March 9, 2021

Jiangsu Micsafe Medical Technology 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: K202205
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 27, 2021
Received: February 5, 2021

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,

Ryan Ortega, PhD
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K202205

Device Name
Surgical Face Mask (Model: METH-03)

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. These face masks are intended for use in infection control practices to reduce potential exposure to blood and body fluids. The face mask is 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 for K202205

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

510(k) Owner's Name: Jiangsu Micsafe Medical Technology Co., Ltd

Establishment Registration Number: 3014570560

Address: Xituan Industrial Park, Dafeng District, Yancheng City, Jiangsu Province, China

Contact Person: Tony Yang

Email: info@micsafe.com

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

Date of the summary prepared: March 8, 2021

2. Subject Device Information

Type of 510(k): Traditional

Classification Name: Mask, Surgical

Common name: Surgical Mask

Trade Name: Surgical Face Mask

Model Name: METH-03

Review Panel: General Hospital

Product Code: FXX

Regulation Number: 878.4040

Regulatory Class: II

3. Predicate Device Information

Sponsor: 3M Health Care

Trade Name: 3M™ High Fluid-Resistant Surgical Mask and 3M™ High Fluid-Resistant Procedure Mask

Classification Name: Mask, Surgical

Common name: Surgical Mask

510(K) Number: K191355

Review Panel: General Hospital

Product Code: FXX

Regulation Number: 878.4040

Regulatory Class: II

4. Device Description

The Surgical Face Mask is flat pleated style mask, utilizing ear Loops way for wearing, and they all have nose piece design for fitting the Surgical Face Mask around the nose.

The Surgical Face Mask is manufactured with three layers, the inner and outer layers are made of spun-bond polypropylene, only the outer layers' color is blue (colorant: 29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32 copper, CAS number: 147-14-8), and the middle layer is made of Melt blown polypropylene filter.

Ear loops, which is held to cover the users' mouth and nose by two Spandex elastic cord and chinlon ultrasonic welded to the Surgical Face Mask. The elastic ear loops are not made with natural rubber latex.

The nose piece contained in the Surgical Face Mask is in the middle layer of Surgical Face Mask to allow the user to fit the Surgical Face Mask around their noses, which is made of steel wire and polypropylene. The Surgical Face Mask is sold non-sterile and is intended to be single use, disposable device.

The dimensions of each Surgical Face Mask is length 17.5cm±1cm and width 9.5cm±1cm. The dimensions of nosepiece is length 115±1 mm and width 3.0±0.5 mm, and the ear loop is length 180±10 mm and width 3.0±0.5 mm.

5. Intended Use / Indications for 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. These face masks are intended for use in infection control practices to reduce potential exposure to blood and body fluids. The face mask is single use, disposable device, provided non-sterile.

6. Test Summary

Surgical Face Mask (Model: METH-03) has been evaluated the safety and performance by lab bench testing as following:

- 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
- Biocompatibility test according to ISO 10993-5 and ISO 10993-10 standards
- 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 Part 1610 Standard for the Flammability of Clothing
- EN 14683: 2019, Annex C Medical face masks - Requirements and test methods

6.1 Summary of Non-Clinical Tests Performed:

- Performance Testing summary

Test item (Performance Level 3)	**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%	99.65% / 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	3.72 mm H_2O/cm^2 / Pass
Sub-micron particulate filtration efficiency at 0.1 μm of Polystyrene Latex Spheres	ASTM F2299-03 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	≥ 98%	99.9% / 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	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 A-Limited (≤24h). 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.

6.2 Summary of Clinical Performance Test

No clinical study is included in this submission.

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	Jiangsu Micsafe Medical Technology Co., Ltd	3M Health Care	--
510 (k)	K202205	K191355	--
Trade Name	Surgical Face Mask	3M™ High Fluid-Resistant Surgical Mask and 3M™ High Fluid-Resistant Procedure Mask	--
Classification Name	Mask, Surgical	Mask, Surgical	Same
Classification	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Intended 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. These face masks are intended for use in infection control practices to reduce potential exposure to blood and body fluids. The face	The 3M™ High Fluid-Resistant Surgical Mask and 3M™ High Fluid-Resistant Procedure 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 in infection control practices to reduce potential exposure to	Same

Elements of Comparison	Subject Device	Predicate Device	Verdict
	mask is single use, disposable device, provided non-sterile.	blood and body fluids. The face mask is single use, disposable device, provided non-sterile.	
Material			
Outer facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
Inner facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
Nose piece	steel wire and polypropylene	Polyethylene coated steel wire	Similar Note 1
Ear loops	Spandex elastic cord and chinlon	Spandex elastic cord (polyurethane core with polyethylene terephthalate /nylon cover)	Similar Note 1
Design features	Color: Blue (Outer) Ear loops	Color: Green (Outer) Ear loops	Different Note 2
Mask Style	Flat Pleated	Flat Pleated	Same
Specification and Dimension	Length: 17.5cm±1cm Width: 9.5cm±1cm	Length: 17.5cm±0.5cm Width: 9.0cm±0.75cm	Similar Note 2
OTC use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100 Level	Level 3	Level 3	Same
Fluid Resistance Performance	Pass at 160 mmHg	32/32 Passed at 160mm Hg ASTM F1862	Same
Particulate Filtration Efficiency	Passed at ≥98%	32/32 Passed at ⩾98% @ 0.1 micron ASTM F2299	Same

Elements of Comparison	Subject Device	Predicate Device	Verdict
Bacterial Filtration Efficiency	Passed at ≥98%	31/32 Passed at ⩾98% ASTM F2101	Same
Differential Pressure	Passed at <5 mmH_2O/cm^2	32/32 Passed at <5 mmH_2O/cm^2 MIL-M36954C	Same
Flammability	Class 1	5/5 Passed ⩾3 Seconds burn time - Class 1 CFR 16 1610	Same
Biocompatibility			
Cytotoxicity	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	Non-cytotoxic.	Same
Irritation	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	Non-irritating.	Same
Sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	Non-sensitizing.	Same

Comparison in Detail(s):

Note 1:

Although the “Ear loops” and “Nose piece” of subject device are a little different from the predicate device, the subject device meets the requirement of 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 “Design features “and “Specification and Dimension” of subject device are a little different from the predicate device, the subject device meets the requirements of essential performance standard ASTM F2100 and ISO 10993. So, the differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

8. Final Conclusion：

The conclusion drawn from the nonclinical tests demonstrates that the subject device Surgical Face Mask in 510(k) K202205, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K191355.