February 2, 2021

Gemtier Medical (Shanghai) Inc
℅ Julie Chen
Technical Manager
Shanghai Medical Business Consulting Co.,Ltd.
No. 170 Huajiang Road, Jiading District
Shanghai, 201803
China

Re: K202331
Trade/Device Name: Medical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 24, 2020
Received: January 6, 2021

Dear Julie Chen:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202331

Device Name
Medical Face Mask

Indications for Use *(Describe)*

The Medical 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. The Medical Face Masks are 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.

510(K) Summary—K202331

I. SUBMITTER:

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Summary prepared：01/18/2021

II. DEVICE

Name of Device: Medical Face Mask
Regulation Number: 21 CFR PART 878.4040
Common Name: Surgical Mask
Classification Name: Surgical Mask
Regulatory Class: II
Product Code: FXX

III. PREDICATE DEVICE

Primary predicate device: Disposable Surgical Face Mask (K153496)

IV. DEVICE DESCRIPTION

The Medical Face Mask is composed of three layers and is flat-pleated. The mask materials consist of an outer layer (spun-bond polypropylene), a middle layer (melt-blown polypropylene), and an inner layer (spun-bond polypropylene). Each mask contains tie strings (spun-bond polypropylene) or ear loops (spandex elastic cord) to secure the mask over the users' mouth and face and includes a malleable nose piece (iron wire with white plastic covering) to provide a firm fit over the nose.

V. Available Models

REF No.	Product Size	Model Description		
		Mask	Ear Loop	Tie-on
NS2R-D1	17.5×9.5cm	X	X	
NS2R-01	17cm×9.5cm	X	X	
NS2R-C1	14.5cm×9.5cm	X	X	
NS2R-I1	17.5×9.5cm	X		X
NS2R-E1	17cm×9.5cm	X		X
NS2R-H1	14.5cm×9cm	X		X

VI. INDICATIONS FOR USE

The Medical 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. The Medical Face Masks are single use, disposable device, provided non-sterile

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Medical Face Masks are compared with the predicate device (Disposable Surgical Face Mask (K153496)). The results are shown below in the Technological Characteristics Comparison Table:

DEVICE	Subject Device Medical Face Mask (K202331)	Primary Predicate Device Disposable Surgical Face Mask (K153496)	Remark
Intended Use	The Medical 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. The Medical Face Masks are single use, disposable device, provided non-sterile.	The Disposable 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(s), provided non-sterile.	Same
Classification Product Code	FXX	FXX	Same
Ear Loop Model and Tie-on Model	Ear Loops, Tie-On	Ear Loops, Tie-On	Same
Materials			
Outer Facing Layer	Spun-bond Polypropylene	Spun-bond polypropylene	Similar
Middle Layer	Melt-blown polypropylene	Melt blown polypropylene filter	Similar
Inner Facing Layer	Spun-bond Polypropylene	Spun-bond polypropylene	Similar
Nose Piece	Malleable iron wire with plastic covering	Malleable aluminum wire	Different 1
Tie Strings	Spun-bond Polypropylene	Spun-bond polypropylene	Similar

Ear Loops	Spandex elastic cord	Polyester	Similar
Design Features			
Color	Blue	Blue	Same
Style	Flat - Pleated	Flat - Pleated	Same
Multiple Layers	3 Layers	3 Layers	Same
Single Use	Single use	Single use	Same
Sterility			
Sterile	Non-sterile	Non-sterile	Same
Dimensions			
Length × Width	175×95mm (±5%)	17.5×9.5cm (±1cm)	Similar
	170×95mm (±5%)		
	145×95mm (±5%)		
Technological Characteristics Product Barrier Specifications Per ASTM F2100 – Meets Level 2			
Fluid Resistance ASTM F1862	32/32 passed at 120 mmHg	32/32 passed at 120 mmHg	Similar
Particulate Filtration Efficiency (PFE) ASTM F2299	99.35%	98.46%	Similar
Bacterial Filtration Efficiency (BFE) ASTM F2101	99.9%	98.7%	Similar
Differential Pressure (Delta P) MIL-M-36954C	2.11mmH_2O/cm^2	4.2mmH_2O/cm^2	Similar
Flammability 16 CFR PART 1610	Class 1 Non-Flammable	Class 1 Non-Flammable	Similar
Biocompatibility			
Cytotoxicity (ISO 10993-5)	Non-cytotoxic	Non-cytotoxic	Same
Irritation (ISO 10993-10)	Non-sensitizing	Non-sensitizing	Same
Sensitization (ISO 10993-10)	Non-irritating	Non-irritating	Same

Analysis 1

The material of nose piece of the subject device is different from the material of nose piece of the predicate device. To illustrate the difference does not raise any safety and effectiveness questions, we conducted non-clinical tests. The data drawn from the tests shows that the subject device is as safe as effective as predicate device.

VIII. PERFORMANCE DATA

Non-Clinical Performance Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the Medical Face Mask complies with the following standards:

- 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)
- ASTM F2299 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- ASTM F2101 Standard Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- MIL-M- 36954C Military Specification, Mask, Surgical, Disposable
- 16 CFR Part 1610 Standard for the Flammability of Clothing
- ISO10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity of medical devices
- ISO10993-10 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization

Clinical Test Conclusion

No clinical study is included in this submission.

Table 1 Summary of Performance Test

Performance Characteristics	Methodology	Purpose	Acceptance Criteria	Test Result
Bacterial Filtration Efficiency Performance(%)	ASTM F2101	This performance test aims to verify Bacterial Filtration Efficiency (BFE) of the Medical face mask reaches level 2 as required in ASTM F 2100-2019	≥98	99.9%
Differential Pressure (Delta-P) (mm H_2O/cm^2)	MIL-M-36954C	This performance test aims to verify the breathing resistance of Medical face mask reaches level 2 as required in ASTM F 2100-2019	＜6.0	2.11mmH_2O/cm^2
Particulate Filtration Efficiency at 0.1micron Performance (%)	ASTM F2299	This performance test aims to verify the Particulate Filtration Efficiency of Medical face mask reaches level 2 as required in ASTM F 2100-2019	≥98	99.35%
Resistance to penetration by synthetic blood, Minimum pressure in mmHg for pass results	ASTM F1862	To verify the fluid resistance of the Medical face mask reaches level 2 as required in ASTM F 2100-2019, through perform the fluid resistance testing.	120	32/32 passed at 120 mmHg
Flammability Class	16 CFR PART 1610	To verify the flammability of the Medical face mask reaches level 2 as required in ASTM F 2100-2019, through conduct the flammability testing	Class 1	Class 1
Cytotoxicity	ISO 10993-5:2009	The purpose of the test is to determine the biological reactivity of mammalian cell culture (mouse fibroblast L929	If viability is reduced to ＜ 70% of the blank, it has a cytotoxic potential.	Non-cytotoxic

		cells) in response to the test article		
Irritation	ISO 10993-10: 2010	The teat was designed to evaluate the potential of a test article cause skin irritation	Use only 24±2h, 48±2h and 72±2h observation for calculation. The primary irritation index for the test article was evaluated according to as follow：(0-0.4)negligible;(0.5-1.9)slight;(2-4.9)moderate;(5-8)severe	Non-sensitizing
Sensitization	ISO 10993-10: 2010	The teat was designed to evaluate the potential of a test article cause skin sensitization	Magnusson and Kingman grades of 1 or greater in the test group generally indicate sensitization.	Non-irritating

IX. 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 Disposable Surgical Face Mask (K153496).