December 14, 2021

Chongqing Pa Xijia Biotechnology Co., Ltd.
% May Wu
Manager of Business Development
Sichuan JIULUEHUI Consulting Co., Ltd.
Room 1401, Building 4, No. 666, Chenglong Avenue
Chengdu, Sichuan 610101
China

Re: K210744
Trade/Device Name: Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: October 21, 2021
Received: October 29, 2021

Dear May Wu:

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, PhD
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210744

Device Name
Surgical 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 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.

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 – K210744

This summary of 510(k) is being submitted in accordance with requirements of the SMDA 21 CFR 807.92.

1. Date of Preparation: February 28, 2021

2. Sponsor Identification

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3. Designated Submission Correspondent

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4. Device Information

Trade name: Surgical Mask

Common name: Surgical Face Mask Model:
Ear-loop

5. Classification

Production code: FXX

Regulation number: 21 CFR 878.4040
Classification: Class II

Classification name: Surgical Face Mask

Review Panel: Surgical Apparel

6. Indication for Use Statement

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 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.

7. Device Description

The Surgical Masks are single use, three-layer, flat-pleated style with ear loops and nose piece.

The Surgical Masks will be provided in blue. The medical face masks are sold non-sterile and are intended to be single use, disposable devices.

The Surgical 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 ear loops are held in place over the users' mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are made of polyester. 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 aluminum wire.

8. Identification of Predicate Device(s)

Manufacturer: Xiantao Rayxin Medical Products Co., Ltd.
Device: Disposable Surgical Face Mask
510(k) number: K153496

9. Technological Characteristics Comparison Table

Table 1 General Comparison

Item	Proposed Device K210744	Predicate Device K153496	Comparison
Product Name	Surgical Mask	Disposable Surgical Face Masks	--
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Product Class	II	II	Same
Product Code	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 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.	The Disposable 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 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,	Same

			disposable device(s), provided non-sterile.	
Design features	Ear Loops, 3 layers		Ear Loops, Tied-On, 3 layers	Same
Mask Styles	Flat pleated		Flat pleated	Same
Material	Outer facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Similar
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Similar
	Inner Facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Similar
	Nose piece	Malleable aluminum wire	Malleable aluminum wire	Similar
	Ear loops	Polyester	Polyester	Similar
Color	Blue		Blue	Similar
Mask Size	M(152mmX70mm),L(175mmX90mm), XL(180mmX100mm)		175mmX90mm	Different
OTC use	Yes		Yes	Same
Sterility	Non-Sterile		Non-Sterile	Same
Single Use	Yes		Yes	Same
Sterile	No		No	Same
ASTM F2100 Level	Level 2		Level 2	Same

Table2 Performance Characteristic Comparison

ITEM	Proposed Device	Predicate Device	ASTM F2100 Requirements for Level 2 Classification	Comparison
Fluid Resistance Performance ASTM F1862-13	182 out of 182 pass at 120 mmHg	32 out of 32 pass at 120 mmHg	Pass at 120 mmHg*	Similar
Particulate Filtration Efficiency ASTM F2299	98.40%	98.46%	≥ 98%*	Similar
Bacterial Filtration Efficiency ASTM F2101	99.86%	98.70%	≥ 98%*	Similar
Differential Pressure (Delta P) MIL-M-36954C	5.3 mmH2O/cm2	4.2 mmH2O/cm2	< 6.0 mmH2O/cm2*	Similar

Flammability 16 CFR 1610	Class 1	Class 1	Class 1*	Same

* Acceptable sampling plans are found in ISO 2859-1 with an acceptable quality limit of 4 %

Table 3 Biocompatibility Comparison

ITEM	Proposed Device	Predicate Device	Biocompatibility Requirement	Comparison
Cytotoxicity	Under the conditions of the study, not cytotoxicity effect	Under the conditions of the study, not cytotoxicity effect	Comply with ISO 10993-5	Similar
Irritation	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Comply with ISO 10993-10	Similar
Sensitization	Under conditions of the study, not a sensitizer	Under conditions of the study, not a sensitizer		Similar

10. Non-Clinical Test Conclusion

Non-clinical tests were conducted on three nonconsecutive lots to demonstrate that the proposed device met all design specifications or acceptance criteria in the standard and test methodology.

Table 1 Performance Test Result Summary

Test Method	**Purpose**	**Acceptance Criteria Level 2**	**Results**
ASTM F2100-19e1 ASTM F2101-19 Bacterial Filtration Efficiency Test (BFE), %	The purpose of the testing was to measure the Bacterial Filtration Efficiency Test	≥ 98	Pass
ASTM F2100-19e1 EN 14683:2019+AC:2019(E) Annex C Differential Pressure Test (mm H_2O/cm^2)	The purpose of the testing was to measure the Differential Pressure Test	< 6.0	Pass
ASTM F2100-19e1 ASTM F2299/F2299M- 2003(2017) Sub-Micron Particulate Filtration Efficiency (PFE) at 0.1 micron Test (%)	The purpose of the testing was to measure the Sub-Micron Particulate Filtration Efficiency	≥ 98	Pass

ASTM F2100- 19e1 ASTM F1862/F1862M-17Resistance to Penetration by Synthetic Blood Test (minimum pressure in mmHg for pass result)	The purpose of the testing was to measure the Penetration by Synthetic Blood Test	120	Pass
ASTM F2100-19e1 16 CFR Part 1610-2012 Flammability Test	The purpose of the testing was to measure the Flammability	Class 1	Pass

Table2 Biocompatibility Testing

Item	Subject Device	Result
Cytotoxicity	Under the conditions of the study, the device is noncytotoxic.	Pass
Irritation	Under the conditions of the study, the device is nonirritating.	Pass
Sensitization	Under the conditions of the study, the device is nonsensitizing	Pass

11. Clinical Test Conclusion

No clinical study is included in this submission.

12. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Xianto Rayxin Medical Products Disposable Surgical Face Mask cleared under K153496.