April 7, 2022

Taizhou Donghaixiang Protective Equipment Co., Ltd
℅ Shuai Wang
CEO
Getilapson (Dalian) Biological Technology Co., Ltd
RM. 408 NO. 207, Zhongnan Rd
Dalian, 116001
China

Re: K212203
Trade/Device Name: Dong Hai Xiang Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 11, 2022
Received: March 7, 2022

Dear Shuai 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)*
K212203

Device Name
Dong Hai Xiang Surgical Mask

Indications for Use *(Describe)*
Dong Hai Xiang Surgical Mask is intended for use in healthcare settings, procedures during which a face mask is necessary to protect both patient and healthcare personnel from transfer of body fluids, microorganisms, and particulate material. The device is indicated to be over-the-counter use. adult only. The device is disposable and is indicated for single use. The device is not provided 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

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

The assigned 510(k) number: K212203

Date of Preparation: 11/01/2022

1. Contact Information

1.1 Applicant

Applicant Name: Taizhou Donghaixiang Protective Equipment Co., Ltd.
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Title: General Manager
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1.2 Consultant

Company: Getilapson (Dalian) Biological Technology Co., Ltd
Address: RM. 408 NO. 207, Zhongnan Rd, Dalian, China, 116001
Contact Person: Shuai Wang
Telephone: +1 503-559-0930
Email: usfdahuamei@hotmail.com

2. Device Information

Trade Name: Dong Hai Xiang Surgical Mask
Common Name: Surgical Face Mask
Regulatory information:
Classification Name: Mask, Surgical
Classification: II
Product Code: FXX
Regulation Number: 21 CFR 878.4040
Review Panel: General Hospital

3. Legally Marketed Primary Predicate Device

Product name: Avianz® Surgical Face Mask
510(k) Number: K200847
Product Code: FXX
Manufacture: MEXPO INTERNATIONAL INC.

4. Indication For Use

Dong Hai Xiang Surgical Mask is intended for use in healthcare settings, procedures during which a face mask is necessary to protect both patient and healthcare personnel from transfer of body fluids, microorganisms, and particulate material. The device is indicated to be over-the-counter use. adults only. The device is disposable and is indicated for single use. The device is not provided sterile.

5. Device Description

The Dong Hai Xiang Surgical Masks are composed of 3-layers and are flat-pleated provided blue color, the mask materials consist of an outer layer (polypropylene), Inner layer (polypropylene), Middle Layer filter

(Polypropylene Melt-blown), Ear-loops (Spandex + Nylon, Ear Loops way for wearing) and Nose piece (a Polyethylene + Galvanized Iron wire nosepiece to provide a firm fit over the nose and then to secure the mask over the users' mouth and face). The Dong Hai Xiang Surgical Masks are single use, adult only, disposable device, provided non-sterile.

6. Technological Characteristics Comparison

Comparison Items	Dong Hai Xiang Surgical Mask	Predicate Device Avianz® Surgical Face Mask (K200847)	Comparison
Product Code	FXX	FXX	Same
Regulation	21 C.F.R Section 878.4040	21 C.F.R Section 878.4040	Same
Classification	Class II	Class II	Same
Intended use	Dong Hai Xiang Surgical Mask is intended for use in healthcare settings, procedures during which a face mask is necessary to protect both patient and healthcare personnel from transfer of body fluids, microorganisms, and particulate material. The device is indicated to be over-the-counter use. adults only. The device is disposable and is indicated for single use. The device is not provided sterile.	The Disposable Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from the 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
Mask Style	Flat-pleated, earloop, 3 layers	Flat-pleated, earloop, 3 layers	Same

6.1 Material Used

Comparison Items	Dong Hai Xiang Surgical Mask	Predicate Device Avianz® Surgical Face Mask (K200847)	Comparison
Inner layer	Polypropylene	Spun-bond polypropylene	Same
Middle layer	Polypropylene Melt-blown	Melt blown polypropylene filter	Same
Outer layer	Polypropylene	Spun-bond polypropylene	Same
Earloop	Spandex + Nylon	Polyester	Different
Nose piece	Polyethylene + Galvanized Iron wire	Malleable aluminum wire	Different

6.2 Design Features

Comparison Items	Dong Hai Xiang Surgical Mask	Predicate Device Avianz® Surgical Face Mask	Comparison

		(K200847)	
Use Environment	OTC, or Healthcare or related settings	OTC, or Healthcare or related settings	Same
Single-use/ Multiple-use	Single-use	Single-use	Same
Color	Blue	Blue	Same

6.3 Sterility

Comparison Items	Dong Hai Xiang Surgical Mask	Predicate Device Avianz® Surgical Face Mask (K200847)	Comparison
Sterilization	No-Sterile	No-Sterile	Same

6.4 Dimension

Comparison Items	Dong Hai Xiang Surgical Mask	Predicate Device Avianz® Surgical Face Mask (K200847)	Comparison
Length	17.5cm	17.5±1cm	Different
Width	9.5cm	9.5±1cm	Different

6.5 Performance

Comparison Items	Dong Hai Xiang Surgical Mask	Predicate Device Avianz® Surgical Face Mask (K200847)	Comparison
Resistance to Penetration by Synthetic blood 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)	Pass (96/96) 32 Samples Each from 3 non-consecutive lots **Lot 1:** 32 Out of 32 pass at 160 mmHg **Lot 2:** 32 Out of 32 pass at 160 mmHg **Lot 3:** 32 Out of 32 pass at 160 mmHg	≥ 30 Out of 32 pass at 120 mmHg	Different
Particulate Filtration Efficiency ASTM F2299/F2299M-03 (2017) Standard Test Method for Determining the Initial Efficiency of Material Used in medical	Pass (96/96) 32 Samples Each from 3 non-consecutive lots **Lot 1:** ≥ 99.96% **Lot 2:** ≥ 99.96% **Lot 3:** ≥ 99.96%	≥ 99.9%	Different

