December 11, 2021

Nanchang Kanghua Health Materials Co., Ltd
% Doris Chen
Regulatory Affairs Staff
Shanghai Jiushun Enterprise Management Technology
Service Co., Ltd.
Room 1502,BaoAn Building,No.800 Dongfang Road
Shanghai, 200122
China

Re: K212867
Trade/Device Name: Medical Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 25, 2021
Received: September 8, 2021

Dear Doris Chen:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212867

Device Name
Medical Surgical Mask

Indications for Use *(Describe)*
The medical surgical mask 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(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
K212867

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

1. Applicant

Sponsor Name: Nanchang Kanghua Health Materials Co., Ltd

Address: Moonlight Road,Medical Device Technology Park, Jinxian County,Nanchang City,Jiangxi Province, 331700,China.

- Contact Person (including title): Jiamin Wang (Manager)
- Phone:+86-791-85621388

2. Submission Correspondent

Contact Person: Doris Chen

Shanghai Jiushun Enterprise Management Technology Service Co., Ltd. Address: Room 1502,BaoAn Buiding,No.800 Dongfang Road,Shanghai,China. Tel: +86-21-50931939

Email: doris-chen@isosh.com

3. Subject Device Information

Type of 510(k):	Traditional
Common Name:	Medical Face Mask
Trade Name:	Medical Surgical Mask
Classification Name:	Mask,Surgical
Review Panel:	General Hospital
Product Code:	FXX
Regulation Number:	21 CFR 878.4040
Regulation Class:	II

4. Predicate Device Information

Predicate Device

Sponsor:	Xiantao Rayxin Medical Products Co., Ltd.
Common Name:	Surgical Face Mask
Trade Name:	Disposable Surgical Face Mask
510(k) number:	K153496
Review Panel:	General Hospital
Product Code:	FXX
Regulation Number:	21 CFR 878.4040
Regulation Class:	II

5. Device Description

The medical surgical mask is pleated three-layer mask with ear loops and nose piece. The inner and outer layers are made of spun-bond non-woven fabric. The middle layer is made of melt blown non-woven fabric. only the outer layers' color is blue (colorant: Pigment Blue 15:3 /CAS number: 147-14-8), which is held to cover the users' mouth and nose by two spandex elastic bands ultrasonic welded to the medical surgical mask. The elastic ear loops are not made with natural rubber latex. The nose piece contained in the medical surgical mask is in the middle layer of medical surgical mask to allow the user to fit the medical surgical mask around their noses, which is made of malleable aluminum wire coated with plastic materials. The dimensions of each medical surgical mask are length 175±5 mm and width 95±5 mm, The dimensions of nose piece is length 110±20 mm, and the ear loop is length 165±10 mm.
The medical surgical mask are sold non-sterile and are intended to be single use, disposable devices.

6. Intended Use / Indications for Use

The medical surgical mask 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(s), provided non-sterile.

7. Comparison with predicate device

Table 1 General Comparison

Elements of Comparison		**Subject Device**	**Predicate Device**	**Comparison**
Manufacturer		Nanchang Kanghua Health Materials Co., Ltd	Xiantao Rayxin Medical Products Co., Ltd.	--
Product Name		Medical Surgical Mask	Disposable Surgical Face Masks	--
K Number		K212867	K153496	--
Product Code		FXX	FXX	Same
Regulation Number		21 CFR 878.4040	21 CFR 878.4040	Same
Intended use/ Indications for Use		The medical surgical mask 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(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 nonsterile.	Same
Mask style		Flat pleated, 3 layers.	Flat pleated,3 layers.	Same
Design feature		Ear loop	Ear Loop and Tie-On	Similar
Material	Outer facing layer	Spun-bond non-woven fabric	Spun-bond polypropylene	Similar
	Middle layer	Melt blown non-woven fabric	Melt blown polypropylene filter	Similar
	Inner facing layer	Spun-bond non-woven fabric	Spun-bond polypropylene	Similar
	Nose	Outer plastic, inner aluminum	Malleable aluminum wire	Different

	piece	wire		Note 1
	Ear loops	Spandex	Polyester	Different Note 1
Color		Blue	Blue	Same
Dimension (Width)		17.5cm±0.5cm	17.5cm±1cm	Different Note 2
Dimension (Length)		9.5cm±0.5cm	9.5cm±1cm	Different Note 2
OTC use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
Use		Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100 Level		Level 2	Level 2	Same
Fluid resistance Performance ASTM F1862		Level 2:32 out of 32 pass at 120mmHg,3non-consecutive lots tested.	32 out of 32 pass at 120 mmHg	Similar
Particle Filtration Efficiency ASTM F2299		3 non-consecutive lots tested, using a sample size of 32/lot. Level 2: Lot A: 98.55% Lot B: 98.63% Lot C: 98.53%	98.46%	Similar Note 3
Bacterial Filtration Efficiency ASTM F2101		3 non-consecutive lots tested, using a sample size of 32/lot. Level 2: Lot A: 99.9% Lot B: 99.875% Lot C: 99.9%	98.7%	Similar Note 3
Flammability Class 16 CFR 1610		Class1, 3 non-consecutive lots tested, using a sample size of 32/lot.	Class 1 Non Flammable	Similar
Differential Pressure (Delta –P)		3 non-consecutive lots tested, using a sample size of 32/lot. Level 2: Lot A: 3.4 mm H_2O/cm^2 Lot B: 3.4 mm H_2O/cm^2 Lot C: 3.4 mm H_2O/cm^2 (EN 14683:2019, Annex C)	4.2mmH_2O/cm^2 (MIL-M-36954C)	Similar Note 3

