January 11, 2021

Jiangmen Sure&Me Medical Product CO., LTD
℅ Cassie Lee
Manager
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road,
Huangpu District
Guangzhou, Guangdong 510700
China

Re: K202577
Trade/Device Name: Medical Surgical Mask-Model MP002-5, MP002-6
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 18, 2020
Received: December 22, 2020

Dear Cassie 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,

For CAPT Elizabeth Claverie, M.S.
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)*

Device Name
Medical Surgical Mask (Model: MP002-5, MP002-6)

Indications for Use *(Describe)*
This product is indicated for infection control practices in the health care industry. When worn properly, The Medical Surgical Mask is intended to protect both patient and wearer from the transfer of microorganisms, body fluids and particulate material.

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 for K202577

1. Submitter's Information

510(k) Owner's Name: JIANGMEN SURE&ME MEDICAL PRODUCT CO., LTD.

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Application Correspondent:

Contact Person: Ms. Cassie Lee

Share Info (Guangzhou) Medical Consultant Ltd.

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Tel: +86 20 8266 2446

Email: regulatory@glomed-info.com

2. Date of the summary prepared: 2021-01-09

3. Subject Device Information

Type of 510(k): Traditional

Classification Name: Mask, Surgical

Common name: Surgical Mask

Trade Name: Medical Surgical Mask

Models: MP002-5, MP002-6

Review Panel: General Hospital

Product Code: FXX

Regulation Number: 878.4040

Regulatory Class: II

4. Predicate Device Information

Sponsor: H&H RESEARCH COMPANY

Trade Name: The New Medical Mask

Classification Name: Mask, Surgical

510(K) Number: K093179

Review Panel: General Hospital

Product Code: FXX

Regulation Number: 878.4040

Regulatory Class: II

5. Device Description

The Medical Surgical Mask is flat style mask, model MP002-5 utilizing tie-on and model MP002-6 utilizing ear Loops way for wearing, and they all has nose clip design for fitting the face mask around the nose.

The Medical Surgical Masks are manufactured with three layers, the inner and outer layers are made of polypropylene, and the middle layer is made of polypropylene melt-blown. The color of the outer layer is blue (colorant: Copper phthalocyanine/ CAS number: 147-14-8)

The models of mask are ear loops and tie-on, masks are held in place over the users' mouth and nose by two high elastic spandex ear loops or bands welded to the face mask.

The nose clip contained in the Medical Surgical Mask is in the layers of face mask to allow the user to fit the mask around their nose, which is made of plastic environmental protection line.

The Medical Surgical Mask are sold non-sterile and are intended to be single use, disposable device.

The dimension of the tie-on band (Model: MP002-5) is 25cm±2cm*1cm±0.2cm (L*W), and the dimension of the ear loop (Model: MP002-6) is 17cm±0.5cm*0.4cm(L*W). What's more, the dimension of the nose clip (Model: MP002-5, MP002-6) is 90mm*2.5mm* 0.45mm (L*W*H).

6. Intended Use / Indications for Use

This product is indicated for infection control practices in the health care industry. When worn properly, The Medical Surgical Mask is intended to protect both patient and wearer from the transfer of microorganisms, body fluids and particulate material.

7. 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**	**Verdict**
Company	JIANGMEN SURE&ME MEDICAL PRODUCT CO., LTD	H&H RESEARCH COMPANY	--
510 (k)	K202577	K093179	--
Trade Name	Medical Surgical Mask	The New Medical Mask	--
Classification Name	Mask, Surgical	Mask, Surgical	Identical
Classification	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Identical