Face Masks to Penetration by Particulates using Latex Spheres			
Bacterial Filtration Efficiency 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	Pass (96/96) 32 Samples Each from 3 non-consecutive lots **Lot 1:** ≥ 99.9% **Lot 2:** ≥ 99.9% **Lot 3:** ≥ 99.9%	≥98%	Different
Differential Pressure EN 14683:2019 Medical face masks- Requirements and test methods	Pass (96/96) 32 Samples Each from 3 non-consecutive lots **Lot 1:** Average 3.96 mmH_20/cm^2 **Lot 2:** Average 4.14 mmH_20/cm^2 **Lot 3:** Average 4.10 mmH_20/cm^2 (EN 14683:2019, Annex C and ASTM F2100-20)	3.0 mmH_20/cm^2 (MILM-36954C)	Different
Flammability 16 CFR 1610 Standard for the Flammability of Clothing Textiles Corrections	Class 1 Pass (96/96) 32 Samples Each from 3 non-consecutive lots **Lot 1:** Class 1 Pass **Lot 2:** Class 1 Pass **Lot 3:** Class 1 Pass	Class 1	Same

6.6 Biocompatibility

Comparison Items	Dong Hai Xiang Surgical Mask	Predicate Device Avianz® Surgical Face Mask (K200847)	Comparison
In Vitro Cytotoxicity Test ISO 10993-5: 2009	ISO 10993-5; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic.	ISO 10993-5; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic.	Same
Skin Irritation Test ISO 10993-10:2010	ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-irritating.	ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-irritating.	Same

Skin Sensitization Test ISO 10993-10:2010	ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-sensitizing.	ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-sensitizing.	Same
Flammability	Class 1	Class 1	Same

7. Nonclinical Test

Nonclinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

7.1 Performance Test:

A bench test was conducted on Dong Hai Xiang Surgical Mask for the proposed device to determine substantial equivalence. The bench tests include the following tests:

Performance Test	Purpose	Acceptance Criteria	Result
Fluid Resistance Performance ASTM F1862-17	Evaluate the resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)	≥29 of 32 pass at 160 mmHg	Passed Pass (96/96) 32 Samples Each from 3 non-consecutive lots **Lot 1:** 32 Out of 32 pass at 160 mmHg **Lot 2:** 32 Out of 32 pass at 160 mmHg **Lot 3:** 32 Out of 32 pass at 160 mmHg
Particulate Filtration Efficiency ASTM F2299-17	Evaluate the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres	≥ 98%	Pass (96/96) 32 Samples Each from 3 non-consecutive lots **Lot 1:** ≥ 99.96% **Lot 2:** ≥ 99.96% **Lot 3:** ≥ 99.96%
Bacterial Filtration Efficiency ASTM F2101-19	Evaluate the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus	≥ 98%	Pass (96/96) 32 Samples Each from 3 non-consecutive lots **Lot 1:** ≥ 99.9% **Lot 2:** ≥ 99.9% **Lot 3:** ≥ 99.9%
Differential Pressure (Delta P) EN 14683:2019, Annex C and ASTM F2100-19.	Evaluate the medical Face Masks' resistance to airflow across the face mask Differential pressure (Delta-P)	<6.0 mmH_20/cm^2	Passed Pass (96/96) 32 Samples Each from 3 non-consecutive lots **Lot 1:** Average 3.96 mmH_20/cm^2 **Lot 2:** Average 4.14 mmH_20/cm^2

			Lot 3: Average 4.10 mmH_20/cm^2 (EN 14683:2019, Annex C and ASTM F2100-20)
Flammability 16 CFR 1610	Evaluate the medical Face Masks' flammability when exposed to a direct source of ignition	Class 1	Class 1 Pass (96/96) 32 Samples Each from 3 non-consecutive lots **Lot 1:** Class 1 Pass **Lot 2:** Class 1 Pass **Lot 3:** Class 1 Pass

7.2 Biocompatibility Evaluation and Test

Biocompatibility evaluation conducted in accordance with the FDA's 2016 guidance supports that the subject devices are biocompatible.

The biocompatibility test includes the following tests:

7.2.1 In Vitro Cytotoxicity Test（ISO 10993-5: 2009）

7.2.2 Skin Irritation Test（ISO 10993-10:2010）

7.2.3 Skin Sensitization Test（ISO 10993-10:2010）

Biocompatibility Evaluation and Test	**Purpose**	**Acceptance Criteria**	**Result**
7.2.1 In Vitro Cytotoxicity Test ISO 10993-5: 2009	Evaluate under the conditions of the study, the proposed device extract was determined to be non- cytotoxic.	Non-cytotoxic.	ISO 10993-5; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic.
7.2.2 Skin Irritation Test ISO 10993-10:2010	Evaluate under the conditions of the study, the proposed device extract was determined to be non- irritating.	Non-irritating.	ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-irritating.
7.2.3 Skin Sensitization Test ISO 10993-10:2010	Evaluate under the conditions of the study, the proposed device extract was determined to be non-sensitizing.	Non-sensitizing	ISO 10993-10. Under the conditions of the study, the proposed device extract was determined to be non-sensitizing.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device, Dong Hai Xiang Surgical Mask, is as safe, as effective and performs as well as or better than the legally marketed device.