August 4, 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: K210643
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 21, 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 and Part 809); 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, Ph.D.
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)*
K210643

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. This face mask 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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510(k) Summary

510k number: K210643
Date: July 26, 2021
This summary of 510(k) is being submitted in accordance with requirements of 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
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Date of Preparation: Jul.26, 2021
Email: 2307426957@qq.com

Designated Submission Correspondent

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2.0 Subject Device information

Type of 510(k): Traditional
Trade name: Disposable Surgical Face Mask
Common name: Surgical mask
Classification name: Mask, Surgical
Model(s): ZS-B, ear-loop.

3.0 Classification

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

4.0 Predicate device information

Manufacturer: Guangdong Haiou Medical Apparatus Co., Ltd.

Device: Disposable Medical Surgical Face Mask
510(k) number: K203200
Classification name: Mask, Surgical
Production code: FXX
Regulation number: 21CFR 878.4040
Classification: Class II
Panel: Surgical apparel

5.0 Device description

The Disposable Surgical Face Mask is single use, three-layer, flat-pleated style with ear-loop and nose piece. The mask is manufactured with three layers, the inner and outer layers, and the ear-loop is made of spandex and polyester, and the middle layer is made of melt blown fabrics. During use, the ear-loop shall be tied over user ear. 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.

6.0 Indication for Use Statement

The Disposable Surgical Face Mask is indicated as a protective nose and mouth covering for healthcare workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of exposure to microorganisms and body fluids.

7.0 Technological Characteristic Comparison

Provided below is a comparison of the proposed device with the predicate device.

Table 3 - 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 Medical Surgical Face Mask	Same
510(k) No.	K210643	K203200	Different
Models	ZS-B, ear-loop.	HO-KZ01	Different
Composite	Flat Pleated, 3 layers	Ear loop, flat pleated, 3 layers	Same
Specification	17.5cm×9.5cm	17.5cm×9.5cm	Different
	17.5cm×9.0cm		

		17.0cm×9.0cm		
		14.5cm×9.5cm		
Intended Use		The Disposable Surgical Face Mask is indicated as a protective nose and mouth covering for healthcare workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of exposure to microorganisms and body fluids.	Disposable Medical Surgical Face Mask is indicated as a protective nose and mouth covering for healthcare workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of exposure to microorganisms and body fluids.	Same
OTC use		Yes	Yes	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 with aluminum wire	Same
	Ear-loop	spandex +polyester	polyester	Similar
Color		Blue	Blue	Same
Dimension (W×L)		17.5cm×9.5cm, ±5%	W: 17.5cm L: 9.5cm	Different
		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
Fluid Resistance Performance		31/32 Passed at 160mmHg Level 3 ASTM F1862-17	Level 3: 160 mmHg	Same
Particulate Filtration Efficiency		32/32 Passed ≥98% ASTMF2299-03	≥98%	Same
Bacterial Filtration Efficiency		32/32 Passed at ≥98% ASTM F2101-19	≥98%	Same
Differential Pressure		32/32 Passed at <6 mmH_2O/cm_2 EN 14683: 2019, Annex C	<6.0 mmH2O/cm2	Similar
Flammability		32/32 Passed ≥ Second's burn Time-Class 1 16 CFR Part 1610	Class 1, Non-Flammable	Same
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

8. Summary of Non-Clinical Performance Testing

Performance Testing Summary

Test Method	Purpose	Pass Criteria	Results
ASTM F2101-19Standard TestMethod for Evaluating the Bacterial Filtration	The purpose of the test is to evaluate the Bacterial filtration efficiency (BFE) (%)	≥98%	3 lots tested with total 96 samples, 94/96 Passed at ≥98% /Pass
EN 14683: 2019, Annex C Medical face masks - Requirements and test methods according to ASTM F2100:2019	The purpose of the test is to evaluate the Different pressure (Delta-P)	<6.0 mmH_2O/cm^2	3 lots tested with total 96 samples, 92/96 Passed <6 $mmH2O/cm^2$ / Pass
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 ASTMF2100:2019	The purpose of the test is to evaluate the Sub-micron particulate filtration efficiency at 0.1 micron, % (PFE)	≥98%	3 lots tested with total 96 samples, 96/96 Passed at ≥98% / Pass
ASTM 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 ASTMF2100:2019for pass result	The purpose of the test is to evaluate the Resistance to penetration by synthetic blood, Minimum pressure in mmHg	Fluid resistant claimed at 160 mm Hg	3 lots tested with total 96 samples, 95 of 96 test articles passed at 160mmHg /Pass

16 CFR Part 1610 Standard for the Flammability of Clothing according to ASTM F2100:2019	The purpose of the test is to evaluate the Flame spread	Class 1	3 lots tested with total 96 samples, 96/96 Passed ≥3 seconds burn Time-Class 1 / 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. Summary of Clinical Performance Test

No clinical study is included in this submission

10.0 Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K210643, 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 K203200.