the study, the proposed device was non-sensitizing.	Under the conditions of the study, the subject device was non-sensitizing.	

Different - Color

The proposed device is blue and the predicate device is provided in two colors, the color of the proposed device can be covered by the predicate device.

Different - Dimension

The dimension for the proposed device is different from the predicate device.

Different - Particulate filtration efficiency

The test result for particulate filtration efficiency for the proposed device is different from the predicate device.

Different - Bacterial filtration efficiency

The test result for bacterial filtration efficiency for the proposed device is different from the predicate device.

Different - Differential pressure

The test result and reference standard of differential pressure for the proposed device is different from predicate device.

Different - Patient Contacting Material

The patient contacting material for the proposed device is different from the predicate device.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was same/similar to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;
- ASTM F1862/F1862M-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/F2299M-03 (2017) Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres
- ASTM F2101: 2019 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- ASTM F2100: 2019 Standard Specification for Performance of Materials Used in Medical Face Masks
- EN 14683: 2019, Annex C, Medical face masks- Requirements and test methods
- ISO 10993-5:2009 Biological evaluation of medical device- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritaion and skin sensitization
- ISO 10993-1:2018 Biological evaluation of medical devices — Part 1 Evaluation and testing within a risk management process.

Test Methodology	Purpose	Acceptance Criteria	Result
Particulate Filtration Efficiency	The test was performed in accordance with ASTM F2299/F2299M-03 (2017) Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres to determine the particle filtration efficiency (PFE) of the test article.	Level 1: ≥95%	Pass at 96.17%
		Level 2: ≥98%	Pass at 98.95%
		Level 3: ≥98%	Pass at 99.06%
Bacterial Filtration Efficiency	The test was performed in accordance with ASTM F2101: 2019 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus to determine the bacterial filtration efficiency (BFE) of the test article.	Level 1: ≥95%	Pass at 96.80%
		Level 2: ≥98%	Pass at 98.90%
		Level 3: ≥98%	Pass at 99.04%
Differential Pressure	The test was performed in accordance with EN 14683:2019+AC: 2019 Annex	<5.0 mmH_2O/cm^2	Pass at 4.0 mmH_2O/cm^2

	C Medical face masks - Requirements and test methods.	<6.0 mmH_2O/cm^2	Pass at 5.1 mmH_2O/cm^2
		<6.0 mmH_2O/cm^2	Pass at 5.2 mmH_2O/cm^2
Flammability	The test was performed in accordance with 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles.	Class 1	Class 1
Resistance to Penetration by Synthetic blood	The test was performed in accordance with ASTM F1862/F1862M: 2017 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) to evaluate the effectiveness of the test sample from possible exposure to blood and other body fluids.	Level 1: No penetration at 80 mmHg	Level 1: Pass at 80 mmHg
		Level 2: No penetration at 120 mmHg	Level 2: Pass at 120 mmHg
		Level 3: No penetration at 160 mmHg	Level 3: Pass at 160 mmHg
Cytotoxicity	The test was performed in accordance with ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity to evaluate the cytotoxicity of the test sample.	The viability should be ≥70% of the blank. And the 50% extract of the test sample should have at least the same or a higher viability than the 100% extract.	The viability was ≥70% of the blank. And the 50% extract of the test sample had a higher viability than the 100% extract. Under the conditions of the study, the proposed device was non-cytotoxic.
Sensitization	The test was performed in accordance with ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization to evaluate the sensitization of the test sample.	Non-sensitizing	Under the conditions of the study, the proposed device was non-sensitizing.
Irritation	The test was performed in accordance with ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization to	Non-irritating	Under the conditions of the study, the proposed device was non-irritating.

	evaluate the irritation of the test sample.		

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the surgical masks is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K160269.