March 19, 2024

Azur Medical Company Inc.
% Esther Zhang
Official Correspondent
Shanghai Ling Fu Technology Co., Ltd.
4F No. 585-2, Wanyuan Rd. Minhang District
Shanghai, Shanghai 201102
China

Re: K231719
Trade/Device Name: Medical Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: March 8, 2024
Received: March 8, 2024

Dear Esther Zhang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231719

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 surgical 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

K231719

I Submitter

Device submitter: Azur Medical Company Inc.
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Contract manufacturer: Wepon Medical Technology CO., LTD.
Floor 4, Building A, No. 58, Jinhu Road, Chengdong Street,
Wenling Zhejiang, CN 317500

Contact person: Di Zhao
General Manager
Phone: 928-5922380
Email: dzhao@azur-ppe.com
Date: March 14, 2024

II Device

Trade Name of Device: Medical Surgical Mask
Common name: Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation name: Mask, Surgical
Regulatory Class: II
Product code: FXX
Review Panel: General Hospital

III Correspondent

Shanghai Ling Fu Technology Co., Ltd.
4F No. 585-2, Wanyuan Rd. Minhang District, Shanghai, P.R.China
Contact: Esther ZHANG
Email: Esther.zhang@llins-tech.com

IV Predicate Device

510(k) Number:	K210030
Trade/Device Name:	Medical Surgical Mask
Regulation Number:	21 CFR 878.4040
Regulation Name:	Surgical Apparel
Classification:	Class II
Product Code:	FXX

V Device description

The Medical Surgical Mask is single use, flat-pleated masks that are provided in blue. The Medical Surgical Mask is available in two types, which are Level 2 and Level 3 based on ASTM F2100-19.

The inner and outer layers of the mask are made of polypropylene non-woven fabric, the middle layer is made of polypropylene meltblown fabric, and the nose clip is made of polypropylene and iron wire. Users can adjust the nose clip according to the shape of the bridge of the nose, and fix the mask on the bridge of the nose to prevent the mask from falling off. The ear loops are made of spandex. The ear loops are held in place over the users' mouth and nose by two ear loops welded to the mask.

This is a single use, disposable device(s), provided non-sterile.

VI 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 surgical 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.

VII Comparison of technological characteristics with the predicate device

The Medical Surgical Mask has similar intended use, technology, design and performance specifications to the proposed legally marketed predicate device.

Table 5-1 Substantial equivalence discussion – Medical Surgical Mask

Item	Subject device (K231719)	Predicate device (K210030)	Discussion
Product name	Medical Surgical Mask	Disposable Surgical Face Mask	NA
Product Code	FXX	FXX	identical
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 surgical masks are intended for use	The Medical 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	identical

		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.	to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	
Mask style		Flat-pleated	Flat-pleated	identical
ASTM F2100 Level		Level 2 and Level 3	Level 2 and Level 3	identical
Design feature		Level 2: Ear loop Level 3: Ear loop	Level 2: Ear loop Level 3: Ear loop and Tie-on	Different, see explanation below
Color		Blue	Blue	identical
Dimension		17.5cmx9.5cm	17.5cmx9.5cm	identical
Sterility		Non-Sterile	Non-Sterile	identical
Shelf life		2 years	Unknown	Different, see explanation below
Use		Single Use, Disposable	Single Use, Disposable	identical
Particulate filtration efficiency		Level 2 and Level 3: average 99.96%	Level 2 mask: average 99.71% Level 3 mask: average 99.93%	Different, see explanation below
Bacterial filtration efficiency		Level 2 and Level 3: average 99.9%	Level 2 mask: average 99.7% Level 3 mask: average 99.9%	Different, see explanation below
Differential pressure		Level 2 and Level 3: average 2.8 mmH_2O/cm_2	Level 2 mask: average 2.8mmH_2O/cm_2 Level 3 mask: average 4.0 mmH_2O/cm_2 EN 14683	Different, see explanation below
Flammability		Class 1	Class 1	identical
Fluid resistance		Level 2: Pass at 120mmHg Level 3: Pass at 160mmHg	Level 2: Pass at 120mmHg Level 3: Pass at 160mmHg	identical
Label/Labeling		Complied with 21 CFR part 801	Complied with 21 CFR part 801	identical
Patient Contacting	Outer facing layer	polypropylene non-woven fabric	Spunbond Polypropylene	Different, see explanation below

