January 19, 2022

Jiangsu Nanfang Medical Co., Ltd.
Charles Mack
Principal Engineer
Irc
2950 E Lindrick Drive
Chandler, Arizona 85249

Re: K212826
Trade/Device Name: Disposable Medical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 17, 2021
Received: December 21, 2021

Dear Charles Mack:

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,

For 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)*

K212826

Device Name
Disposable Medical Mask

Indications for Use *(Describe)*
The Disposable Medical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. It is a single use, disposable device(s), 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 K212826

I. Submitter Information

Preparation Date:	January 7, 2022
Manufacturer's Name and Address:	Jiangsu Nanfang Medical Co., Ltd. No.1 Guoxiang RD, Wujin Economic Development Zone, Wujin, Changzhou City, Jiangsu Province, CHINA213149 Mrs. Li Xia Sales Director Tel: 86-519-86362198 Email: singerli@nanfangmedical.com FDA Establishment Registration No.: 9710583
Designated Submission Correspondent and US Agent:	IRC USA 2950 E Lindrick Dr., Chandler, Arizona 85249, USA Mr. Charles Mack Principal Engineer Tel: 931-6254938 Email: charliemack@irc-us.com
Telephone Number:	931-625-4938
Email Address:	charliemack@irc-us.com
Trade Name:	Disposable Medical Mask

II. Device

Common Name(s):	Disposable Medical Mask
Regulation Name(s):	mask, surgical
Regulation Number(s):	21CFR878.4040
Product Code:	FXX
Device Class:	Class II

III. Predicate Device:

Xiantao Rayxin Medical Products Co., Ltd.
Disposable Surgical Face Mask
K153496

IV. Device Description:

The Disposable Medical Mask is a blue, flat pleated type mask, which utilizes an Earloop to Wear. It has a nose piece design to fit the facemask around the nose. The Disposable Medical Masks are manufactured with three layers and 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 the proposed device, earloop, is held in place over the user's mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are not made with natural rubber latex. The nose piece in the mask is in the facemask layers to allow the user to fit the facemask around their nose, made of malleable aluminum wire. The Disposable Medical Masks are sold non-sterile and are intended to be a single-use, disposable device.

This product contains no components made from natural rubber latex.

V. Indications for Use

The Disposable Medical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. It is a single-use, disposable device(s), provided non-sterile.

VI. Comparison of Technological Characteristics with the Predicate Device

Features	Subject Device	Predicate Device	Comparison
Device	Disposable Medical Mask	Disposable Surgical Face Mask	-
Model	Ear Loop	Ear Loop and Tie-On	-
510(k)	K212826	K153496	-
Indication for Use	The Disposable Medical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. It is a single-use, disposable device(s), 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, disposable device(s), provided non-sterile.	Identical
OTC or Prescription	OTC	OTC	Identical
Product Code	FXX	FXX	Identical
Classification	Class 2, CFR878.4040	Class 2, CFR878.4040	Identical
Material:			
Outer facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Identical
Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Identical
Inner facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Identical
Nose piece	Malleable aluminum wire	Malleable aluminum wire	Identical
Earloop	Polyurethane + Polyester	Polyester	*Note 1*
Colorant	Polypropylene (PP) master batch	Polypropylene (PP) master batch	Identical
Design features	Color: Blue Ear Loop	Color: Blue Ear Loop	Identical
Mask Style	Flat Pleated	Flat Pleated	Identical
Specification and Dimension	Length: 17.5 cm ± 1 cm Width: 9.5 cm ± 1 cm	Length: 17.5cm±1cm Width: 9.5cm±1cm	Identical
Sterility	Non-sterile	Non-sterile	Identical
Usage	Disposable, Single Use	Disposable, Single Use	Identical

