January 16, 2022

Zhejiang The Purples Protective Products Co.,Ltd
% Doris Chen
Staff
Shanghai Jiushun Enterprise Management
Technology Service Co., Ltd.
Room 1502, BaoAn Building, No.800 Dongfang Road
Shanghai, 200122
China

Re: K211833
Trade/Device Name: Disposable Medical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 17, 2021
Received: December 22, 2021

Dear Doris Chen:

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)*
K211833

Device Name
Disposable Medical Face Mask

Indications for Use *(Describe)*
The disposable 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 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Chapter 5. 510(k) Summary

510(k) Summary

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

The assigned 510(k) Number:K211833

Summary Prepared Date:December 17, 2021

1. Applicant :

Sponsor Name: Zhejiang The Purples Protective Products Co.,Ltd

Address:No.45, Suhua Street, Suxi Town, Yiwu City, Zhejiang Province, China.

Contact Person (including title): Lihui Jiang (Manager)

Phone:+86-579-85178961

2. Submission Correspondent:

Contact Person: Doris Chen

Shanghai Jiushun Enterprise Management Technology Service Co., Ltd.

Address: Room 1502,BaoAn Buiding,No.800 Dongfang Road,Shanghai,China.

Tel: +86-21-50931939

Email: doris-chen@isosh.com

3. Subject Device Information

Type of 510(k):	Traditional
Common Name:	Face Mask
Trade Name:	Disposable Medical Face Mask
Classification Name:	Mask,Surgical
Review Panel:	General Hospital
Product Code:	FXX
Regulation Number:	21 CFR 878.4040
Regulation Class:	II

4. Predicate Device Information

Predicate Device

Sponsor:	Foshan Xinbao Technology Co., Ltd.
Common Name:	Surgical apparel
Trade Name:	Surgical Mask
510(k) number:	K202424
Review Panel:	General Hospital
Product Code:	FXX
Regulation Number:	21 CFR 878.4040
Regulation Class:	II

5. Device Description

The disposable medical face mask is pleated three-layer mask with ear loops and nose piece. The inner and outer layers are made of spun-bond non-woven fabric.The middle layer is made of melt blown polypropylene filter.only the outer layers' color is blue (colorant: Pigment Blue 15:3/Model:147-14-8), which is held to cover the users' mouth and nose by two spandex elastic bands ultrasonic welded to the disposable medical face mask. The elastic ear loops are not made with natural rubber latex. The nose piece contained in the disposable medical face mask is in the middle layer of disposable medical face mask to allow the user to fit the disposable medical face mask around their noses, which is made of malleable aluminum wire. The dimensions of each disposable medical face mask are length 175±10 mm and width 95±10 mm, The dimensions of nose piece is length 120±10 mm, and the ear loop is length 180±10 mm.

The mask model TP-001 meets both level 2 & level 3 performance requirements in ASTM F2100.The disposable medical face mask are sold non-sterile and are intended to be single use,disposable devices.

6. Intended Use / Indications for Use

The disposable 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 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.

7. Comparison with predicate device

Table 1 General Comparison

Elements of Comparison	**Subject Device**	**Predicate Device**	**Verdict**
Manufacturer	Zhejiang The Purples Protective Products Co.,Ltd	Foshan Xinbao Technology Co., Ltd.	--
Product Name	Disposable Medical Face Mask	Surgical Mask	--
K Number	K211833	K202424	--
Product Code	FXX	FXX	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Intended use/ Indications for Use	The disposable medical mask 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(s), provided non-sterile.	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 potential exposure to blood and body fluids. This is a single use, disposable device, provided nonsterile.	Same
Mask style	Flat pleated, 3 layers.	Flat pleated,3 layers.	Same
Design feature	Ear loop	Ear loop	Same

Material	Outer facing layer	Spun-bond non-woven fabric		Spun-bond polypropylene	Similar Note 1
	Middle layer	Melt blown polypropylene filter		Melt blown polypropylene	Same
	Inner facing layer	Spun-bond non-woven fabric		Spun-bond polypropylene	Similar Note 1
	Nose piece	Malleable aluminum wire		Galvanized iron wire	Different Note 1
	Ear loops	Spandex		Nylon and Spandex	Different Note 1
Color		Blue		Blue	Same
Dimension (Width)		17.5cm±1cm		17.5cm±1cm	Same
Dimension (Length)		9.5cm±1cm		9.5cm±1cm	Same
OTC use		Yes		Yes	Same
Sterility		Non-Sterile		Non-Sterile	Same
Use		Single Use, Disposable		Single Use, Disposable	Same
ASTM F2100 Level		Level 2	Level 3	Level 2	Level 3	Same
		3non-consecutive lots tested, using a sample size of 32/lot.				
Fluid resistance Performance ASTM F1862		32 out of 32 pass at 120mmHg	32 out of 32 pass at 160mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Same
Particle Filtration Efficiency ASTM F2299		Lot A: 99.9% Lot B: 99.9% Lot C:99.9%	Lot A: 99.9% Lot B: 99.9% Lot C: 99.9%	Pass at ≥98%	Pass at ≥98%	Similar Note 2
Bacterial Filtration Efficiency ASTM F2101		Lot A: 99.9% Lot B: 99.9% Lot C:99.9%	Lot A: 99.9% Lot B: 99.9% Lot C:99.9%	Pass at ≥98%	Pass at ≥98%	Similar Note 2
Flammability Class 16 CFR 1610		Class 1	Class 1	Class 1	Class 1	Same
Differential Pressure (Delta –P) EN 14683 Annex C		Lot A: 2.24mmH_2O/cm^2 Lot B: 2.17mmH_2O/cm^2 Lot C: 2.07mmH_2O/cm^2	Lot A: 2.24mmH_2O/cm^2 Lot B: 2.17mmH_2O/cm^2 Lot C: 2.07mmH_2O/cm^2	Pass at <6.0 mmH_2O/cm^2	Pass at <6.0 mmH_2O/cm^2	Similar Note 2
Biocompatibility						

