April 9, 2021

Shenzhen Jinko Industrial 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: K202513
Trade/Device Name: Disposable Medical Face Mask (Model FM-04)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: March 3, 2021
Received: March 12, 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,

Bifeng Qian -S

For Clarence W. Murray, III, Ph.D.
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)*
K202513

Device Name
Disposable Medical Face Mask (Model FM-04)

Indications for Use *(Describe)*
The Disposable Medical 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.

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: K202513
Date of Summary prepared: April 8, 2021

This summary of 510(K) safety and effectiveness information is submitted as required by requirements of SMDA and 21 CFR §807.92.

1. Submission Sponsor

Applicant Name	Shenzhen Jinko industrial Co., Ltd.
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Contact person	Wang Yinghui
Phone	+0086-400-990-9777

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:	Disposable Medical Face Mask
Model:	FM-04
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	Disposable Surgical Face Mask
Regulation number	878.4040
Regulation class	II
Regulation name	Surgical Apparel
510(k) Number	K153496
Product Code	FXX
Manufacturer	Xiantao Rayxin Medical Products Co.,Ltd.

5. Device Description

The proposed devices are single use, three-layer, flat masks with straps and nose piece. The Disposable Medical 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 polyethylene with steel wire.

The proposed devices are sold non-sterile and are intended to be single use, disposable devices.

6. Intended Use/ Indications for Use

The Disposable Medical 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. Technological characteristics of the subject device compared to the predicate device

7.1 Predicate Device Information:

510(K) No.: K153496

Common name: Disposable Surgical Face Mask

Classification name: Mask, Surgical

Production regulation: 21 CFR § 878.4040

Product code: FXX

Panel: Surgical Apparel

7.2 Comparison to predicate device:

The Disposable Medical Face Mask is compared with the predicate device Disposable Surgical Face Mask(K153496). The product characteristics are shown as follow:

Table 1: General Comparison

Comparison item	Subject Device (K202513)	Predicate Device (K153496)	Comments
Applicant	Shenzhen Jinko industrial Co., Ltd.	Xiantao Rayxin Medical Products Co.,Ltd.	/
Product name	Disposable Medical Face Mask	Disposable Surgical Face Mask	/
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 Disposable Medical 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.	The Disposable Surgical 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 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.	Same
Design feature	Ear-loop	Ear-loop, Tie-on	Similar Issue 1
Usage	Single use	Single use	Same
Color	Blue	Blue	Same
Size	(175±8)mm×(95+4.5)cm	(17.5±1)cm×(9.5±1)cm	Similar Issue 2

Comparison item	Subject Device (K202513)	Predicate Device (K153496)	Comments
Sterile	Non-sterile	Non-sterile	Same
Material	Outer layer: Spun-bond polypropylene	Outer layer: Spun-bond polypropylene	Same
	Middle layer: Melt blown polypropylene filter	Middle layer: Melt blown polypropylene filter	Same
	Inner layer: Spun-bond polypropylene	Inner layer:Spun-bond polypropylene	Same
	Nose piece:PE+Steel wire	Nose piece:Malleable aluminum wire	Difference Issue 3
	Ear loops: Spandex	Ear loops:Polyester	Similar Issue 4
ASTM F 2100 Level	Level 2	Level 2	Same
Fluid Resistance Performance ASTM F 1862-13	32 out of 32 pass at 120 mmHg	32 out of 32 pass at 120 mmHg	Same
Particulate Filtration Efficiency ASTM F 2299	99.8%	98.46%	Similar
Bacterial Filtration Efficiency ASTM F 2101	99.9%	98.7%	Similar
Differential Pressure (Delta P) EN 14683:2019+ AC：2019	3.7 mmH_2O/cm^2	4.2 mmH_2O/cm^2	Similar
Flammability 16CFR 1610	Class 1	Class 1	Same
Cytotoxicity	Non cytotoxic	Non cytotoxic	Same
Irritation	Non irritating	Non irritating	Same
Sensitization	Non sensitizing	Non sensitizing	Same

Issue 1: The design feature of the proposed device is covered by the predicate device.

Issue 2: The size of the proposed device is the same as that of the predicate device, but the tolerance range is different, and this difference will not cause new safety risks.

Issue 3: The nose piece of the proposed device is made by polypropylene and iron, 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 4: The Ear loops of the proposed device are made by spandex, which of the predicate device is made by polyester. Both of these materials are commonly used for mask straps. 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

The purpose of non-clinical testing is to evaluate whether the face mask in accordance with the requirements of technical specification.

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.

Table 2: Performance testing

Items	Acceptance criteria	Results
Fluid Resistance Performance (ASTM F1862)	29 out of 32 pass at 120 mmHg	32 out of 32 pass at 120 mmHg
Particulate Filtration Efficiency （ASTM F2299）	⩾98%	99.8%
Bacterial Filtration Efficiency (ASTM F2101)	⩾98%	99.9%
Differential Pressure (EN 14683:2019)	＜6.0mmH_2O/cm^2	3.7 mmH_2O/cm^2
Flammability (16 CFR 1610)	Class 1	Class 1

Table 3: Biocompatibility testing

Items	Acceptance criteria	Results
Cytotoxicity (ISO 10993-5:2009)	No toxicity	No potential toxicity
Irritation (ISO 10993-10:2010)	No irritation	No potential skin irritation
Sensitization (ISO 10993-10:2010)	No sensitization	No potential skin sensitization

9. Brief discussion of clinical tests

N/A.

10. Other information (such as required by FDA guidance/Test)

N/A.

11. Conclusions

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.