October 8, 2021

Sichuan Pharmaceutical. Inc.
Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K210813
Trade/Device Name: Medical Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 25, 2021
Received: September 9, 2021

Dear Boyle Wang:

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 Clarence W. Murray III, Ph.D.
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)*
K210813

Device Name
Medical Surgical Mask

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. 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.

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

(K210813)

This summary is submitted in accordance with 21 CFR 807.92.

1.0 Submitter's Information

Name: Sichuan Pharmaceutical,Inc.
Address: Sichuan Pharmaceutical.Inc No. 18 Baiye Road, Hi-Tech West Zone, Chengdu, Sichuan Province, China.
Contact: Yunrui Zhang
Tel: 86-13678040510

Designated Submission Correspondent

Contact: Mr. Boyle Wang
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Email: info@truthful.com.cn

Date of Preparation: Oct.8,2021

2.0 Device Information

Trade name: Medical Surgical Mask
Common name: Surgical Face Mask
Classification name: Surgical Face Mask
Production code: FXX
Regulation number: 21CFR 878.4040
Classification: Class II
Review Panel: Surgical Apparel

3.0 Predicate Device Information

Manufacturer: DemeTECH Corporation.
Device: DemeMASK Surgical Mask
510(k) number: K201479

4.0 Device Description

The Medical Surgical Mask is a single use, three-layer, flat-pleated style surgical mask with ear loops and nose piece. The mask is manufactured with three layers, the inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter. The surgical masks is held over the user's mouth and nose via earloops made of nylon with spandex. The nose piece in the layers of facemask is to allow the user to fit the facemask around their nose, which is made of malleable polyethylene wire. The medical surgical mask includes blue colorant, Shining Blue R603. The medical surgical mask is sold non-sterile and is intended to be single use, and disposable.

5.0 Indication for Use Statement

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 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.

6.0 Comparison to the Predicate Device

Table 1 General Comparison

Item	Subject Device K210813	Predicate Device K201479	Comparison
Product Name	Medical Surgical Mask	DemeMASK Surgical Mask	--
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
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. 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),	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	Same

		provided non-sterile.	blood and body fluids. This is a single use, disposable device provided non-sterile.	
Design features		Ear Loops, 3 layers	Ear Loops, 3 layers	Same
Mask Styles		Flat pleated	Flat pleated	Same
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	Malleable polyethylene wire	Galvanized wire coated with polyethylene	*Different
	Ear loops	Nylon and spandex	Nylon and spandex	Same
Color		Blue	Blue	Same
Dimension (Length)		17.5 cm +/- 0.2 cm	17.5 cm +/- 1cm	*Different
Dimension (Width)		9.5 cm +/- 0.2 cm	9.5 cm +/- 1cm	
OTC use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
Single Use		Yes	Yes	Same
Sterile		No	No	Same
ASTM F2100 Level		Level 3	Level 3	Same
Biocompatibility ISO 10993-5/ ISO 10993-10		Non-cytotoxic, non-sensitizing, and non-irrtating	Non-cytotoxic, non-sensitizing, and non-irrtating	Same

* Performance testing including biocompatibility evaluation has been performed on the final finished device which includes all construction materials. The difference in the materials does not raise additional questions for safety and effectiveness.

7.0 Non-Clinical Test Conclusion

The proposed device was tested and conformed to the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004.

Table 2 - Performance Testing

Test	Subject Device	Predicate Device	Results
Synthetic Blood Penetration Resistance ASTM F1862	No penetration at 160 mmHg	No penetration at 160 mmHg	Pass
Particulate Filtration Efficiency ASTM F2299	Particle filtration efficiency at 0.1 micron (%) >98 %	Particle filtration efficiency at 0.1 micron (%) >98 %	Pass
Bacterial Filtration Efficiency ASTM F2101	>98 %	>98 %	Pass
Differential Pressure (Delta P) EN 14683:2019+AC:2019 Annex C	Differential pressure ≤ 6.0 mmH_2O/cm^2	Differential pressure ≤ 6.0 mmH_2O/cm^2	Pass
Flammability 16 CFR 1610	Class 1	Class 1	Pass

Table 3 - Biocompatibility Testing

Item	Subject Device	Result
Cytotoxicity ISO 10993-5	Under the conditions of the study, the device is non-cytotoxic.	Pass
Irritation ISO 10993-10	Under the conditions of the study, the device is non-irritating.	Pass
Sensitization ISO 10993-10	Under the conditions of the study, the device is non-sensitizing	Pass

8.0 Clinical Test Conclusion

No clinical study is included in this submission.

9.0 Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device in K201479.