January 14, 2022

Guangdong Zhizhen Biological Medical Co., Ltd
℅ Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K212997
Trade/Device Name: Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: October 11, 2021
Received: October 15, 2021

Dear Diana Hong:

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,

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)*
K212997

Device Name
Surgical Mask

Indications for Use *(Describe)*
The surgical mask is 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 the potential exposure to blood and body fluids. This is a single use, disposable device, provided sterile.
Serial number: ZZ-YYKZ-01, size 175x95mm, Blue
ZZ-YYKZ-02, size 145x95mm, Blue
ZZ-YYKZ-03, size 175x95mm, Black
ZZ-YYKZ-04, size 145x95mm, Black

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

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: _ K212997 _

1. Date of Preparation: 01/12/2022

2. Sponsor Identification

Guangdong ZhiZhen Biological Medicine Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Tingting Su (Alternative Contact Person)

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Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Surgical Mask
Common Name: Surgical mask

Regulatory Information
Classification Name: Mask, Surgical;
Classification: II;
Product Code: FXX;
Regulation Number: 21CFR 878.4040;
Review Panel: General Hospital;

Indication for use:
The surgical mask is 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 the potential exposure to blood and body fluids. This is a single use, disposable device, provided sterile.
Serial number: ZZ-YYKZ-01, size 175x95mm, Blue
ZZ-YYKZ-02, size 145x95mm, Blue
ZZ-YYKZ-03, size 175x95mm, Black
ZZ-YYKZ-04, size 145x95mm, Black

Device Description:
The proposed device, Surgical Mask is a three-layer, plane bandage type mask with ear strap and nose clip. The ear straps are held in place over the users' mouth and nose by two elastic ear straps welded to the facemask. The proposed device includes masks in two colors and two sizes, as shown in Table 1. The device is single use and provided sterile.

Table 1 Product Model

Serial number	Length (mm)	Width (mm)	Color
ZZ-YYKZ-01	175	95	Blue
ZZ-YYKZ-02	145	95	Blue
ZZ-YYKZ-03	175	95	Black
ZZ-YYKZ-04	145	95	Black

5. Identification of Predicate Device

Predicate Device:
510(k) Number: K202905
Product Name: Disposable Face Mask

6. Technological Characteristic Comparison Table

Table 1 Comparison of Surgical Mask

ITEM	Proposed Device K212997	Predicate Device K202905	Remark
Product Code	FXX	FXX	same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	same
Class	II	II	same
Indication for Use	The surgical mask is 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 the potential exposure to blood and body fluids. This is a single use, disposable device, provided sterile. Serial number: ZZ-YYKZ-01, size 175x95mm, Blue ZZ-YYKZ-02, size 145x95mm, Blue ZZ-YYKZ-03, size 175x95mm, Black ZZ-YYKZ-04, size 145x95mm, Black	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.	different
Configuration	ear strap nose clip mask body	ear strap nose clip mask body	same
Mask color	Blue, Black	Blue	different
Dimension	17.5×9.5 cm 14.5×9.5 cm	14.5×9.5cm, 17.0×9.5cm, 17.5×9.5cm	different
Level	Level I	Level I	same
Fluid Resistance	Pass at 80mmHg	Pass at 80mmHg	same
Particulate efficiency level	Blue: Passed at 99.14% Black: Passed at 99.14 %	≥95%	different
Bacterial filtration level	Blue: Passed at 99.60% Black: Passed at 99.61 %	≥95%	different

Differential pressure		＜5 mmH_2O/cm^2	＜5mmH_2O/cm^2	same
Flammability		Class 1	Class 1	same
Label/Labeling		Complied with 21 CFR part 801	Complied with 21 CFR part 801	same
Patient Contacting Material				
Ear strap		Polyamide and Polyurethane	Spandex and Polyester	different
Nose clip		Polyethylene terephthalate and Iron	HDPE and Iron	
Mask body	Outer material	Polypropylene nonwoven fabric	PP meltblown non-woven cloth	
	Middle material	Polypropylene melt-blown cloth	PP spunbond non-woven cloth	
	Inner material	Polypropylene nonwoven fabric	PP spunbond non-woven cloth	
Biocompatibility				
Cytotoxicity		No Cytotoxicity	No Cytotoxicity	same
Sensitization		No Sensitization	No Sensitization	same
Irritation		No Irritation	No Irritation	same
Sterilization				
Method		EO sterilized	Non-sterile	different
SAL		10^{-6}	/	

Different Analysis 1- Indication for Use
The proposed device and predicate devices have essentially same indications for use.