Biocompatibility	ISO10993-5 and ISO10993-10;Under the conditions of the studies employed, the device is non-cytotoxic, non-sensitizing, and non-irritating.	ISO10993-5 and ISO10993-10; Under the conditions of the studies employed, the device is non-cytotoxic, non-sensitizing, and non-irritating.	Same

Note 1

The difference in the materials of the current nose piece and the ear loop were different from the predicate device. The biocompatibility evaluation test of the subject devices have been performed on the final finished device.

Note 2

Compare with the predicate and reference device, the different of the physical feature or size does not affect the intended use of the subject device.

Note 3

For the Performance testing, the test results are not identical to each other, but they are similar and they both meet the requirement of Level 2 medical mask according to the ASTM F 2100.

8. Summary of Non-Clinical Tests Performed

Non-clinical tests were conducted to verify that the proposed device met all design specifications as to the predicate device. The test results demonstrated that the proposed device complies with the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks - Premarket Notification [510(k)] Submission issued on March 5, 2004:

- ASTM F2299-03, Standard Test Method for Determining the Initial Efficiency of Materials Used in Surgical face masks to Penetration by Particulates Using Latex Spheres.
- EN 14683:2019, Annex C. Method for determination of breathability (differential pressure)
- ASTM F1862/ASTM F1862M-17, Standard test method for resistance of Surgical face masks to penetration by synthetic blood (Horizontal projection of fixed volume at a known velocity)

- ASTM F2101-19, Standard Test Method For Evaluating The Bacterial Filtration Efficiency (BFE) Of Surgical face mask Materials, Using A Biological Aerosol Of Staphylococcus Aureus.
- 16 CFR Part 1610, Standard for the flammability of clothing textiles.
- 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

Test item (Performance Level 2)	**Purpose**	**Acceptance criteria (Level 2)**	**Test results**
Bacterial filtration efficiency (BFE) ASTM F2101-19	The purpose of this testing was to evaluate the Bacterial filtration efficiency.	BFE≥98%.	3 non-consecutive lots tested, using a sample size of 32/lot. Level 2: Lot A: 99.9% Lot B: 99.875% Lot C: 99.9%
Differential pressure mm, (Delta-P) EN 14683:2019, Annex C	The purpose of this testing was to evaluate the Differential pressure.	Delta P<6.0H_2O/cm^2	3 non-consecutive lots tested, using a sample size of 32/lot. Level 2: Lot A: 3.4 mm H_2O/cm^2 Lot B: 3.4 mm H_2O/cm^2 Lot C: 3.4 mm H_2O/cm^2 (EN 14683:2019, Annex C)
Sub-micron particulate filtration efficiency at 0.1 micron. ASTM F2299	The purpose of this testing was to evaluate sub-micron particulate filtration efficiency.	PFE≥98%.	3 non-consecutive lots tested, using a sample size of 32/lot. Level 2: Lot A: 98.55% Lot B: 98.63% Lot C: 98.53%

Resistance to penetration by synthetic blood ASTM F1862	The purpose of this testing was to evaluate the resistance to penetration by synthetic blood.	29 out of 32 pass at 120mmHg	Level 2:32 out of 32 pass at 120mmHg,3non-consecutive tested.
Flammability (Flame spread) 16 CFR Part 1610	The purpose of this testing was to evaluate the flammability.	Class 1: Burn time ≥ 3.5 seconds	Class 1, 3 non-consecutive tested, using a sample size of 32/lot.

Results: All tests were passed.

Biocompatibility evaluation and test

Biocompatibility evaluation conducted in accordance with the FDA's 2016 guidance and ISO10993-1:2018 supports that the subject devices are biocompatible.

The biocompatibility test includes the following tests:

- In vitro Cytotoxicity Test per ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity.
- Skin Sensitization Tests per ISO 10993-10:2010 Biological evaluation of medical devices —Part 10: Tests for irritation and skin sensitization
- Skin Irritation Tests per ISO 10993-10:2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization.

9. Summary of Clinical Performance Test

No clinical study is included in this submission.

10. Final Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Medical surgical mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Disposable Surgical Face Masks (K153496).

11. Summary Prepared Date

9/2/2021