Elements of Comparison	Subject Device	Predicate Device	Verdict
Intended use	This product is indicated for infection control practices in the health care industry. When worn properly, The Medical Surgical Mask is intended to protect both patient and wearer from the transfer of microorganisms, body fluids and particulate material.	This product is indicated for infection control practices in the health care industry. When worn properly, The New Medical Mask is intended to protect both patient and wearer from the transfer of microorganisms, body fluids and particulate material.	Identical
Material			
Outer facing layer	Polypropylene	Polypropylene	Identical
Middle layer	Polypropylene melt-blown	Polypropylene	Identical Note 1
Inner facing layer	Polypropylene	Polypropylene	Identical
Nose clip	Plastic environmental protection line	Adhesive tape	Identical Note 1
Ear Loops/ Tie-on	Ear Loops/ Tie-on: High elastic spandex	Ear Loops: Non-latex elastic ear bands	Similar Note 1
Design features	Color: blue	Color: blue	Identical
Mask Style	Ear Loops (model: MP002-6) and Tie-on (model: MP002-5) flat style	Ear loop flat style	Identical Note 3
Specification and	17.5cm x 9.5 cm	Length: 7.1 inches (18 cm)	Similar

Elements of Comparison	Subject Device	Predicate Device	Verdict
Dimension		Width: 3.9 inches (10 cm)	Note 3
OTC use	Yes	Yes	Identical
Sterility	Non-Sterile	Non-Sterile	Identical
Use	Single Use, Disposable	Single Use, Disposable	Identical
Performance Testing	Level 3	Level 3	Identical
Fluid Resistance Performance	160 mmHg	160 mmHg	Identical
Particulate Filtration Efficiency	≥98%	99.9%	Identical Note 2
Bacterial Filtration Efficiency	>99.9%	>99.9%	Identical
Differential Pressure	<6.0 mmH2O/cm^2	Pass at 2.7 mmH2O/cm^2	Identical Note 2
Flammability	Class 1	Class 1	Identical
Latex	Not Made With Natural Rubber Latex	Not Made With Natural Rubber Latex	Identical
Biocompatibility			
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic.	Under the conditions of the study, the device is non-cytotoxic.	Identical
Irritation	Under the conditions of the study, the device is non-irritating.	Under the conditions of the study, the device is non-irritating.	Identical

Elements of Comparison	Subject Device	Predicate Device	Verdict
Sensitization	Under the conditions of the study, the device is non-sensitizing	Under the conditions of the study, the device is non-sensitizing	Identical

Comparison in Detail(s):

Note 1:

Although the “Middle layer”, “Nose clip” and “Ear Loops” of subject device is slightly difference with predicate device, it meets the requirement standard ISO 10993. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

Note 2:

Although the “Particulate Filtration Efficiency” and “Differential Pressure” of subject device is little difference with predicate device, it meets the requirement of essential performance standard ASTM 2100. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

Note 3:

Although the “Mask Style” and “Specification and Dimension” of subject device is little difference with predicate device, these dimensions differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

8. Test Summary

Medical Surgical Mask (Models: MP002-5, MP002-6) has been evaluated the safety and performance by lab bench testing as following:

- Biocompatibility test according to ISO 10993-5 and ISO 10993-10 standards

- 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)
- 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 F2100 Standard Specification For Performance Of Materials Used In Medical Face Masks

8.1 Summary of Non-Clinical Tests Performed:

- Performance Testing summary

Test item	**Test method**	**Pass criteria**	**Test results /Verdict**
Bacterial filtration efficiency	ASTM F2101-14 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	≥ 98%	>99.9% / Pass
Differential pressure (Delta-P)	EN 14683: 2019, Annex C Medical face masks - Requirements and test methods according to ASTM F2100:2019	<6.0 mm H_2O/cm^2	<6.0 mm H_2O/cm^2 / Pass
Sub-micron particulate filtration	ASTM F2299-03 Standard Test	≥ 98%	≥ 98% / Pass

efficiency at 0.1 µm of Polystyrene Latex Spheres	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		
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	Fluid resistant claimed at 160 mm Hg	Fluid Resistant claimed 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

According to ISO 10993-1:2009, the nature of body contact for the subject device is Surface Device category, Skin Contact and duration of contact is B-prolonged (>24 h to 30 d). 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.

8.2 Summary of Clinical Performance Test

No clinical study is included in this submission.

9. Final Conclusion:

The conclusion drawn from the nonclinical tests demonstrates that the subject device Medical surgical mask in 510(k) K202577, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K093179.