July 6, 2022

Jiangxi SanHao Medical Instruments Co., Ltd
℅ Ms. Cassie Lee
Manager
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road,
Huangpu District
Guangzhou, Guangdong
China

Re: K221173
Trade/Device Name: Surgical Mask (Model: 0868F, 0866F)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 14, 2022
Received: April 25, 2022

Dear Ms. Lee:

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,

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K221173

Device Name
Surgical Mask (Model: 0868F, 0866F)

Indications for Use *(Describe)*
The Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. The Surgical 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, 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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

Sponsor Name: Jiangxi SanHao Medical Instruments Co.,Ltd
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Application Correspondent:
Contact Person: Ms. Cassie Lee
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Tel: +86 20 8200 6973
Email: regulatory@share-info.com

Date of the summary prepared: July 1, 2022

2. Subject Device Information

Common Name: Surgical Mask
Classification Name: Mask, Surgical
Trade Name: Surgical Mask
Model Name: 0868F, 0866F
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 21 CFR 878.4040
Regulatory Class: Class II

3. Predicate Device Information

Predicate Device 1 (Primary predicate device):
Sponsor: Jiangmen Ningrui Medical Supplies Co., Ltd.
Trade Name: Surgical Mask (Model: WK1701-02A, WK1701-03A, WK1701-04A)

Classification Name: Mask, Surgical
510(k) Number: K212293
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 21 CFR 878.4040
Regulation Class: II

Predicate Device 2 (Additional predicate device):
Sponsor: Shandong Shengquan New Materials Co., Ltd.
Trade Name: Surgical mask
Classification Name: Mask, Surgical
510(k) Number: K211552
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 21 CFR 878.4040
Regulation Class: II

4. Device Description

The subject device is a non-sterile, single-use, and flat pleated mask with ear loops and a Nose piece. The product is manufactured with three layers, the inner and outer layer is made of polypropylene spunbond, the middle layer is made of melt blown polypropylene. The elastic ear loops are not made with natural rubber latex. The Nose piece in the layers of the face mask is to allow the user to fit the face mask around their nose, which is made of polyethylene coated iron wire.
The mask will be provided in black and blue color, the colorant for the model 0868F is Carbon black (CAS No.1333-86-4), and for the model 0866F is Pigment Blue 15 (CAS No.147-14-8). The model 0866F will be provided in blue and labeled in Level 3, the model 0868F will be provided in black and labeled in Level 1.

5. Intended Use / Indications for Use

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

6. Comparison to predicate device and conclusion

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device 1 (Primary predicate device)	Predicate Device 2 (Additional predicate device)	Remark
Company	Jiangxi SanHao Medical Instruments Co.,Ltd	Jiangmen Ningrui Medical Supplies Co., Ltd.	Shandong Shengquan New Materials Co., Ltd.	--
510 (k)	K221173	K212293	K211552	--
Trade Name	Surgical Mask	Surgical Mask	Surgical mask	--
Model	0868F, 0866F	WK1701-02A, WK1701-03A, WK1701-04A	SMDP20608	--
Classification Name	Mask, Surgical	Mask, Surgical	Mask, Surgical	Same
Classification	Class II	Class II	Class II	Same
Product Code	FXX	FXX	FXX	Same
Intended use	The Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. The Surgical Mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single-	The Surgical 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 Surgical 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 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	Same

Elements of Comparison	Subject Device	Predicate Device 1 (Primary predicate device)	Predicate Device 2 (Reference predicate device)	Remark
	use, disposable device, provided non-sterile.		exposure to blood and body fluids. This is a single use, disposable device, and provided non-sterile.	
Materials				
Outer facing layer	Polypropylene spunbond	Polypropylene spunbond fabric	Polypropylene Spunbond	Same
Middle filter layer	Melt blown polypropylene	Polypropylene spunbond fabric	Melt blown polypropylene filter	Same
Inner facing layer	Polypropylene spunbond	Polypropylene spunbond fabric	Polypropylene Spunbond	Same
Nose piece	Polyethylene coated iron wire	Polypropylene coated galvanized iron wire	Malleable polyethylene	Similar Note 1
Ear loops	Spandex	Nylon, spandex	Spandex, Polyester	Similar Note 1
Mask Style	Flat-pleated	Flat-pleated	Flat-pleated	Same
Color	Blue (0866F), Black (0868F)	Bule	Black and White	Similar Note 1
Dimensions	175mm x 95mm (±5mm) Ear loop: 175mm Nose piece: 80 ± 2mm	Length: 17.5 cm ±5mm Width: 9.5 cm±3mm	Length: 17.5cm±0.88cm Width: 9.5cm±0.48cm	Same Note 1
OTC use	Yes	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Same
Single-use	Yes	Yes	Yes	Same