Cytotoxicity	Under the conditions of the study, the device is noncytotoxic. Comply with ISO 10993-5.	Under the conditions of the study, the device is noncytotoxic. Comply with ISO 10993-5.	Same
Irritation	Under the conditions of the study, the device is nonirritating. Comply with ISO 10993-10.	Under the conditions of the study, the device is nonirritating. Comply with ISO 10993-10.	Same
Sensitization	Under the conditions of the study, the device is nonsensitizing, Comply with ISO 10993-10.	Under the conditions of the study, the device is nonsensitizing, Comply with ISO 10993-10.	Same

Note 1

The difference in the materials of the outer facing layer, Inner facing layer,nose piece and the ear loop were different from the predicate device.

The biocompatibility evaluation test of the subject devices have been performed on the final finished device. The test results shows pass the requirements.

Note 2

For the Performance testing, the test results are not identical to each other, but they are similar and they both meet the requirement of Level 2/Level 3 medical mask according to the ASTM F2100.

8. Summary of Non-Clinical Tests Performed

Non-clinical tests were conducted to verify that the proposed device met all design specifications as to the predicate device. The test results demonstrated that the proposed device complies with 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:

- ASTM F2299-03, Standard Test Method for Determining the Initial Efficiency of Materials Used in Surgical face masks to Penetration by Particulates Using Latex Spheres.
- EN 14683:2019,Annex C.Method for determination of breathability (differential pressure)

- ASTM F1862/ASTM F1862M-17, Standard test method for resistance of Surgical face masks to penetration by synthetic blood (Horizontal projection of fixed volume at a known velocity)
- ASTM F2101-19, Standard Test Method For Evaluating The Bacterial Filtration Efficiency (BFE) Of Surgical face mask Materials, Using A Biological Aerosol Of Staphylococcus Aureus.
- 16 CFR Part 1610, Standard for the flammability of clothing textiles.
- ISO 10993-5:2009, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity.
- ISO 10993-10:2010, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

Table 2:Performance Testing

Test item (Performance Level 2/Level 3)	**Proposed device**		**Acceptance criteria**		**Test results /Verdict**
	Level 2	**Level 3**	**Level 2**	**Level 3**	
Bacterial filtration efficiency (BFE) ASTM F2101-19	Lot A: 99.9% Lot B: 99.9% Lot C:99.9%	Lot A: 99.9% Lot B: 99.9% Lot C:99.9%	BFE≥98%.	BFE≥98%.	Pass
Differential pressure,(Delta-P) EN 14683:2019, Annex C	Lot A: 2.24mmH_2O/cm^2 Lot B: 2.17mmH_2O/cm^2 Lot C: 2.07mmH_2O/cm^2	Lot A: 2.24mmH_2O/cm^2 Lot B: 2.17mmH_2O/cm^2 Lot C: 2.07mmH_2O/cm^2	Delta-P< 6.0H_2O/cm^2	Delta-P< 6.0H_2O/cm^2	Pass
Sub-micron particulate filltration efficiency at 0.1 micron. ASTM F2299	Lot A: 99.9% Lot B: 99.9% Lot C:99.9%	Lot A: 99.9% Lot B: 99.9% Lot C:99.9%	PFE≥98%.	PFE≥98%.	Pass

Resistance to penetration by synthetic blood ASTM F1862	32 out of 32 per lot pass at 120 mmHg	32 out of 32 per lot pass at 160 mmHg	Fluid resistant claimed at 120 mm Hg	Fluid resistant claimed at 160 mm Hg	Pass
Flame spread 16 CFR Part 1610	Class1		Class 1	Class 1	Pass

Results: All tests were passed.

Biocompatibility evaluation and test

Biocompatibility evaluation conducted in accordance with the FDA's 2016 guidance and ISO10993-1:2018 supports that the subject devices are biocompatible.

The biocompatibility test includes the following tests:

- In Vitro Cytotoxicity Test per ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity.
- Skin Sensitization Tests per ISO 10993-10:2010 Biological evaluation of medical devices —Part 10: Tests for irritation and skin sensitization
- Skin Irritation Tests per ISO 10993-10:2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization.

Item	Proposed device	Result
Cytotoxicity	Under the conditions of the study, the device is noncytotoxic.	Pass
Irritation	Under the conditions of the study, the device is nonirritating.	Pass
Sensitization	Under the conditions of the study, the device is nonsensitizing	Pass

9. Summary of Clinical Performance Test

No clinical study is included in this submission.

10. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Disposable Medical Face Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Surgical Mask (K202424).