April 28, 2021

Zhende Medical Co., Ltd.
% Joyce Yang
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square,
Nanshan District
Shenzhen, Guangdong 518100
China

Re: K210020
Trade/Device Name: Medical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: March 24, 2021
Received: March 29, 2021

Dear Joyce Yang:

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,

Ryan Ortega -S

Ryan Ortega PhD
Acting 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)*
K210020

Device Name
Medical Mask

Indications for Use *(Describe)*
The Medical 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.

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.

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510(k) Summary

510(k) Number: K210020

Date of Summary prepared: April 27, 2021

1. Submission Sponsor

Applicant Name	Zhende Medical Co., Ltd.
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Contact person	Chen Ming
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2. Submission correspondent

Name	Shenzhen Joyantech Consulting Co., Ltd
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Phone No.	+86-755-86069197
Contact Person	Joyce Yang
Email	joyce@cefda.com

3. Device Identification

Type of 510(k) submission:	Traditional
Trade Name:	Medical Mask
Classification name:	Mask, Surgical
Review Panel:	Surgical Apparel
Product Code:	FXX
Device Class:	II
Regulation Number:	878.4040

4. Legally Marketed Predicate Device

Trade Name	Single-use Surgical Mask
Regulation number	878.4040
Regulation class	II
Regulation name	Surgical Apparel
510(k) Number	K200923
Product Code	FXX
Manufacturer	BYD Precision Manufacturer Co.,Ltd.

5. Device Description

The Medical Masks are single use, three-layer, flat masks with ear loops/straps and nose clamp. The Medical Masks are manufactured with three layers, the inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter.

The model of proposed device, Ear-loop, 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 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 nose clamp contained in the proposed device is in the layers of face mask to allow the user to fit the face mask around their nose, which is made of metal core plastic.

The proposed devices are single use, disposable device, provided in both non-sterile and sterile forms.

6. Intended Use/ Indications for Use

The Medical 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.

7. Technological characteristics comparison

The Medical Mask is compared with the predicate device Single-use Surgical Mask(K200923). The product characteristics are shown as follow:

Table 1: General Comparison

Comparison item	Subject Device (K210020)	Predicate Device (K200923)	Comments
Product Code	FXX	FXX	Same
Regulation Number	21 CFR § 878.4040	21 CFR § 878.4040	Same
Classification	Class II	Class II	Same
OTC use	Yes	Yes	Same
	The Medical 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	The Single-use Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate	

Indications for Use	masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids.	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.	Same
Level	Level 3	Level 3	Similar
Design feature	Ear-loop, Tie-on Flat Pleated, 3 layers	Ear-loop Flat Pleated, 3 layers	Similar
Usage	Single use	Single use	Same
Color	Blue	Blue	Same
Size	Width: 18.0cm+/-1.0cm, 14.0cm +/-1.0cm Length: 9.5cm+/-1.0cm	Width: 17.5cm+/-0.4cm Length: 9.5cm+/-0.4cm	Different
Sterile	Non-sterile, Sterile	Non-sterile	Different
Sterilization method	EO	/	Different
Material	Outer layer: Spun-bond polypropylene	Outer layer: Spun-bond polypropylene	Same
	Middle layer: Melt blown polypropylene	Middle layer: Melt blown polypropylene	Same
	Inner layer: Spun-bond polypropylene	Inner layer: Spun-bond polypropylene	Same
	Nose clamp: Metal Core Plastic	Nose piece: Metal Core Plastic	Same
	Ear loops: Polyester and spandex/Elastic laminate Straps: Spun-bond polypropylene	Ear loops: Polyester	Different
Fluid Resistance Performance (ASTM F1862)	Pass at 160 mmHg	Pass at 160 mmHg	Same
Particulate Filtration Efficiency (ASTM F2299)	> 98%	> 98%	Same
Bacterial Filtration Efficiency (ASTM F2101)	> 98%	> 98%	Same
Differential Pressure (EN 14683:2019)	5.0mmH2O/cm2 (< 6.0mm H2O/cm2)	5.62 mmH2O/cm2 (< 6.0mm H2O/cm2)	Similar
Flammability (16 CFR 1610)	Class 1	Class 1	same

Cytotoxicity (ISO 10993-5)	Under the conditions of the study, non cytotoxicity effect	Under the conditions of the study, non cytotoxicity effect	Same
Irritation (ISO 10993-10)	Under the conditions of the study, non irritation	Under the conditions of the study, non irritation	Same
Sensitization (ISO 10993-10)	Under the conditions of the study, non sensitization	Under the conditions of the study, non sensitization	Same

8. Summary of Non-clinical Testing

Non-clinical tests were conducted and conformed to the following standards and the requirements state in the Guidance for Industry and FDA Staff: Surgical Masks - Premarket Notification [510(k)] Submission issued on March 05, 2004.

Standards:

- ASTM F2100-19 Standard Specification For Performance of Materials used in Medical Face Masks.
- ASTM F1862-13 Standard Test Method For Resistance of Medical Face Masks to Penetration by Synthetic Blood.
- ASTM F2299-03 Stand 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.
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
- ANSI/AAMI/ISO 11135:2014 Sterilization of health care products - Ethylene oxide - Requirements for Development, validation, and routine control of a sterilization process for Medical devices
- 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.

9. Brief discussion of clinical tests

No clinical tests were performed.

10. Conclusions

The conclusion drawn from the nonclinical tests demonstrates that the subject device in this 510(K) submission K210020, the Medical Mask is as safe, effective, and performs as well as or better than the legally marketed predicate device cleared under K200923.