December 14, 2020

Shandong Shengquan New Material Co., Ltd.
% Shelley Li
Director
Shanghai Landlink Medical Information Technology Co., Ltd.
Room 703, 705, Baohua International Plaza, West Guangzhong
Road 555, Jingan
Shanghai, 200071
China

Re: K201629
Trade/Device Name: Medical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 4, 2020
Received: December 9, 2020

Dear Shelley Li:

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 CAPT Elizabeth Claverie, M.S.
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)*
K201629

Device Name
Medical Face Mask

Indications for Use *(Describe)*
The 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 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.

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: K201629

I Submitter

Shandong Shengquan New Material Co., Ltd.
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Preparation date: Dec. 03, 2020

II Proposed Device

Trade Name of Device:	Medical Face Mask
Common name:	Surgical Mask
Regulation Number:	21 CFR 878.4040
Regulatory Class:	Class II
Product code:	FXX
Review Panel	General Hospital

III Predicate Devices

510(k) Number:	K153496
Trade name:	Disposable Surgical Face Mask
Common name:	Surgical Mask
Classification:	Class II
Product Code:	FXX
Manufacturer	Xiantao Rayxin Medical Product Co., Ltd.

IV Device description

The Medical Face Masks are Flat Pleated type mask, utilizing Ear Loops way for wearing, and they all have Nose Piece design for fitting the face mask around the

nose. The Medical Face Masks are manufactured with three layers. The outer layer is made of spun-bonded polypropylene (PP) non-woven fabric. The middle layer with filtration function is made of melt blown polypropylene (PP) non-woven fabric. The inner layer contact with face is made of polypropylene (PP) fabric. The face mask is provided white color.
The Medical Face Masks are single use, disposable device, provided non-sterile.

V Indication for use

The 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 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.

VI Comparison of technological characteristics with the predicate devices

Item	Proposed device	Predicate device (K153496)	Discuss
Product name	Medial Face Mask	Disposable Surgical Face Mask	-
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	Class II	Class II	Same
Mask style	Flat-pleated, ear loop, 3 layers	Flat-pleated, ear loop, tie-on, 3 Layers	Same
Indication for use	The 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 face masks are intended for use in infection control practices to reduce the	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	Same

		potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	
Material	Inner layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Outer layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Ear loop	Spandex + Polyester	Polyester	Similar[1]
	Nose piece	Malleable polyethylene	Malleable aluminum wire	Different[1]
Color		White	Blue	Different[1]
Length		17.5±0.88cm	17.5±1cm	Same
Width		9.5±0.48cm	9.5±1cm	Same
OTC use		Yes	Yes	Same
Sterile		Non-sterile	Non-sterile	Same
For single use		Yes	Yes	Same
ASTM F2100 Level		Level 2	Level 2	Same
Biocompatibility		Confirm to the requirements of ISO 10993 series standards	Confirm to the requirements of ISO 10993 series standards	Same

[1] The difference in the materials and colors does not raise additional questions for safety and effectiveness of the device. The biocompatibility evaluation test of the subject devices have been performed on the final finished device which includes all construction materials and color additives. The test results shows pass the requirements.

VII Non-Clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications and is Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- 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.
- ASTM F2100-19, Standard Specification for Performance of Materials Used In Medical Face Masks.
- ASTM 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)
- EN 14683:2019, Medical Face Mask-Requirements and Test Methods
- 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;
- 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;

VIII Clinical Testing

No clinical study is included in this submission.

Ⅸ Conclusion

The proposed device has the same indication for use and has similar design features and technological characteristic as the predicate device. Performance testing data demonstrates that the proposed device is as safe and as effective as the predicate device. Accordingly, the proposed device is substantially equivalent to the predicate device.