May 24, 2022

Jiujiang Taixin Technology Co., Ltd.
℅ Cassie Lee
Manager
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road
Huangpu District
Guangzhou, Guangdong 510700
China

Re: K220191
Trade/Device Name: DISPOSABLE FACE MASK (Model: TX-005, TX-006)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 19, 2022
Received: April 25, 2022

Dear Cassie Lee:

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
Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K220191

Device Name
DISPOSABLE FACE MASK (Model: TX-005, TX-006)

Indications for Use *(Describe)*
The DISPOSABLE 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.

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."

510(k) Summary of K220191

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

Subject Device: DISPOSABLE FACE MASK (Model: TX-005, TX-006)

510(k) Number: K220191

1. Date of the summary prepared: April 19, 2022

2. Submitter's Information

510(k) Owner's Name: Jiujiang Taixin Technology Co., Ltd.

Establishment Registration Number: 3017207447

Address: Zone A, Ruichang Science and Technology Park, Ruichang City, Jiujiang City, Jiangxi Province, China

Contact Person: Xiaojie Li

Email: 43590288@qq.com

Application Correspondent:

Contact Person: Ms. Cassie Lee

Share Info (Guangzhou) Medical Consultant Ltd.

Address: No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District, Guangzhou, China

Tel: +86 20 8266 2446

Email: regulatory@share-info.com

3. Subject Device Information

Type of 510(k): Traditional

Classification Name: Surgical Face Mask

Trade Name: DISPOSABLE FACE MASK

Model Name: TX-005, TX-006

Review Panel: General Hospital

Product Code: FXX

Regulation Number: 21 CFR 878.4040

Regulatory Class: II

4. Primary Predicate Device Information

Sponsor: Foshan Xinbao Technology Co., Ltd.

Trade Name: Surgical Mask

Common name: Surgical apparel

Classification Name: Mask, Surgical

510(K) Number: K202424

Review Panel: General Hospital

Product Code: FXX

Regulation Number: 21 CFR 878.4040

Regulation Class: II

5. Indications for Use

The DISPOSABLE 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.

6. Device Description

The DISPOSABLE FACE MASK is flat pleated style mask, utilizing ear loops way for wearing, and they all has nose clip design for fitting the face mask around the nose.

The proposed device(s) are manufactured with three layers, the inner and outer facing layers are made of spunbonded non-woven, and the middle layer is made of melt-blown non-woven the model of proposed device, ear loops, is held in place over the users' mouth and nose by two elastic ear loops welded to the face mask. The elastic ear loops are not made with natural

rubber latex.

The nose clip contained in the proposed device(s) is in the layers of face mask to allow the user to fit the mask around their nose, which is made of PE coated Tin-plate wire.

The proposed device(s) are sold non-sterile and are intended to be single use, disposable device.

7. Summary of Technological Characteristics

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	**Subject Device**	**Predicate Device**	**Verdict**
Company	Jiujiang Taixin Technology Co., Ltd.	Zhejiang The Purples Protective Products Co.,Ltd	--
510 (k)	K220191	K202424	--
Trade Name	DISPOSABLE FACE MASK	Surgical Mask	--
Classification	Class II Device, FXX (21 CFR 878.4040)	Class II Device, FXX (21 CFR 878.4040)	Same
Intended use	The DISPOSABLE 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 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

