March 24, 2022

Rizhao Sanqi Medical & Health Articles Co., Ltd.
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Co., Ltd.
Room 1309, Dongfang Building, 1500# Century Ave.,
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China

Re: K202903
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 24, 2021
Received: December 29, 2021

Dear Ivy Wang:

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)*
K202903

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 transfer of microorganisms, body fluids, and particulate material. When worn properly, 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, provided non-sterile.

Level 1 Surgical Face Mask models: SQ-1001
Level 2 Surgical Face Mask models: SQ-2001, SQ-2001H, SQ-2004, SQ-2004H
Level 3 Surgical Face Mask models: SQ-3001, SQ-3001H

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

K202903

Date of Summary prepared: 2021-12-24

A. Applicant:

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B. Device:

Trade Name: SURGICAL FACE MASK
Common Name: SURGICAL MASK
Model:
Table 1 – Surgical face mask model numbers

Mask Style	Ear loops	Tie-on	Color
Level 1	SQ-1001	-	Blue, white, pink, green, yellow
Level 2	SQ-2001	SQ-2001H	
Level 2 with visor	SQ-2004	SQ-2004H	
Level 3	SQ-3001	SQ-3001H	

Regulatory Information
Classification Name: Surgical Face Mask
Classification: Class II
Product code: FXX
Regulation Number: 878.4040
Review Panel: Surgical Apparel

C. Predicate device:

K160269	Surgical Face Masks (Ear loops and Tie-on)	SAN-M PACKAGE CO., LTD.

D. Indications for use of the device:

The Surgical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. When worn properly, 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, provided non-sterile.

E. Device Description:

The Surgical Face Masks are 3-layer or 4-layer, flat-folded masks constructed of nonwoven polypropylene materials. The mask is provided with ear loops (Spandex) or ties (polypropylene). A malleable nose clip is placed in the layers of facemask for comfort and individualized fit. The surgical face mask will be provided in blue, white, pink, green, yellow and with the option for a visor. The surgical face masks are single-use, disposable devices, provided non-sterile.

F. Technological Comparison with predicate device

Table 2 General Comparison

Device	**Subject Device**	**Predicate Device**	**Result**
510K #	K202903	K160269	
Manufacturer	Rizhao Sanqi Medical & Health Articles Co., Ltd.	SAN-M PACKAGE CO., LTD.	
Model Name	SURGICAL FACE MASK	Surgical Face Masks (Ear loops and Tie-on)	Similar
Classification	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Intend use	The Surgical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. When worn properly, 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, provided non-sterile. This is a single use, disposable device(s), provided non-sterile.	The 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, provided non-sterile.	Same
Materials	Level 1 / Level 2 / Level 3	Level 1 / Level 2 / Level 3	-
Outer layer	Spunbond Polypropylene	Polypropylene	Same
Inner layer	Spunbond Polypropylene	Polypropylene	Same
Filter layer	Melt-blown / 1.Melt-blown	1. Polypropylene spunbond	Similar

	Polypropylene		Polypropylene 2.Microporous Film	2. Polypropylene meltblown			
Nose wire	Steel coated by polypropylene			Polyethylene coated steel wire			Different
Ear loops	Spandex			Polyester, polyurethane			Different
Tie-on	Spunbond Polypropylene			Polypropylene spunbond or polyester spunbond			Similar
Design Features	Ear Loops, Tie-on			Ear Loops, Tie-on			Same
Offer with visor	Yes			Yes			Same
Mask style	3 Flat Pleated		4 Flat Pleated	4 Flat Pleated			Similar
Color	Blue, white, pink, green, yellow			white or blue			Different
Dimension (Length)	175±5mm			175±5mm			Same
Dimension (Width)	95±5mm			95±5mm			Same
OTC use	Yes			Yes			Same
Sterility	Non-Sterile			Non-Sterile			Same
Use	Single Use, Disposable			Single Use, Disposable			Same
Biocompatibility	Non-cytotoxic, Non-sensitizing, non-irritating			Non-cytotoxic, Non-sensitizing, non-irritating			Same
Performance Testing (ASTM 2100)	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	-
Fluid Resistance	Meet ASTM F1862-17			Meet ASTM F1862-13			similar
Particulate Filtration Efficiency	Meet ASTM F2299-17			Meet ASTM F2299-03			Similar
Bacterial Filtration Efficiency	Meet ASTM F2101-19			Meet ASTM F2101-14			Similar
Differential Pressure	Meet EN 14683: 2019, Annex C			Meet MIL-M36945C			Different
Flammability	Meet 16 CFR 1610			Meet 16 CFR 1610			Similar
Biocompatibility	Non-cytotoxic, non-sensitizing, non-irritating			Non-cytotoxic, non-sensitizing, non-irritating			Same

G. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was same 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:

- 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, Standard Specification for Performance of Materials Used In Medical Face Masks
- ASTM F1862, 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, Medical Face Masks—Requirements and Test Methods;
- ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using A Biological Aerosol of Staphylococcus Aureus;
- ASTM F2299, Standard 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;