Features	Subject Device	Predicate Device	Comparison
Performance:			
Performance Testing (ASTM F2100-19)	Level 2	Level 2	Identical
Fluid Resistance Performance ASTM F1862	31 out of 32 pass at 120mmHg	32 out of 32 pass at 120mmHg	*Note 2*
Particulate Filtration Efficiency ASTM F2299	Average 99.13%	Average 98.46%	
Bacterial Filtration Efficiency ASTM F2101	Average 99.79%	Average 98.70%	
Differential Pressure (Delta P) EN 14683:2019, Annex C	4.4 mm H_2O/cm^2	4.2 mm H_2O/cm^2	
Flammability 16 CFR 1610	Class 1 Non Flammable	Class 1 Non Flammable	Identical
Biocompatibility	Complied with ISO10993-1	Complied with ISO10993-1	Identical
Cytotoxicity (ISO 10993-5)	Under the conditions of the study, not cytotoxic. Complies with ISO-10993-5.	Under the conditions of the study, not cytotoxicity effect	Identical
Sensitization (ISO 10993-10)	Under conditions of the study, not a sensitizer. Complies with ISO-10993-10.	Under conditions of the study, not a sensitizer.	Identical
Irritation (ISO 10993-10)	Under the conditions of the study, not an irritant. Complies with ISO-10993-10.	Under the conditions of the study, not an irritant	Identical

Discussion:

Note 1:

Although the materials used in the ear loops of the subject device and predicate masks are not the same, the subject device confirms the same biocompatibility and performance standards requirements as the predicate device. Therefore, this difference does not raise any new questions about safety and effectiveness.

Note 2

Although there is a slight difference in performance test results between the subject and predicate devices, they comply with the same performance standards ASTM F2100-19 Requirements for Level 2 face masks. The minor differences in the technological characteristics do not raise issues on the safety and effectiveness of the subject device.

VII. Performance Testing

Performance testing was provided to validate and verify that the Disposable Medical Mask, non-sterile, earloop met all requirements of related international standards, including biocompatibility and product specifications. These tests' results demonstrate compliance with the requirements of the consensus standards noted below.

Non-clinical Testing

Table of Conformity to Standards

Standards	Scope
ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks	Performance
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	Performance: Fluid Resistance Performance
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	Performance: Bacterial Filtration Efficiency (BFE)
ASTM F2299-2003 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres	Performance: Particulate Filtration Efficiency (PFE)
ASTM F2100-19 EN14683: 2019 Annex C	Performance: Differential Pressure (Delta P)
16 CFR 1610	Performance: Flammability
ISO10993-1:2009 Biological evaluation of medical devices--Part 1: Evaluation and testing	Biocompatibility
ISO10993-5:2009 Biological Evaluation of Medical Devices – Part 5 Tests for In Vitro Cytotoxicity.	Biocompatibility
ISO10993-10:2002/Amd. 1:2006(E) Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity	Biocompatibility
FDA Guidance: Surgical Masks - Premarket Notification [510(k)] Submissions; Guidance for Industry and FDA	Guidance

Test	Standards	Acceptance Criteria for Level 2 Mask	Result	Pass/Fail
Bacterial Filtration Efficiency (BFE, %)	ASTM F2101	≥ 98	Average 99.79%	Pass
Particulate Filtration Efficiency (PFE, at 0.1µm, %)	ASTM F2299	≥ 98	Average 99.13%	Pass
Differential Pressure (Delta P, mm H2O/cm2)	ASTM F2100-19 EN 14683:2019, Annex C	< 6.0	4.4mm H_2O/cm^2	Pass
Resistance to penetration by synthetic blood (minimum pressure in mmHg for pass result)	ASTM F1862/F1862M-17	29 out of 32 pass at 120 mmHg	31 of 32 pass at 120 mmHg	Pass
Flame Spread	16 CFR 1610	Class 1 Non-Flammable	Class 1 Non-Flammable	Pass

Table of Biocompatibility Testing

Biocompatibility

The new device complies with the biocompatibility requirement defined in ISO10993-1. Patient contact classification: The subject device is classified as a surface device and contact intact skin for limited contact duration. The verification test shows that the new devices comply with the biocompatibility requirement defined in ISO10993-1, the same as the predicate device.

Standard	Device Tests	Test Results
In Vitro Cytotoxicity (ISO10993-5: 2009)	Following the standard's defined conditions, the device is non-cytotoxic.	Pass
Skin Sensitization (ISO10993-10: 2010)	Following the standard's defined conditions, the device is non-sensitizing.	Pass
Skin Irritation (ISO10993-10)	Following the standard's defined conditions, the device is non-irritating.	Pass

All of the pre-determined acceptance criteria were met.

Clinical Test:

No clinical study is included in this submission.

VIII. Conclusions:

The differences between the predicate and the subject device do not raise any new or different safety or effectiveness questions. The Disposable Medical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device Xiantao Rayxin Medical Products Co., Ltd. Disposable Surgical Face Mask cleared under K153496.

END