Different Analysis 2- Color
The color of the proposed device is different from the predicate device.

Different Analysis 3- Dimension
The dimension for the proposed device is similar to the predicate device,

Different Analysis 4-Particulate efficiency level
The test result for particulate efficiency for the proposed device is different from predicate device.

Different Analysis 5-Bacterial filtration level
The test result for bacteria efficiency for the proposed device is different from predicate device.

Different Analysis 6-Patient Contacting Material
The patient contact material for the propose device is different from predicate device.

Different Analysis 7-Sterilezation

The final product status of the proposed device is different from predicate device,

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications and the acceptance criteria in the standard and test methodology. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical device- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-7:2008 Biological Evaluation of Medical Device- Part 7: Ethylene Oxide Sterilization Residuals
- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritation and skin sensitization
- ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials. (Sterility)
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- ASTM F1886 / F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- 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)
- ASTM F2299/F2299M-03 (2017) Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres
- ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- 16 CFR 1610 Standard for the Flammability of Clothing Textiles Corrections
- EN14683 Medical face masks-Requirements and test methods

The results of performance tests, biocompatibility tests, sterility test, conducted on the Surgical Mask demonstrate that the device met the specification and the acceptance criteria. A summary of the tests performed is provided in the table below:

Table 2 Performance Testing

Test	Purpose	Acceptance Criteria per ASTM F2100-19	Results (Statistics of three lots, 32 per lot)	
			Blue	Black
Fluid Resistance (ASTM F1862)	Verify the fluid resistance of the proposed device can meet the requirements for Level 1 specified in ASTM F2100-19.	Pass at 80 mmHg	96 out of 96 pass at 80 mmHg	96 out of 96 pass at 80 mmHg
Bacterial filtration efficiency (BFE) (ASTM F2101)	Verify the bacterial filtration efficiency of the proposed device can meet the requirements for Level 1 specified in ASTM F2100-19.	≥95%	Passed at 99.60%	Passed at 99.61%
Particulate filtration efficiency (PFE) (ASTM F2299)	Verify the particulate filtration efficiency of the proposed device can meet the requirements for Level 1 specified in ASTM F2100-19.	≥95%	Passed at 99.14%	Passed at 99.14%
Differential pressure (EN 14683)	Verify the differential pressure of the proposed device can meet the requirements for Level 1 specified in ASTM F2100-19.	＜5.0 mmH_2O/cm^2	＜5.0 mmH_2O/cm^2	＜5.0 mmH_2O/cm^2
Flammability (16 CFR 1610)	Verify the flammability of the proposed device can meet the requirements for Level 1 specified in ASTM F2100-19.	Class 1	Class 1	Class 1

Table 3 Biocompatibility Testing

Test	Purpose	Acceptance Criteria	Result
In vitro Cytotoxicity (ISO 10993-5)	Verify that the proposed device extract is non-cytotoxic.	The extract is non-cytotoxic under the testing conditions.	Pass

Skin Irritation (ISO 10993-10)	Verify that the proposed device extract is non-irritating.	The polar and non-polar extracts are non-irritating under the testing conditions.	Pass
Skin Sensitization (ISO 10993-10)	Verify that the proposed device extract is non-sensitizing.	The polar and non-polar extracts are non-sensitizing under the testing conditions.	Pass

Table 4 Sterilization

Test	Purpose	Acceptance Criteria	Result
EO ECH residuals (ISO 10993-7)	Verify the EO ECH residuals of the proposed device can meet the requirements of ISO 10993-7.	The average daily dose of EO to patient shall not exceed 4mg. The average daily dose of ECH to patient shall not exceed 9mg.	Pass
Bacterial Endotoxin (USP <85>)	Verify the bacterial endotoxin of the proposed device can meet the requirements of USP <85>.	Bacterial Endotoxin Levels were below the level of 20 EU/device	Pass
Package Integrity (ASTM F1886 / F1886M-16, ASTM F88/F88M-15, ASTM F1929-15)	Verify the package integrity of the proposed device can meet the requirements of ASTM F1886 / F1886M-16, ASTM F88/F88M-15, ASTM F1929-15.	There should be no channel on the package and no damage on device. The maximum seal strength should be no less than 2.0N/15mm. There should be no dye penetration on the package.	Pass

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in the 510(k) submission, the Surgical Masks are as safe and effective, and performs as well as or better than the legally marketed predicate device cleared under K202905.