March 25, 2022

Guangdong Jia Mei Biological technology 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: K220187
Trade/Device Name: Medical Surgical Mask (Model: JM92, JM92B)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 21, 2022
Received: January 24, 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 L. 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)*
K220187

Device Name
MEDICAL SURGICAL MASK (Model: JM92, JM92B)

Indications for Use *(Describe)*
The MEDICAL 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 MEDICAL 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.

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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: Guangdong Jia Mei Biological technology Co.Ltd
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Application Correspondent:

Contact Person: Ms. Cassie Lee
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Tel: +86 20 8266 2446
Email: regulatory@share-info.com

2. Date of the summary prepared: November 26, 2020

3. Revision date: January 21, 2022

4. Subject Device Information

Type of 510(k): Traditional
Classification Name: Mask, Surgical
Trade Name: MEDICAL SURGICAL MASK
Model Name: JM92, JM92B
Review Panel: General Hospital
Product Code: FXX
Regulation: 21 CFR 878.4040 - Surgical apparel
Regulatory Class: II

5. Predicate Device Information

Predicate Device 1 (Primary Predicate):

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:
Sponsor: Shandong Shengquan New Materials Co., Ltd.
Trade Name: Surgical mask (Model: SMDP20608)
Classification Name: Surgical Apparel
510(K) Number: K211552
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 21 CFR 878.4040
Regulation Class: II

6. 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 facemask is to allow the user to fit the facemask 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 JM92B is Carbon black (CAS No.1333-86-4), and for the model JM92 is Pigment Blue 15 (CAS No.147-14-8). The model JM92 will be provided in blue and labeled in Level 3, the model JM92B will be provided in black and labeled in Level 1.

7. Intended Use / Indications for Use

The MEDICAL 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 MEDICAL 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.

8. 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	Predicate Device 2	Remark
Company	Guangdong Jia Mei Biological technology Co.Ltd	Jiangmen Ningrui Medical Supplies Co., Ltd.	Shandong Shengquan New Materials Co., Ltd.	--
510 (k)	Applying	K212293	K211552	--
Trade Name	MEDICAL SURGICAL MASK	Surgical Mask	Surgical mask	--
Model	JM92, JM92B	WK1701-02A, WK1701-03A, WK1701-04A	SMDP20608	--
Classification Name	Mask, Surgical	Mask, Surgical	Surgical Apparel	SE
Classification	Class II	Class II	Class II	SE
Product Code	FXX	FXX	FXX	SE
Intended use	The MEDICAL SURGICAL MASK is 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	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	SE

Elements of Comparison	Subject Device		Predicate Device 1			Predicate Device 2	Remark
	in infection control practices to reduce the potential exposure to blood and body fluids. This is a single-use, disposable device, provided non-sterile.					reduce the potential 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	SE
Middle filter layer	Melt blown polypropylene		Polypropylene meltblown fabric			Melt blown polypropylene filter	SE
Inner facing layer	Polypropylene spunbond		Polypropylene spunbond fabric			Polypropylene Spunbond	SE
Nose piece	Polyethylene coated iron wire		Polypropylene coated galvanized iron wire			Malleable polyethylene	SE Note 1
Ear loops	Spandex		Nylon, spandex			Spandex, Polyester	SE Note 1
Mask Style	Flat-pleated		Flat-pleated			Flat-pleated	SE
Color	Blue (JM92), Black (JM92B)		Blue			Black and White	SE
Dimensions	Length: 17.5 cm ±5% Width: 9.5 cm ±5%		Length: 17.5 cm ±5mm Width: 9.5 cm±3mm			Length: 17.5cm±0.88cm Width: 9.5cm±0.48cm	SE
OTC use	Yes		Yes			Yes	SE
Sterility	Non-Sterile		Non-Sterile			Non-Sterile	SE
Single-use	Yes		Yes			Yes	SE
Performance Testing	Level 1, Level 3		Level 1; Level 2; Level 3			Level 3	SE
Level	Level 1 (JM92B)	Level 3 (JM92)	Level 1	Level 2	Level 3	Level 3	/
Fluid	Pass at	Pass at	Pass at	Pass at	Pass at	Passed at 29 out of	SE

Elements of Comparison	Subject Device		Predicate Device 1			Predicate Device 2	Remark
Resistance Performance (ASTM F1862)	80 mmHg	160 mmHg	80 mm Hg	120 mm Hg	160 mm Hg	32 pass at 160 mmHg	
Particulate Filtration Efficiency (ASTM F1215)	Pass at ≥ 95%	Pass at ≥ 98%	Pass at ≥ 99%	Pass at ≥ 99%	Pass at ≥ 99%	≥98%	SE Note 2
Bacterial Filtration Efficiency (ASTM F2101)	Pass at ≥ 95%	Pass at ≥ 98%	Pass at ≥ 99%	Pass at ≥ 99%	Pass at ≥ 99%	≥98%	SE 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	SE Note 2
Flammability	Class 1		Class 1			Class 1	SE
Biocompatibility							
Cytotoxicity	Non-cytotoxic		Non-cytotoxic			Conform to ISO 10993-5:2009	SE
Irritation	Non-irritating		Non-irritating			Conform to ISO 10993-10:2010	SE
Sensitization	Non-sensitizing		Non-sensitizing			Conform to ISO 10993-10:2010	SE

Comparison in Detail(s):

Note 1:

Although the “Nose piece” and “Ear loops” of subject device are a little different from predicate devices,

they all met the requirements of biocompatibility standard 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 subject device is 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.

9. 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 (Delta-P)	EN 14683: 2019, Annex C Medical face masks - Requirements and test methods according to ASTM F2100: 2019	<5.0 mm H_2O/cm^2	<6.0 mm H_2O/cm^2	Pass
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	ASTM F1862/F1862M-17 Standard Test Method for Resistance of	Pass at 80 mm	Pass at 160 mm	Pass

synthetic blood, minimum pressure in mm Hg for pass result	Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) according to ASTM F2100:2019	Hg	Hg	
Flame spread	16 CFR Part 1610 Standard for the Flammability of Clothing according to ASTM F2100:2019	Class 1	Class 1	Pass

Biocompatibility Testing

According to ISO 10993-1: 2018, the nature of body contact for the subject device is Surface Device category, Skin Contact and duration of contact is A-prolonged (＜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:

1) In vitro Cytotoxicity Test per ISO 10993-5: 2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity,

2) Skin Sensitization Tests per ISO 10993-10: 2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization,

3) Skin Irritation Tests per ISO 10993-10: 2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

10. Summary of Clinical Performance Test

No clinical study is included in this submission.

11. Final Conclusion:

The conclusion drawn from the nonclinical tests demonstrate that the subject device MEDICAL SURGICAL MASK (Model: JM92, JM92B) is substantially equivalent to the legally marketed devices identified in K212293 and K211552.