August 19, 2021

Xiantao S&J Protective Products Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K211462
Trade/Device Name: Disposable Ear-loop Medical Face Mask, Disposable Tie-On Medical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 8, 2021
Received: July 15, 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,

For 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)*

K211462

Device Name
Disposable Ear-loop Medical Face Mask
Disposable Tie-On Medical Face Mask

Indications for Use *(Describe)*

The Disposable Ear-loop Medical Face Mask/Disposable Tie-On Medical Face 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, 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 – K211462

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

The assigned 510(k) Number: K211462

1. Date of Preparation: 08/02/2021

2. Sponsor Identification

Xiantao S&J Protective Products Co., Ltd.
103 Mianyang Road, Xiantao, Hubei, China.

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3. Designated Submission Correspondent

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

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4. Identification of Proposed Device

Trade Name: Disposable Ear-loop Medical Face Mask
Disposable Tie-On Medical Face Mask
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 Disposable Ear-loop Medical Face Mask/Disposable Tie-On Medical Face 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, provided non-sterile.

Device Description:
The proposed device is a three-layers, flat-pleated mask. Its size is 17.5 cm x 9.5 cm, and it is available in two types, Ear-loop and Tie-On. Both the ear loop and tie-on masks are available in three barrier levels (Level 1, Level 2, Level 3) based on ASTM F2100: 2019. The mask body is composed of three layers which is made of PP non-woven cloth. The difference between the three levels mask is the density of middle material. The ear loop or tie strings is used to secure the mask over the users' mouth and face. The nosepiece provides a firm fit over the nose. Ear loops are made of Nylon and spandex, and tie strings are made of PP non-woven cloth. The nose clip is made of Aluminum wire.

5. Identification of Predicate Device

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

6. Technological Characteristics Comparison

Table 1 General Comparison

ITEM	Proposed Device Disposable Ear-loop Medical Face Mask/Disposable Tie-On Medical Face Mask			Predicate Device K160269 Surgical Face Masks (Ear loops and Tie-on)			Comparison
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	
Product Code	FXX			FXX			Same
Regulation No.	21 CFR 878.4040			21 CFR 878.4040			Same
Class	II			II			Same
Indication for Use	The Disposable Ear-loop Medical Face Mask/Disposable Tie-On Medical Face 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, 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, provided non-sterile. Level 1 Face Mask Models: # EL 10000, EL 10010, TO 10000, TO 10010 Level 2 Face Mask Models: # EL 20000, EL 20010, TO 20000, TO 20010 Level 3 Face Mask Models: # EL 30000, EL 30010, TO 30000, TO 30010			Same
Mask style	Flat pleated			Flat pleated			Same
Design feature	Ear-loop / Tie-on			Ear loop / Tie-on			Same

Dimension (mm)	Ear loops: Body: 175 mm×95 mm, nose clip: 125mm, Ear-loop: 175mm Tie-on: Body: 175 mm×95 mm, nose clip: 125mm, Tie strings: 910mm			175 mm×90 mm 180 mm×90 mm			Analysis 1
ASTM F2100 Level	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	Same
Fluid resistance	Pass at 80mmHg	Pass at 120mmHg	Pass at 160mmHg	Pass at 80mmHg	Pass at 120mmHg	Pass at 160mmHg	Same
Particulate efficiency level	Pass at 98.2%	Pass at 99.3%	Pass at 99.6%	Pass at 99.6%	Pass at 99.6%	Pass at 99.7%	Analysis 2
Bacterial filtration level	Pass at 98.9%	Pass at 99.4%	Pass at 99.6%	Pass at >98%	Pass at >98%	Pass at >99%	Analysis 3
Differential pressure	Pass at 3.6 mmH_2O/cm^2	Pass at 4.0 mmH_2O/cm^2	Pass at 4.6 mmH_2O/cm^2	Passed at 2.0 mmH_2O/cm^2	Passed at 1.6 mmH_2O/cm^2	Passed at 2.5 mmH_2O/cm^2	Analysis 4
Flammability	Class 1			Class 1			Same
Label/Labeling	Complied with 21 CFR part 801			Complied with 21 CFR part 801			Same
Materials							
Outer layer Material	23g/m^2 PP non-woven cloth			Polypropylene			Analysis 5
Inner layer Material	20g/m^2 PP non-woven cloth			Polypropylene			
Middle layer Material	22g/m^2 PP non-woven cloth	25g/m^2 PP non-woven cloth	33g/m^2 PP non-woven cloth	1. Polypropylene spunbond 2. Polypropylene melt blown			
Nose Clip	Aluminum wire			Polyethylene coated steel wire			
Ear-Loop	Nylon and Spandex			Polyester, Polyurethane, Side tapes: Polyester spunbond (ear loops mask only)			
Tie strings	35 g/m^2 PP non-woven cloth			Polypropylene spunbond or Polyester spunbond			
Colors	Blue			Blue and white			Analysis 6

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
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.	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.	Same
Sterility	Non-Sterile	Non-Sterile	Same

Analysis 1 - Dimension (mm)

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

Analysis 2 - Particulate efficiency level

The test result of particulate filtration efficiency for the proposed device is different from predicate device. However, the test result of the proposed devices can meet the requirements of level 1/level 2/level 3 based on ASTM F2100-19.

Analysis 3 - Bacterial filtration level

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

Analysis 4 - Differential pressure

The test result and reference standard of differential pressure for the proposed device is different from predicate device. However, the proposed device can meet the requirements of the standard ASTM F2100: 2019 which was recognized by FDA.

Analysis 5 - Materials

The material for the proposed device is different from predicate device. However, biocompatibility test has been performed on the proposed device and the results does not show any adverse effect.

Analysis 6 - 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.

7. Summary of Non-Clinical Test

Nonclinical tests were conducted to verify that the proposed device met all design specifications as was same/similar to the predicate device. The test results from three nonconsecutive lots of 32 samples per lots (total of 96 samples) for each level claimed below demonstrated that the proposed device complies with the following standards:

- 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);
- 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+AC: 2019 Annex C Medical face masks - Requirements and test methods
- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;
- 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 Testing

Test Methodology	Purpose	Acceptance Criteria	Result
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 80mmHg
		Level 2: No penetration at 120 mmHg	Level 2: Pass at 120mmHg
		Level 3: No penetration at 160 mmHg	Level 3: Pass at 160mmHg
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 98.2%
		Level 2: ≥98%	Pass at 99.3%
		Level 3: ≥98%	Pass at 99.6%

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 98.9%
		Level 2: ≥98%	Pass at 99.4%
		Level 3: ≥98%	Pass at 99.6%
Differential Pressure	The test was performed in accordance with EN 14683:2019+AC: 2019 Annex C Medical face masks - Requirements and test methods.	<5.0 mmH_2O/cm^2	Pass at 3.6 mmH_2O/cm^2
		<6.0 mmH_2O/cm^2	Pass at 4.0 mmH_2O/cm^2
		<6.0 mmH_2O/cm^2	Pass at 4.6 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
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 evaluate the irritation of the test sample.	Non-irritating	Under the conditions of the study, the proposed device was non-irritating.

8. Clinical Test Conclusion

   No clinical study is included in this submission.

9. Conclusion

   The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device K160269.