December 17, 2021

Zhongshan Saifute Labor Protective Articles CO., LTD
Qionghua Ke
General Manager
No.7, Xihuan 4th road, Southern District
Zhongshan, Guangdong 528400
China

Re: K212059
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 5, 2021
Received: November 15, 2021

Dear Qionghua Ke:

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)*
K212059

Device Name
Surgical Face Mask

Indications for Use *(Describe)*
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(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
K212059

A. Applicant Information:

Name: ZHONGSHAN SAIFUTE LABOR PROTECTIVE ARTICLES CO., LTD
Address: NO.7, XIHUAN 4TH ROAD, SOUTHERNDISTRICT, ZHONGSHAN, GUANGDONG, CHINA 528400

Contact Person: Qionghua Ke
Tel: +86-13802652169
Mail: ke.qionghua1@gmail.com

Date of Preparation: December 7, 2021

B. Device Information:

Trade Name: Surgical Face Mask
Common Name: Surgical Face Mask
Model(s): TY123

Regulatory Information
Classification Name: Surgical Face Mask
Classification: Class II
Product code: FXX
Regulation Number: 21CFR 878.4040
Review Panel: Surgical Apparel

C. Predicate Device Information:

K182514 SURGICAL FACE MASK
The predicate has not been subject to a design-related recall.

D. Device Description:

The Surgical Face Mask is composed of mask body, nose clip and ear loops. The body of the mask is composed of three layers: the inner and outer layers are made of Spun-bond polypropylene, and the middle layer is made of melt blown non-woven fabric, the nose clip is made of plastic materials and iron wire, ear loop is made of spandex.
The size of the Surgical Face Mask is 17.5*9.5cm with tolerance ± 5% cm, the length of the ear loopis 16cm, and the length of the nose clip should no less than 8.0cm.
The outer layer of Surgical Face Mask will be provided in blue, the inner layer of the Surgical Face Mask will be provided in white. The Surgical Face Mask will be provided non-sterile and is intended to be single use.

E. Indications for use:

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(s), provided non-sterile.

F. Comparison of Technological Characteristics

Table 1 General Comparison

Device		**Subject Device (K212059)**	**Predicate Device (K182514)**	**Result**
Manufacturer		ZHONGSHAN SAIFUTELABOR PROTECTIVE ARTICLES CO., LTD	Xiantao Zhibo Non-wovenProducts Co., Ltd	-
Product Name		Surgical Face Mask	SURGICAL FACE MASK	Similar
Model		TY123	---	-
Classification		Class II Device, FXX (21 CFR 878.4040)	Class II Device, FXX (21 CFR 878.4040)	Same
Indications for use		The Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids andparticulate 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.	The Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids andparticulate 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
Material	**Outer layer**	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown non-woven fabric	Melt blown polypropylene filter	Same

	Inner layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose clip	Iron wire	Malleable aluminum wire	Different
	Ear loops	Spandex	Polyester	Different
Color		Blue	White	Different
Design Feature		Ear Loops, Flat Pleated, 3 layers	Ear Loops, Flat Pleated, 3 layers	Same
Dimension (Length)		17.5 ± 5%	17.5cm ± 1cm	Similar
Dimension (Width)		9.5cm ± 5%	9.5cm ± 1cm	Similar
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 2	Same
Biocompatibility ISO 10993-5/ ISO 10993-10		Non-cytotoxic, non-sensitizing, and non-irritating	Non-cytotoxic, non-sensitizing, and non-irritating	Same

The difference in the materials does not raise additional questions for safety and effectiveness.

G. Summary of Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications as same 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:

- 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
- ASTM F2100, Standard Specification for Performance of Materials Used In Medical Face Masks
- ASTM F1862, Standard Test Method for Resistance of Medical Face Masks To Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume At A Known Velocity);
- EN 14683, Medical Face Masks—Requirements and Test Methods;
- ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using A Biological Aerosol of Staphylococcus Aureus;
- ASTM F2299, Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres;
- 16 CFR 1610, Standard for the Flammability of clothing textiles.

Table 2 – Summary of Performance Testing

Item	Subject device	Acceptance Criteria (level 2)	Result
Fluid Resistance Performance ASTM F1862	No penetration at 120 mmHg	No penetration at 120 mmHg	Pass
Particulate Filtration Efficiency ASTM F2299	>99.16%	≥ 98%	Pass
Bacterial Filtration Efficiency ASTM F2101	99.9%	≥ 98%	Pass
Differential Pressure (Delta P)EN 14683 Annex C	<5.3mmH_2O/cm^2	< 6.0mmH_2O/cm^2	Pass
Flammability 16 CFR 1610	Class 1	Class 1	Pass

Table 3 Summary of Biocompatibility Testing

Tests	Subject Device	Result
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic.	Same
Irritation	Under the conditions of the study, the device is non-irritating.	Same
Sensitization	Under the conditions of the study, the device is non-sensitizing.	Same

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

Based on the non-clinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, K182514.