Elements of Comparison	Subject Device		Predicate Device 1 (Primary predicate device)			Predicate Device 2 (Reference predicate device)	Remark
Performance Testing	Level 1 (0868F)	Level 3 (0866F)	Level 1	Level 2	Level 3	Level 3	Same
Fluid Resistance Performance (ASTM F1862)	Pass at 80 mmHg	Pass at 160 mmHg	Pass at 80 mm Hg	Pass at 120 mm Hg	Pass at 160 mm Hg	Passed at 29 out of 32 pass at 160 mmHg	Same
Particulate Filtration Efficiency (ASTM F1215)	Pass at ≥ 95%	Pass at ≥ 98%	Pass at ≥ 99%	Pass at ≥ 99%	Pass at ≥ 99%	≥98%	Similar Note 2
Bacterial Filtration Efficiency (ASTM F2101)	Pass at ≥ 95%	Pass at ≥ 98%	Pass at ≥ 99%	Pass at ≥ 99%	Pass at ≥ 99%	≥98%	Similar Note 2
Differential Pressure (ASTM F2100)	Pass at < 5.0 mm H_2O/cm^2	Pass at < 6.0 mm H_2O/cm^2	Pass at < 3.4 mmH_2O /cm^2	Pass at < 3.5 mmH_2O /cm^2	Pass at < 3.4 mmH_2O /cm^2	＜6.0 mm H_2O/cm^2	Similar Note 2
Flammability	Class 1		Class 1			Class 1	Same
Biocompatibility							
Cytotoxicity	Non-cytotoxic		Non-cytotoxic			Conform to ISO 10993-5:2009	Same
Irritation	Non-irritating		Non-irritating			Conform to ISO 10993-10:2010	Same
Sensitization	Non-sensitizing		Non-sensitizing			Conform to ISO 10993-	Same

Elements of Comparison	Subject Device	Predicate Device 1 (Primary predicate device)	Predicate Device 2 (Reference predicate device)	Remark
			10:2010	

Comparison in Detail(s):

Note 1:

Although the Materials of “Nose piece”, “Ear loops”, “Color” and “Dimensions” of subject device are a little different from the predicate devices, they all met the requirements of biocompatibility standards ISO 10993-5 and ISO 10993-10. So, the differences between the subject device and predicate devices will not affect the safety and effectiveness.

Note 2:

Although the “Particulate Filtration Efficiency”, “Bacterial Filtration Efficiency” and “Differential Pressure” of the subject device are a little different from predicate devices, they all met the requirements of performance standard ASTM F2100. So, the differences between the subject device and predicate devices will not affect the safety and effectiveness.

7. Summary of Non-Clinical Performance Testing

Performance Testing Summary

Test item	Test method	Pass criteria		Test results /Verdict
		For Level 1	For Level 3	
Bacterial filtration efficiency	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 according to ASTM F2100: 2019	≥ 95%	≥ 98%	Pass
Differential pressure	EN 14683: 2019, Annex C Medical face masks - Requirements and test	<5.0 mm H_2O/cm^2	<6.0 mm H_2O/cm^2	Pass

(Delta-P)	methods according to ASTM F2100: 2019			
Sub-micron particulate filtration efficiency at 0.1 µm of Polystyrene Latex Spheres	ASTM F2299 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres according to ASTM F2100: 2019	≥ 95%	≥ 98%	Pass
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	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) according to ASTM F2100:2019	Pass at 80 mm Hg	Pass at 160 mm Hg	Pass
Flame spread	16 CFR Part 1610 Standard for the Flammability of Clothing according to ASTM F2100:2019	Class 1	Class 1	Pass

Biocompatibility Testing Summary

According to ISO 10993-1: 2018, the nature of body contact for the subject device is direct surface contact with skin and indirect contact with the respiratory tract, and the duration of the contact is A-Limited (<24 h). The following tests for the subject device were conducted to demonstrate that the subject device is biocompatible and safe for its intended use:

Title of the test	**Purpose of the test**	**Reference for Test method**	**Acceptance criteria**	**Test results**

In vitro Cytotoxicity Test	Under the research conditions, determine whether the target device extract is cytotoxic.	ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	Pass
Skin Sensitization Test	Under the research conditions, determine whether the non-polar and polar extracts of the target device are sensitive.	ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	Pass
Skin Irritation Test	Under the research conditions, determine whether the non-polar and polar extracts of the target device are irritating.	ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	Pass

8. Summary of Clinical Performance Test

No clinical study is included in this submission.

9. Final Conclusion:

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices K212293 and K211552.