October 18, 2024

Xiantao Daoqi Plastic Co., Ltd.
Honghong Bie
Quality Manager
No.83, Wagou New District
Pengchang Town
Xiantao, Hubei 433018
China

Re: K240916
Trade/Device Name: Surgical Face Mask (Tie on/ Ear loops)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 12, 2024
Received: September 12, 2024

Dear Honghong Bie:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection
Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240916

Device Name
Surgical Face Mask (Tie on/ Ear loops)

Indications for Use *(Describe)*
Surgical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It is 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.

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510(k) Summary (K240916)

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

1.0 Submitter's information

Name: XIANTAO DAOQI PLASTIC CO., LTD.
Address: No.83, Wagou New District, Pengchang Town, Xiantao City, Hubei Province, 433018, China
Phone Number: +86-728 2620008
Contact: Ms. Bie Honghong
Date of Preparation: 10/18/2024

Designated Submission Correspondent

Mr. Boyle Wang
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2.0 Device information

Trade name: Surgical Face Mask
Common name: Surgical Mask
Classification name: Mask, Surgical
Model(s): Ear loops (17.5cm×9.5cm)
Tie-on (17.5cm×9.5cm)

3.0 Classification

Production code: FXX
Regulation number: 21CFR 878.4040
Classification: Class II
Panel: Surgical apparel

4.0 Predicate device information

Manufacturer: Hubei Qianjiang Kingphar Medical Material Co., Ltd
Device: Surgical face mask
510(k) number: K220777

5.0 Indication for Use Statement

Surgical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It is 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.

6.0 Device description

The Surgical face mask is single use, three-layer, flat-pleated style with ear loops/ties and nose piece. The mask is manufactured with three layers, the inner and outer layers, and the straps are made of nonwoven fabrics, the middle layer is made of melt blown fabrics.

The model of proposed device, tie-on, is held in place over the user's mouth and nose by four ties welded to the face mask. The tie is made of spun-bond polypropylene.

The model of proposed device, ear loops, is held in place over the user's 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 ties/ear loops are not made with natural rubber latex. The nose piece on the layers of face mask is to allow the user to fit the face mask around their nose, which is made of Polypropylene with iron core. The Surgical face mask will be provided in blue. The masks are sold non-sterile and are intended to be single use, disposable devices.

7.0 Technological Characteristic Comparison Table

Table 1 - General Comparison

Item	Proposed device	Predicate device	Comparison
Product Code	FXX	FXX	Same

Regulation No.		21 CFR 878.4040	21 CFR 878.4040	Same
Class		II	II	Same
Product name		Surgical Face Mask	Surgical Face Mask	Same
510(k) No.		K240916	K220777	-
Mask styles		Ear loops/Tie on	Ear loops/Tie on	Same
Intended Use		The surgical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It is 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 Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It is 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
OTC use		Yes	Yes	Same
Design Features		Flat Pleated, 3 layers	Flat Pleated, 3 layers	Same
Materials	Internal layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene	Melt blown polypropylene	Same
	External layer	Melt blown polypropylene	Spun-bond polypropylene	Same
	Nose piece	Polypropylene+iron core	Polypropylene+Galvanize d-iron dual core	Similar
	Ear loops	Polyester+spandex	Polyester, spandex	* Gap 1
	Ties	Spun-bond polypropylene		
Color		Blue	Blue	Same
Dimension (Length)		17.5cm±0.5cm	17.5cm±0.5cm	Same
Dimension (Width)		9.5cm±0.5cm	9.5cm±0.5cm	Same
Sterility		Non-Sterile	Non-Sterile	Same
Single Use		Yes	Yes	Same
Sterile		No	No	Same
ASTM F2100 Level		Level 3	Level 3	Similar
Shelf Life		2 years	5 years	Different

* Gap analysis:

Gap 1: the two devices have some difference in materials, product materials safety is proved by its biocompatibility, and the difference does not raise additional questions for safety and effectiveness of device.