Outer facing layer	Spunbonded non-woven		Spun-bond polypropylene		Similar Note 1
Middle layer	Melt-Blown non-woven		Melt blown polypropylene		Similar Note 1
Inner facing layer	Melt-Blown non-woven		Spun-bond polypropylene		Similar Note 1
Nose clip	PE coated Tin-plate wire		Galvanized iron wire		Similar Note 1
Ear loops	Spandex		Nylon and Spandex		Similar Note 1
Color	white + blue		Blue		Similar Note 1
Specification and Dimension	175mm×95mm		Width: 17.5cm±1cm Length: 9.5cm±1cm		Same
Sterility	Non-Sterile		Non-Sterile		Same
Use	Single Use, Disposable		Single Use, Disposable		Same
ASTM F2100 Level	Level 3 (Model: TX-006)	Level 2 (Model: TX-005)	Level 3	Level 2	Same
Fluid Resistance Performance	Pass at 160 mmHg (Model: TX-006)	Pass at 120 mmHg (Model: TX-005)	Pass at 160 mmHg	Pass at 120 mmHg	Same
Particulate Filtration Efficiency	98.57% (Model: TX-006)	98.6% (Model: TX-005)	Pass at ≥98%	Pass at ≥98%	Similar Note 2
Bacterial Filtration	99.83% (Model: TX-006)	99.84% (Model:	Pass at ≥98%	Pass at ≥98%	Similar Note 2

Efficiency		TX-005)			
Differential Pressure	5.0mm H_2 O/cm² (Model: TX-006)	4.9mm H_2 O/cm² (Model: TX-005)	Pass at <6.0 mmH2O/cm2	Pass at <6.0 mmH2O/cm2	Similar Note 2
Flammability	Class 1		Class 1		Same
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

Comparison in Detail(s):

Note 1:

Although the “Outer facing Layer”, “Middle layer”, “Inner facing layer”, “Nose clip”, “Ear loops” and “Color” of subject device are slightly difference with predicate device, it meets the requirement standard ASTM F2100, ASTM F1862, ASTM F2101, ISO 10993-5 and ISO 10993-10.

Note 2:

Although the “Particulate Filtration Efficiency”, “Bacterial Filtration Efficiency” and “Differential Pressure” of subject device is a little different from the predicate device, and they all meet the requirements of essential performance standard ASTM F2100.

8. Summary of Non-Clinical Performance Testing

Performance Testing summary:

Test item	Test method	Pass criteria	Test results

(Performance Level 2 and Level 3)			**/Verdict**
Bacterial filtration efficiency	ASTM F2101-14 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus according to ASTM F2100:2019	Level 2: ≥98%	99.84% / Pass Model: TX-005
		Level 3: ≥98%	99.83% / Pass Model: TX-006
Differential pressure (Delta-P)	EN 14683: 2019, Annex C Medical face masks - Requirements and test methods according to ASTM F2100:2019	Level 2: <6.0 mm H_2O/cm^2	4.9 mm H_2O/cm^2 / Pass Model: TX-005
		Level 3:<6.0 mm H_2O/cm^2	5.0 mm H_2O/cm^2 / Pass ModelTX-006
Sub-micron particulate filtration efficiency at 0.1 µm of Polystyrene Latex Spheres	ASTM F2299-03 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres according to ASTM F2100:2019	Level 2: ≥ 98%	98.60% / Pass Model: TX-005
		Level 3: ≥ 98%	98.57% / Pass Model: TX-006
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	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) according to ASTM F2100:2019	Level 2: Fluid resistant claimed at 120 mm Hg	Fluid Resistant claimed at 120 mm Hg / Pass Model: TX-005
		Level 3: Fluid resistant claimed at 160 mm Hg	Fluid Resistant claimed at 160 mm Hg

			/ Pass Model: TX-006
Flame spread	16 CFR Part 1610 Standard for the Flammability of Clothing according to ASTM F2100:2019	Level 2: Class 1	Class 1 / Pass Model: TX-005
		Level 3: Class 1	Class 1 / Pass Model: TX-006

Biocompatibility Testing Summary:

According to ISO 10993-1: 2018, the nature of body contact for the subject device is the Surface Device category, Skin Contact, and duration of the contact is A-Limited (<24 h). The two levels(Model:TX-005,TX-006) of masks are produced using the same material and process. The following tests for the subject device were conducted to demonstrate that the subject device is biocompatible and safe for its intended use:

Test Item	Proposed device	Result
Cytotoxicity	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	PASS
Irritation	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	PASS
Sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	PASS

9. Summary of Clinical Performance Test

No clinical study is included in this submission.

10. Final Conclusion

The subject device is a safe, as effective, and perform as well or better than the legally marketed predicated K202424.