	Middle layer	polypropylene meltblown fabric	Meltblown Polypropylene Filter	
	Inner facing layer	polypropylene non-woven fabric	Spunbond Polypropylene	
	Nose clip	polypropylene and iron wire	PE and Iron	
	Ear loops	spandex	Spandex	
Biocompatibility		ISO 10993-5 and ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic, non-sensitizing, and non-irritating.	ISO 10993-5 and ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic, non-sensitizing, and non-irritating.	identical

Different- Design feature

The proposed masks are ear-loop masks. The predicate Level 3 masks are available in two types, ear-loop and Tie-on. The design features of the two levels of masks for the proposed device can be covered by the design features of the predicate device. Thus, this difference will not affect the safety and effectiveness between the proposed device and the predicate device.

Different-Shelf life

The shelf life of the predicate device is unknown and the proposed mask is 2 years. Shelf life testing has been conducted for the proposed device based on accelerated aging. A real-time aging study is underway. Therefore, this difference will not affect the safety and effectiveness between the proposed device and the predicate device.

Different - Particulate filtration efficiency

The test result for particulate filtration efficiency for the proposed device is different from the predicate device. However, the test result for the proposed device can meet the requirements of level 2 mask and Level 3 mask based on ASTM F2100-19. Thus, this difference will not affect the safety and effectiveness between the proposed device and the predicate device.

Different - Bacterial filtration efficiency

The test result for bacterial filtration efficiency for the proposed device is different from the predicate device. However, the test result for the proposed device can meet the requirements of level 2 mask and Level 3 mask based on ASTM F2100-19. Thus, this

difference will not affect the safety and effectiveness between the proposed device and the predicate device.

Different - Differential pressure
The test result for differential pressure for the proposed device is different from the predicate device. However, the test result for the proposed device can meet the requirements of level 2 mask and Level 3 mask based on ASTM F2100-19. Thus, this difference will not affect the safety and effectiveness between the proposed device and the predicate device.

Different - Patient Contacting Material
The patient contacting material for the proposed device is different from the predicate device. However, biocompatibility test has been performed on the proposed device and the results does not show any adverse effect. Thus, this difference will not affect the safety and effectiveness between the proposed device and the predicate device.

VIII Summary of Non-Clinical Tests
Non-clinical tests were conducted to verify that the proposed device met all design specifications as was same/similar to the predicate device.

Performance testing

No.	Test Item	Reference Standard	Acceptance criteria	Test results
1.	Particulate Filtration Efficiency (PFE)	ASTM F2299/F2299M-03 (2017) Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres.	⩾98%	Pass
2.	Differential Pressure	ASTM F2100: 2019 Standard Specification for Performance of Materials Used in Medical Face Masks.	＜6.0 mmH_2O/cm^2	Pass
3.	Bacterial Filtration Efficiency (BFE)	ASTM F2101: 2019 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus.	⩾98%	Pass

4.	Flammability of Clothing Textiles	16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;	Class I	Pass
5.	Synthetic Blood Penetration Resistance	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);	Level 2: Pass at 120mmHg Level 3: Pass at 160mmHg	Pass

Biocompatibility testing

Biocompatibility of the Medical Surgical Mask was evaluated in accordance with ISO 10993-1:2018.

No.	Test Item	Reference Standard	Acceptance criteria	Test results
1.	In Vitro Cytotoxicity	ISO10993-5: 2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Under the conditions of the study, the proposed device extract is determined to be non-cytotoxic	Pass
2.	Skin Irritation	ISO10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation	Under the conditions of the study, the proposed device extract is determined to be non-irritating	Pass
3.	Skin Sensitization	ISO10993-10: 2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization	Under the conditions of the study, the proposed device extract is determined to be non-sensitizing	Pass

IX Summary of Clinical Tests

N/A

X Conclusion

The conclusions drawn from the non-clinical tests demonstrates that the subject device, Medical Surgical Mask, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K210030.