March 10, 2021

Wanxinda (Guangzhou) Technology Product Co., Ltd
℅ Joyce No Last Name Provided
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square,
Nanshan District
Shenzhen, Guangdong 518100
China

Re: K202548
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 13, 2020
Received: September 2, 2020

Dear Joyce No Last Name Provided:

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,

For 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)*
K202548

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 mask 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.

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

Submission Number: K202548

Date of Summary revised: March 10, 2021

1. Submission Sponsor

Applicant Name	Wanxinda(Guangzhou)Technology Product Co.,Ltd.
Address	Ling Xi Road, Accessory Section 2, Automobile Zone,Huadu District, Guangzhou, Guangdong, China.
Contact person	Zeng Xueping
Phone	86-020-61816666

2. Submission correspondent

Name	Shenzhen Joyantech Consulting Co., Ltd
Address	1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen
Post Code	518000
Phone No.	86-755-86069197
Contact Person	Joyce Yang
Email	joyce@cefda.com

3. Device Identification

Type of 510(k) submission:	Traditional
Trade Name:	Surgical Face Mask
Model:	WXDKZ0001，WXDKZ0006
Classification name:	Mask, Surgical
Review Panel:	Surgical Apparel
Product Code:	FXX
Common name:	Surgical face mask
Device Class:	II
Regulation Number:	878.4040

4. Legally Marketed Predicate Device

Trade Name	Surgical Face Mask
Regulation number	878.4040
Regulation class	II
Regulation name	Surgical Apparel
510(k) Number	K133070
Product Code	FXX
Manufacturer	BH Medical Products Co.,Ltd.

5. Device Description

The proposed devices are single use, three-layer, flat masks with ear loops and nose piece. The Surgical Face 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 proposed device, 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 nose piece 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 polypropylene with steel wire.

The colorants used for mask are Copper phthalocyanine, Titanium dioxide and Polyethylene. The proposed devices are sold non-sterile and are intended to be single use, disposable devices.

The proposed device including two models, WXDKZ0001 and WXDKZ0006, the difference is the color of the outer layer.

Model	Color	Performance Level
WXDKZ0001	White	Level 2
WXDKZ0006	Blue	Level 2

6. Intended Use/ 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 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.

7. Summary of Technological Characteristics

Comparison item	Subject Device (K202548)	Predicate Device (K133070)	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
Intended use & Indications for Use	The Surgical Face Masks are intended to be worn to protect both the patient and healthcare	The Disposable Surgical Masks are intended to be worn to protect both the	Same

Comparison item	Subject Device (K202548)	Predicate Device (K133070)	Comments
	personnel from transfer of microorganisms, body fluids and particulate material. These mask 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.	patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face mask 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.	
Design feature	Ear-loop	Ear-loop, Tie-on	Same
Usage	Single use	Single use	Same
Color	White, Blue	Blue, Green	Different (Issue 1)
Size	Width:175mm±5% Length: 95mm±5% The length of nose piece: 100mm± 5mm The length of ear loop: 190mm± 5mm	Width:6.5”+/-0.25” Length:3.5”+/-0.25” 4.2”+/-0.25”	Same
Sterile	Non-sterile	Non-sterile	Same
Material	Outer layer: polypropylene non-woven	Outer layer: Spun-bond polypropylene	Same
	Middle layer: Melt blown fabric	Middle layer: Melt blown polypropylene	Same
	Inner layer: polypropylene non-woven	Inner layer:Spun-bond polypropylene	Same
	Nose piece: PP+Steel wire	Nose piece: Aluminum wire	Different (Issue 2)
	Ear-loops: Spandex	Ear-loops:Polyester	Different (Issue 3)

Comparison item	Subject Device (K202548)	Predicate Device (K133070)	Comments
ASTM F 2100 Level	Level 2	Level 1, Level 2, Level 3	Same
Fluid Resistance Performance ASTM F 1862-13	32 out of 32 pass at 120mmHg	Level 1: 32 out of 32 pass at 80mmHg Level 2: 32 out of 32 pass at 120mmHg Level 3: 32 out of 32 pass at 160mmHg	Same
Particulate Filtration Efficiency ASTM F 2299	99.8%	Level 1: > 95% Level 2 : > 98% Level 3: > 98%	Same
Bacterial Filtration Efficiency ASTM F 2101	99.8%	Level 1: > 95% Level 2 : > 98% Level 3: > 98%	Same
Differential Pressure (Delta P) EN 14683:2019+ AC：2019	4.0 mm H_2O/cm^2	Level 1: < 5 mm H_2O/cm^2 Level 2: < 6 mmH_2O/cm^2 Level 3: < 6 mm H_2O/cm^2	Same
Flammability 16CFR 1610	Class 1	Class 1	Same
Cytotoxicity	Under the conditions of the study the subject device was found non-cytotoxic	Under the conditions of the study the subject device was found non-cytotoxic	Same
Irritation	Under the conditions of the study the subject device was found non-irritating	Under the conditions of the study the subject device was found non- irritating	Same
Sensitization	Under the conditions of the study the subject device was found non-sensitizing	Under the conditions of the study the subject device was found non-sensitizing	Same

Issue 1: The color master batch of proposed device outer layer is different from the predicate device. This difference will not affect the performance of the mask. Moreover, the proposed product has been tested for biocompatibility and has no potential toxicity or irritation.

Issue 2: The nose piece of the proposed device is made polypropylene with steel wire, which of the predicate device is made by Malleable aluminum wire. The Nose piece is between the inner and outer layers of the mask, which does not contact with the human body directly when used. Moreover, the whole product has been tested for biocompatibility, and the test results confirm that they have good biocompatibility, so their differences will not cause new safety risks.

Issue 3: The Ear-loops of the proposed device are made by spandex, which of the predicate device is made by polyester. The major chemical composition of the spandex is segmented polyurethane-urea, which is similar to polyester. In addition, the proposed devices have been tested for biocompatibility, and the test results confirm that they have good biocompatibility, so their differences will not cause new safety risks.

8. Non-clinical Testing

Surgical Face Mask conforms to the following standards:

ASTM F 2100-19, Standard Specification for Performance of Materials Use in Medical Face Masks.

ISO 10993-1:2018, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process.

Bench testing

The bench testing of Surgical Face Mask include the following tests:

*Fluid Resistance Performance

*Particulate Filtration Efficiency

*Bacterial Filtration Efficiency

*Differential Pressure

*Flammability

Biocompatibility testing

The biocompatibility evaluations were conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process”, as recognized by FDA. The tests of Surgical Face Mask include the following tests:

* Cytotoxicity

* Sensitization

* Irritation

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 K202548, the Surgical Face Mask is as safe, effective, and performs as well as or better than the legally marketed predicate device cleared under K133070.