



September 25, 2020

Jiangxi 3L Medical Products Group Co., Ltd
% Charles Mack
Principal Engineer
IRC
2950 E Lindrick Drive
Chandler, Arizona 85249

Re: K202277

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 7, 2020
Received: T

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/pmnmn.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 Elizabeth F. Claverie-Williams, MS
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

Indications for Use

510(k) Number (if known)

K202277

Device Name

Surgical Face Mask

Indications for Use (Describe)

The surgical face mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. The face mask is 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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K202277 510(k) SUMMARY

Preparation Date: September 24, 2020

Manufacturer's Name and Address: Jiangxi 3L Medical Products Group
Co., Ltd
No.599, Huoju Street, High-tech
Development Zone, Nanchang City,
Jiangxi Province, China 330029

Corresponding Official: Charles Mack

Telephone Number: 931-625-4938

Email Address: charliemack@irc-us.com

Trade Name: Surgical Face Mask

Common Name(s): Surgical Face Mask

Regulation Name(s): mask, surgical

Regulation Number(s): 21CFR878.4040

Product Code: FXX

Device Class: Class II

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

Device Description:

The surgical face mask is green color, and Flat Pleated type mask, utilizing Tie-On way for wearing, and it has a Nose Piece design for fitting the facemask around the nose. 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 a melt-blown polypropylene filter. The model of the proposed device, tie-on, is held in place over the user's mouth and nose by four ties welded to the facemask. The tie is made of spun-bond polypropylene. The nose piece contained in masks is in the layers of the facemask to allow the user to fit the facemask around their nose, which is made of malleable aluminum wire. The surgical face masks are sold non-sterile and are intended to be single-use, disposable devices.

This product contains no components made with natural rubber latex.

Intended Use / Indications for Use

The surgical face mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The face mask is 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.

Comparison of Technological Characteristics with the Predicate Device

Features	Subject Device	Predicate Device	Comparison
Device	Surgical Face Mask	Disposable Surgical Face Mask	N/A
Model	Tie on	Ear Loop and Tie-On	Identical
Manufacturer	JIANGXI 3L MEDICAL PRODUCTS GROUP CO., LTD	Xiantao Rayxin Medical Products Co., Ltd.	N/A
510(k)	K202277	K153496	N/A
Indication for Use	The Surgical Face Mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. The face mask is 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 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
Tie-on:	Spun-bond polypropylene	Spun-bond polypropylene	Identical
Colorant	Polypropylene (PP) masterbatch	Polypropylene (PP) masterbatch	Identical
Design features	Color: Green Tie on	Color: Blue Tie on	The proposed device and the predicate devices are biocompatible and conform to ISO 10993 series standards
Mask Style	Flat Pleated	Flat Pleated	Identical

Features	Subject Device	Predicate Device	Comparison
Specification and Dimension	Length: 17.5cm±1cm Width: 9.5cm±1cm	Length: 17.5cm±1cm Width: 9.5cm±1cm	Identical
Sterility	Non-sterile	Non-sterile	Identical
Usage	Disposable, Single-Use	Disposable, Single-Use	Identical
Performance:			
Performance Testing (ASTM F2100-19)	Level 2	Level 2	Identical
Fluid Resistance Performance ASTM F1862	≥ 120 mmHg	32 out of 32 passes at 120mmHg	Meet ASTM F2100-19 Requirements for Level 2 Classification
Particulate Filtration Efficiency ASTM F2299	≥ 98%	Average 98.46%	Meet ASTM F2100-19 Requirements for Level 2 Classification
Bacterial Filtration Efficiency ASTM F2101	≥ 98%	Average 98.70%	Meet ASTM F2100-19 Requirements for Level 2 Classification
Differential Pressure (Delta P) EN 14683:2019, Annex C	3.0 mm H ₂ O/cm ²	4.2 mm H ₂ O/cm ²	Meet ASTM F2100-19 Requirements for Level 2 Classification
Flammability 16 CFR 1610	Class 1 Non-Flammable	Class 1 Non-Flammable	Identical
Biocompatibility	Complies with ISO10993-1	Complies with ISO10993-1	Identical

Discussion:

There is a little difference in performance test results between the subject device and the predicate device. Both the submitted device and the predicate comply with the same performance standards. The minor differences in the technological characteristics do not raise issues on the safety and effectiveness of the subject device.

The proposed device and the predicate device are biocompatible and conform to the same ISO 10993 series standards.

Therefore, the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device.

Performance Testing

Performance testing was provided in support of the substantial equivalence determination and to validate and verify that the Surgical Face Mask, non-sterile, tie on met all requirements of related international standards, including biocompatibility and product specifications. The results of these tests 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

Test	Subject device	Acceptance Criteria for Level 2 Mask	Test Result
Bacterial Filtration Efficiency (BFE, %) ASTM F2101	≥ 98%	≥ 98%	Pass
Particulate Filtration Efficiency (PFE, at 0.1µm, %) ASTM F2299	≥ 98%	≥ 98%	Pass
Differential Pressure (Delta P, mm H2O/cm2) ASTM F2100-19 EN 14683:2019, Annex C	< 6.0	< 6.0	Pass
Resistance to penetration by synthetic blood ASTM F1862/F1862M-17	≥ 120 mmHg	29 out of 32 passes in ≥ 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 a classified surface device and contact intact skin for limited contact duration. The verification tests show 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.

Conclusions:

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