July 28, 2021

Shandong Zhushi Pharmaceutical Group Co., Ltd
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K210409
Trade/Device Name: Disposable Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 20, 2021
Received: June 28, 2021

Dear Boyle 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,

For Clarence Murray
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)*
K210409

Device Name
Disposable Surgical Face Mask

Indications for Use *(Describe)*
The Disposable 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.

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K210409 510(k) Summary

510k number: K210409
Date: July 26, 2021
This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

1.0 Submitter's information

Name: Shandong Zhushi Pharmaceutical Group Co., Ltd
Address: No.6 Shande Road, Shan County, Heze City, Shandong, China
Contact: Mr. Junhui Zhu
Phone Number: 86-530-7150111
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Date of Preparation: Jul.26, 2021
Email: 2307426957@qq.com

Designated Submission Correspondent

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2.0 Device information

Trade name: Disposable Surgical Face Mask
Common name: Surgical mask
Classification name: Mask, Surgical
Model(s): ZS-S, tie-on.

3.0 Classification

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

4.0 Predicate device information

Manufacturer: Xiantao Rayxin Medical Products Co., Ltd.
Device: Disposable Surgical Face Mask
510(k) number: K153496

5.0 Indication for Use Statement

The Disposable 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 Disposable Surgical Face Mask is single use, three-layer, flat-pleated style with tie on and nose piece. The mask is manufactured with three layers, the inner and outer layers, and the tie on are made of nonwoven fabrics, and the middle layer is made of melt blown fabrics. During use, the tie on shall be tied over user head. The nose piece in the layers of facemask is to allow the user to fit the facemask around their nose, which is made of malleable polyethylene wire. The Disposable Surgical Face Mask is provided in blue color. The mask is sold non-sterile and are intended to be single use, disposable devices.

The specification of the device as follows:

Item	Specification(cm)	Tolerance(cm)
Length (L) x Width (H)	17.5cm×9.5cm	±5%
	17.5cm×9.0cm	
	17.0cm×9.0cm	
	14.5cm×9.5cm	
Nose Piece Length	10.5cm×0.3cm	±5%
Ties	40cm×1.0cm	±5%

7.0 Technological Characteristic Comparison Table

Table 1 - General Comparison

Item	Proposed device	Predicated device	Remark
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Product name	Disposable Surgical Face Mask	Disposable Surgical Face Mask	-
510(k) No.	K210409	K153496	-
Models	ZS-S, Tie-on.	Tie on, ear-loop, Flat Pleated, 3 layers	-
Specification	17.5cm×9.5cm	17.5cm×9.5cm	-
	17.5cm×9.0cm		
	17.0cm×9.0cm		
	14.5cm×9.5cm		
Intended Use	The Disposable Surgical	The Surgical Face Masks	Same

		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.	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.	
OTC use		Yes	Yes	Same
Composite		Flat Pleated, 3 layers	Flat Pleated, 3 layers	Same
Material	Internal layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene	Melt blown polypropylene	Same
	External layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose piece	Malleable polyethylene wire	Malleable polyethylene wire	Same
	Tie-on	Spun-bond polypropylene	Spun-bond polypropylene	Same
Color		Blue	Blue	Same
Dimension (Length)		17.5cm×9.5cm, ±5%	17.5cm×9.5cm, ±1cm	* Gap 1
		17.5cm×9.0cm, ±5%		
		17.0cm×9.0cm, ±5%		
		14.5cm×9.5cm, ±5%		
Sterility		Non-Sterile	Non-Sterile	Same
Single Use		Yes	Yes	Same
Sterile		No	No	Same
ASTM F2100 Level		Level 3	Level 2	* Gap 2
Shelf life		2 years	No shelf life claimed	* Gap 3
Biocompatibility				
Cytotoxicity		Under the conditions of the study, the subject device was non-cytotoxic	Under the conditions of the study, the predicate device was non-cytotoxic	Same
Irritation		Under the conditions of the study, the subject device was non-irritating	Under the conditions of the study, the predicate device was non-irritating	Same
Sensitization		Under the conditions of the study, the subject device was non-sensitization	Under the conditions of the study, the predicate device was non-sensitization	Same

* Gap analysis:

Gap 1: the proposed device has 4 specifications, with lower dimension tolerance than the predicate device, the different specifications does not impact the surgical mask

performance and safety, considering the stricter tolerance of proposed device, the difference does not bring additional risks to the device.
Gap 2: the proposed device has higher performance level (Level 3) higher than the predicate device, the higher performance does not bring additional risks to the device.
Gap 3: the predicate device does not claim specific shelf life while the proposed device define its 2 years shelf life which is proved by its shelf life performance study, the clear shelf life does not bring additional risks to the product use.

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.

Table 2 - Performance Testing

Items	Performance	Acceptance Criteria (Level 3, ASTM F2100-19)	Result
Bacterial filtration efficiency (BFE) (%)	>98%	≥98	Pass
Different pressure (mmH_2O/cm^2)	<6.0 mmH_2O/cm^2	<6.0 mmH_2O/cm^2	Pass
Sub-micron particulate filtration efficiency at 0.1 micron, % (PFE)	>98%	≥98	Pass
Resistance to penetration by synthetic blood, Minimum pressure in mmHg for pass result	31 of 32 test articles passed at 160mmHg	29 of 32 test articles passed at 160mmHg	Pass
Flame spread	Class 1	Class 1	Pass

Table 3 - Biocompatibility Testing

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

- Biocompatibility Testing According to ISO 10993-1:2009, the nature of body contact for the subject device is Surface Device category, Skin Contact and duration of contact is A-Limited (≤24h). The following tests for the subject device were conducted to demonstrate that the subject device is biocompatible and safe for its intended use:
  1) In vitro Cytotoxicity Test per ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity,
  2) Skin Sensitization Tests per ISO 10993-10:2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization,
  3) Skin Irritation Tests per ISO 10993-10:2010 Biological evaluation of medical

devices— Part 10: Tests for irritation and skin sensitization.

9.0 Clinical Test Conclusion

No clinical study implemented for the Disposable Surgical Face Mask.

10.0 Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K210409, the Disposable Surgical Face Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K153496.