Table 2 Performance Comparison

Item	Proposed device	Predicate device	Remark
Bacterial filtration efficiency (BFE) (%)	ASTM F2100-23 Level 3, ≥98	ASTM F2100-19 Level 3, ≥98	Same
Different pressure (mmH_2O/cm^2)	ASTM F2100-23 Level 3, <6.0	ASTM F2100-19 Level 3, <6.0	Same

Sub-micron particulate filtration efficiency at 0.1 micron, % (PFE)	ASTM F2100-23 Level 3, ≥85	ASTM F2100-19 Level 3, ≥98	Similar
Resistance to penetration by synthetic blood, Minimum pressure in mmHg for pass result	ASTM F2100-23 Level 3, 160	ASTM F2100-19 Level 3, 160	Same
Flame spread	Class 1	Class 1	Same

Table 3 Biocompatibility Comparison

Item	Proposed Device	Predicate Device	Remark
Cytotoxicity	Comply with ISO 10993-5	Comply with ISO 10993-5	Same
Irritation	Comply with ISO 10993-23	Comply with ISO 10993-10	Same
Sensitization	Comply with ISO 10993-10	Comply with ISO 10993-10	Same

8.0 Summary of Non-Clinical Testing

The proposed device was tested and conformed to the related recognized 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 and following recognized standards:

Biocompatibility Testing

2-245 ISO 10993-5 Third edition 2009-06-01 *Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity*

2-291 ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices- Part 23: Tests for irritation

2-296 ISO 10993-10 Fourth edition 2021-11 *Biological Evaluation of Medical Devices - Part 10: Tests for Skin Sensitization.*

Performance Testing (Bench)

6-492 ASTM F2100-23 Standard Specification for Performance of Materials Used in Medical Face Masks
6-493 ASTM F2101-23 Standard Test Method of Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus

6-406 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)

Table 4 - Performance Testing

Items	Purpose	Acceptance Criteria Level 3 (ASTM F2100-23)	Result
Bacterial filtration efficiency (BFE) (%)	The purpose of the test is to evaluate the Bacterial filtration efficiency (BFE) (%)	≥98	99.7%-99.9% Pass
Different pressure (mmH2O/cm2)	The purpose of the test is to evaluate the Different pressure (mmH2O/cm2)	<6.0 mmH_2O/cm^2	3.2-3.7 $mmH2O/cm^2$ Pass
Sub-micron particulate filtration efficiency at 0.1 micron, % (PFE)	The purpose of the test is to evaluate the Sub-micron particulate filtration efficiency at 0.1 micron, % (PFE)	≥85	97.16-99.52% Pass
Resistance to penetration by synthetic blood, Minimum pressure in mmHg for pass result	The purpose of the test is to evaluate the Resistance to penetration by synthetic blood, Minimum pressure in mmHg for pass result	29 of 32 test articles passed at 160mmHg	32 of 32 test articles Pass
Flame spread	The purpose of the test is to evaluate the Flammability	Class 1	32 of 32 test articles Pass

Table 5 - Biocompatibility Testing

Items	Purposes	Acceptance Criteria	Result	Summary
Cytotoxicity	To evaluate the risk of the sample to induce biological response of L-929	ISO 10993-5:2009 Viability < 70 %, it has a cytotoxic potential.	Tie on: the viability ratio of the 100% test article extract was 91.0%, no potential	Pass

	cells		toxicity of L-929 cells. Ear loops: the viability ratio of the 100% test article extract was 70.5%, no potential toxicity of L-929 cells.	
Irritation	To evaluate the potential of skin irritation of samples under of the test conditions	ISO 10993-23:2021 If the primary irritation index is 0-0,4, the response category is Negligible. 0,5-1,9 means slight 2-4,9 means moderate 5-8 means severe Primary Irritation-Index≤ 2.0	Tie on: The primary irritation indexes of the polar and non-polar test group were both calculated to be 0. The extract of the test article did not induce skin irritation. Ear loops: The primary irritation indexes of the polar and non-polar test group were both calculated to be 0. The extract of the test article did not induce skin irritation.	Pass
Sensitization	To evaluate the potential of a test article to cause skin sensitization using Guinea Pig Maximization Test	ISO 10993-10:2021 provided grades less than 1, otherwise sensitization.	Tie on: The skin sensitization rates of polar and non-polar extract group were both determined with 0%. Ear loops: The skin sensitization rates of polar and non-polar extract group were both determined with 0%.	Pass

9.0 Summary of Clinical Testing

No clinical study conducted for the Surgical Face Mask.

10.0 Conclusion

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