510(K) Summary

K202903

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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.