Mask Style	**Ear loops**	**Tie-on**	**Color**
Level 1	SQ-1001	-	Blue, white, pink, green, yellow
Level 2	SQ-2001	SQ-2001H	
Level 2 with visor	SQ-2004	SQ-2004H	
Level 3	SQ-3001	SQ-3001H	

For level 1: SQ-1001

Item	**Purpose**	**Acceptance Criteria**	**Result**
		Level 1	**3 nonconsecutive lots tested**
Fluid Resistance Performance ASTM F1862	The purpose of the performance testing is to demonstrate the functionality of the subject device.	29 out of 32 pass at 80 mmHg	PASS
Particulate Filtration Efficiency ASTM F2299		⩾ 95%	PASS
Bacterial Filtration Efficiency ASTM F2101		⩾ 95%	PASS
Differential Pressure (Delta P) EN 14683 Annex C		<5.0 mmH_2O/cm^2	PASS
Flammability 16 CFR 1610		Class 1	PASS

For: Blue, white, pink, green, yellow

Item	**Purpose**	**Acceptance Criteria**	**Result**
Cytotoxicity	The purpose of the testing is to demonstrate the safety of the subject device.	Non-Cytotoxic	Under the conditions of the study, the device is non-cytotoxic.
Irritation		Non-Irritating	Under the conditions of the study, the device is non-irritating.
Sensitization		Non-Sensitizing	Under the conditions of the study, the device is non-sensitizing

For level 2: SQ-2001 and SQ-2001H

Item	Purpose	Acceptance Criteria	Result
		Level 2	**3 nonconsecutive lots tested**
Fluid Resistance Performance ASTM F1862	The purpose of the performance testing is to demonstrate the functionality of the subject device.	29 out of 32 pass at 120 mmHg	PASS
Particulate Filtration Efficiency ASTM F2299		⩾ 98%	PASS
Bacterial Filtration Efficiency ASTM F2101		⩾ 98%	PASS
Differential Pressure (Delta P) EN 14683 Annex C		<6.0 mmH_2O/cm^2	PASS
Flammability 16 CFR 1610		Class 1	PASS

For: Blue, white, pink, green, yellow

Item	Purpose	Acceptance Criteria	Result
Cytotoxicity	The purpose of the testing is to demonstrate the safety of the subject device.	Non-Cytotoxic	Under the conditions of the study, the device is non-cytotoxic.
Irritation		Non-Irritating	Under the conditions of the study, the device is non-irritating.
Sensitization		Non-Sensitizing	Under the conditions of the study, the device is non-sensitizing

For Level 2 with visor: SQ-2004 and SQ-2004H

Item	Purpose	Acceptance Criteria	Result
		Level 2	**3 nonconsecutive lots tested**
Fluid Resistance Performance ASTM F1862	The purpose of the performance testing is to demonstrate the functionality of the subject device.	29 out of 32 pass at 120 mmHg	PASS
Particulate Filtration Efficiency ASTM F2299		⩾ 98%	PASS
Bacterial Filtration Efficiency ASTM F2101		⩾ 98%	PASS

Differential Pressure (Delta P) EN 14683 Annex C		<6.0 mmH_2O/cm^2	PASS
Flammability 16 CFR 1610		Class 1	PASS

For: Blue, white, pink, green, yellow

Item	Purpose	Acceptance Criteria	Result
Cytotoxicity	The purpose of the testing is to demonstrate the safety of the subject device.	Non-Cytotoxic	Under the conditions of the study, the device is non-cytotoxic.
Irritation		Non-Irritating	Under the conditions of the study, the device is non-irritating.
Sensitization		Non-Sensitizing	Under the conditions of the study, the device is non-sensitizing

For level 3: SQ-3001 and SQ-3001H

Item	**Purpose**	**Acceptance Criteria**	**Result**
		Level 3	**3 nonconsecutive lots tested**
Fluid Resistance Performance ASTM F1862	The purpose of the performance testing is to demonstrate the functionality of the subject device.	29 out of 32 pass at 160 mmHg	PASS
Particulate Filtration Efficiency ASTM F2299		⩾ 98%	PASS
Bacterial Filtration Efficiency ASTM F2101		⩾ 98%	PASS
Differential Pressure (Delta P) EN 14683 Annex C		<6.0 mmH_2O/cm^2	PASS
Flammability 16 CFR 1610		Class 1	PASS

For: Blue, white, pink, green, yellow

Item	Purpose	Acceptance Criteria	Result
Cytotoxicity	The purpose of the testing is to demonstrate the safety of the subject device.	Non-Cytotoxic	Under the conditions of the study, the device is non-cytotoxic.
Irritation		Non-Irritating	Under the conditions of the study, the device is non-irritating.
Sensitization		Non-Sensitizing	Under the conditions of the study, the device is non-sensitizing

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K160269.