January 5, 2026

Makrite Industries, Inc.
% Ivy Wang
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Building, 1500# Century Ave.
Shanghai,
China

Re: K252650
Trade/Device Name: Disposable Medical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 22, 2025
Received: December 22, 2025

Dear Ivy 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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

BIFENG QIAN -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection Control Devices
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Office of Product Evaluation and Quality
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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)*
K252650

Device Name
Disposable Medical Face Mask

Indications for Use *(Describe)*
The Disposable Medical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The Disposable Medical Face Mask is 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- K252650

(As required by 21 CFR 807.92)

Date prepared: 11/06/2025

A. Applicant:

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B. Device:

Trade Name: Disposable Medical Face Mask
Common Name: Disposable Surgical Mask
Classification Name: Surgical Face Mask
Classification: Class II
Product code: FXX
Regulation Number: 21 CFR 878.4040
Review Panel: Surgical Apparel
510(k) number: K252650

C. Identification of Primary Predicate device:

K202903
SURGICAL FACE MASK
Rizhao Sanqi Medical & Health Articles Co., Ltd.

D. Indications for use:

The Disposable Medical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The Disposable Medical Face Mask is 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.

E. Device Description:

The Disposable Medical Face Mask is single use, three-layer, 3-pleated or 4-pleated flat-folded masks with nose piece and ear loops or ties. The masks will be provided in blue or black color with option for a visor. The colorant is polypropylene (PP) master batch.

The body of the mask is composed of three layers: the inner and outer layers are made of spun-bond polypropylene, the 2nd layer is made of melt blown polypropylene. The only difference between Level 1, Level 2, and Level 3 masks is the material density in the middle layer. The nose piece is made of Iron wire covered with polypropylene plastic, ear loop is made of elastic band, the ties are made of spun-bond polypropylene, and the visor is made of polyethylene terephthalate (PET).

Each mask contains ear loops or ties to secure the mask over the user's face and mouth with a bendable nose piece to firmly fit over the nose. This device is not made with natural rubber latex.

The disposable medical face masks are sold non-sterile and are intended to be single use, disposable devices.

Models:

Mask Style	Three-pleated		Four-pleated	
	Ear loops	Tie-on	Ear loops	Tie-on
Level 1	-	M643BT	S643BE	S643BT
Level 1 with visor	M643BEF	M643BTF	S643BEF	S643BTF
Level 2	M653BE, M653KE (black)	M653BT	S653BE, S653KE (black)	S653BT
Level 2 with visor	M653BEF, M653KEF (black)	M653BTF	S653BEF, S653KEF (black)	S653BTF
Level 3	-	-	S663BE	S663BT
Level 3 with visor	M663BEF	M663BTF	S663BEF	S663BTF

B-Blue , K-Black, E-earloop, T-Tie-on, F-Visor, M -3 pleated, S-4 pleated

F. Comparison of technological characteristics with the predicate device

The Disposable Medical Face Masks are essentially the same as or similar to the predicate device in terms of the indications for use, design and construction, performance characteristics. Provided below table 1 is a comparison of the proposed device with the predicate device.

Table 1 Comparison of Proposed and Predicate Devices

Comparison between proposed device and predicate device			
Comparison Items	**Proposed Device**	**Predicate Device**	**Result**
Device Name	Disposable Medical Face Mask	Surgical Face Mask	Different
510k Number	K252650	K202903	Different
Product Code	FXX	FXX	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Regulatory Class	Class II	Class II	Same

Indications for Use		The Disposable Medical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The Disposable Medical Face Mask is 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.	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. When worn properly, 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, provided non-sterile.	Same
Size specification (Dimension)		175×95mm	175×95mm	Same
Color		Blue, Black	Blue, white, pink, green, yellow	Different
Design Feature		Ear Loops, Tie-on	Ear Loops, Tie-on	Same
Offer with visor		Yes	Yes	Same
Mask style		3 or 4 Flat-pleated, 3 layers	3 Flat-pleated, 3 or 4 layers	Similar
Use		Single Use, Disposable	Single Use, Disposable	Same
Materials	Outer layer	Spun-bond polypropylene	Spunbond Polypropylene	Same
	Inner layer	Spun-bond polypropylene	Spunbond Polypropylene	Same
	Middle layer (Filter layer)	Melt blown polypropylene filter	Melt-blown Polypropylene	Same
	Nose piece	Iron covered with polypropylene	Steel coated by polypropylene	Similar
	Ear loop	Nylon, Spandex	Spandex	Different
OTC use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
ASTM F2100 Level		ASTM F2100-23 Level 1, Level 2, Level 3	ASTM F2100-19 Level 1, Level 2, Level 3	Similar
Fluid Resistance Performance		Meet ASTM F1862/F1862M-24	Meet ASTM F1862/F1862M-17	Similar
Sub-micron particulate filtration efficiency		Meet ASTM F3502-2022a	Meet ASTM F2299-17	Different
Bacterial Filtration Efficiency		Meet ASTM F2101-23	Meet ASTM F2101-19	Similar

Differential Pressure (Delta P)	Meet EN 14683: 2019, Annex C	Meet EN 14683: 2019, Annex C	Same
Flammability	Meet 16 CFR 1610	Meet 16 CFR 1610	Same
Biocompatibility	Non-cytotoxic, non-sensitizing, non-irritating	Non-cytotoxic, non-sensitizing, non-irritating	Same

G. Summary of Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specification. The test results demonstrated that the proposed device complies with the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Mask - Premarket Notification [510(K)] Submission issued on March 5, 2004:

• ISO10993-5 Biological evaluations of medical devices -- Part 5: Tests for In Vitro cytotoxicity
• ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
• ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation
• ASTM F2100, Standard Specification for Performance of Materials Used in Medical Face Masks.
• ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using A Biological Aerosol of Staphylococcus Aureus;
• EN 14683, Medical Face Masks- Requirements and Test Methods;
• ASTM F1862/F1862M, Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at A Known Velocity)
• 16 CFR 1610, Standard for the Flammability of clothing textiles;
• ASTM F3502, Standard Specification for Barrier Face Coverings.

Performance testing is summarized in below table 2.

Table 2: Summary of Performance Testing

Test Methodology	Purpose	Acceptance Criteria			Result
		Level 1	Level 2	Level 3	
Bacterial Filtration Efficiency ASTM F2101	The purpose of the performance testing is to demonstrate the functionality of the subject device.	≥95%	≥ 98%	≥ 98%	Pass
Differential Pressure (mmH_2O/cm^2) EN 14683:2019 Annex C		<5.0 mmH_2O/cm^2	< 6.0 mmH_2O/cm^2	< 6.0 mmH_2O/cm^2	Pass
Sub-micron Particulate Filtration Efficiency ASTM F3502-2022a		≥80%	≥85%	≥85%	Pass
Resistance to		29 out of 32	29 out of 32	29 out of 32	Pass

Penetration by Synthetic Blood ASTM F1862/F1862M-24		pass at 80 mmHg	pass at 120 mmHg	pass at 160 mmHg	
Flammability 16 CFR Part 1610-2008		Class I	Class I	Class I	Pass

Item	Purpose	Acceptance Criteria	Result
Cytotoxicity	The purpose of the testing is to demonstrate the safety of the subject device.	Non-Cytotoxic	Under the conditions of the study, the device is non-cytotoxic.
Irritation		Non-Irritating	Under the conditions of the study, the device is non-irritating.
Sensitization		Non-Sensitizing	Under the conditions of the study, the device is non-sensitizing

H. Summary of Clinical Testing

No clinical study is included in this submission.

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in this 510(K) submission, the Disposable Medical Face Mask, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K202903.