August 11, 2021

Shandong Shengquan New Materials Co., Ltd.
% Daniel Qiu
Project Manager
Shanghai Qisheng Business Consulting Co., Ltd.
Room 1301, Bld 46, Jing Gu Zhong Rd.
No.58, Min Hang District
Shanghai, Shanghai 200240
China

Re: K211552
Trade/Device Name: Surgical mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: May 19, 2021
Received: May 19, 2021

Dear Daniel Qiu:

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)*
K211552

Device Name
Surgical mask

Indications for Use *(Describe)*
The surgical masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These surgical 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, and 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: K211552

I. Submitter

Shandong Shengquan New Materials Co.,Ltd.
Diaozhen Industrial Development Zone, Zhangqiu District, Jinan, Shandong Province, China.

Telephone: +86-13864136816
Fax: 0086-400-777-8118

Contact person: Xiumei Zhang
Date prepared: August 03,2021

II. Device

Name of Device: Surgical mask
Model name: SMDP20608
Classification Name: surgical apparel (21 CFR 878.4040)
Regulatory Class: II
Product Code: FXX

III. Predicative device

510(k) Number: K201629
Name of Device: Medical Face Mask
Classification Name: surgical apparel (21 CFR 878.4040)
Regulatory Class: II
Product code: FXX

IV. Device description

The Surgical Mask is a non-sterile, single use, and flat pleated mask with ear loops and nose clip. The product is manufactured with three layers, the inner layer is made of white polypropylene spunbond, the outer layer is made of black polypropylene spunbond (a common colorant named carbon black was added) and the middle layer is made of melt blown polypropylene filter. The elastic ear loops are not made with natural rubber latex. The nose clip in the layers of facemask is to allow the user

to fit the facemask around their nose, which is made of malleable polyethylene wire. The mask will be provided in black and white. The colour of outer layer is black. The colour of inner layer is white.

V. Indication for use

The surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These surgical 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, and provided non-sterile.

VI. Comparison of technological characteristics with the predicate devices

Item	Subject device	Predicate device	Discussion
Product Namew	Surgical Mask	Medial Face Mask	
Manufacturer	Shandong Shengquan New Materials Co., Ltd.	Shandong Shengquan New Material Co., Ltd.	N/A
510(k) number	K211552	K201629	N/A
Product code	FXX	FXX	Same
Regulation No.	21 CFR878.4040	21 CFR878.4040	Same
Class	Class II	Class II	Same
Intended use	The surgical masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These surgical 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, and provided non-sterile.	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, and provided non-sterile.	Same
Model	Ear Loops, Flat Pleated, 3	Ear Loops, Flat Pleated, 3	Same

		layers	layers	
Material	Outer layer	Polypropylene spunbond	Spunbond polypropylene	Same
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Inner layer	Polypropylene spunbond	Spunbond polypropylene	Same
	Nose clip	Malleable polyethylene	Malleable polyethylene	Same
	Ear loops	Spandex, Polyester	Spandex, Polyester	Same
Color		Black and White	White	Different
Dimension (Length)		17.5cm±0.88cm	17.5cm±0.88cm	Same
Dimension (Width)		9.5cm±0.48cm	9.5cm±0.48cm	Same
OTC use		Yes	Yes	Same
Sterility		Non-sterile	Non-sterile	Same
Single-use		Yes	Yes	Same
ASTM F2100 Level		Level 3	Level 2	Different
Biocompatibility	In-vitro cytotoxicity	Conform to ISO 10993-5:2009	Conform to ISO 10993-05:2009	Same
	Irritation	Conform to ISO 10993-10:2010	Conform to ISO 10993-10:2010	Same
	Skin sensitization	Conform to ISO 10993-10:2010	Conform to ISO 10993-10:2010	Same

The difference in the color and ASTM F2100 level does not raise additional questions for safety and effectiveness. Performance testing including biocompatibility evaluation was performed on the final finished device.

VII. Summary of non-clinical testing

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.

Table.1 Performance testing

Performance Characteristics	References for Test Method	Acceptance Criteria	Results
Fluid Resistance Performance (mmHg)	ASTM F1862/F1862M-17	29 out of 32 pass at 160 mmHg	Pass
Particulate Filtration Efficiency (%)	ASTM F2299-03	≥ 98%	Pass
Bacterial Filtration Efficiency (%)	ASTM F2101-19	≥ 98%	Pass
Differential Pressure (Delta-P) Test (mm H_2O/cm^2)	EN 14683:2019	< 6	Pass
Flammability	16 CFR 1610	Class I	Pass

Table.2 Biocompatibility Testing

Item	Test method	Results
In vitro cytotoxicity	ISO 10993-5:2009	Under the conditions of this study, the test article extract did not show potential toxicity to L-929 cells.
Irritation	ISO 10993-10:2010	The test result showed that the extract of applied sample did not induce skin irritation in rabbit skin.
Skin sensitization	ISO 10993-10:2010	Under the conditions of this study, the test article extract showed no significant evidence of causing skin sensitization in the guinea pig.

VIII. Summary of clinical testing

Clinical testing was not required to demonstrate the substantial equivalence of Shengquan Surgical Mask to its predicate device.

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 demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.