April 18, 2024

Makrite Industries, Inc.
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Century Avenue
Shanghai, 200122
China

Re: K240258
Trade/Device Name: Disposable Medical Face Mask (M643BE)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 31, 2024
Received: January 31, 2024

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.

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 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.

Submission Number *(if known)*

K240258

Device Name

Disposable Medical Face Mask (M643BE)

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 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

K240258

(As required by 21 CFR 807.92)

Date prepared: April 9, 2024

A. Applicant:

Name: MAKRITE INDUSTRIES INC.
Address: 11F-5., NO.79, Sec.1, Xintai 5th Rd., XiZhi Dist., New Taipei City 221, Taiwan
Contact Person: Bob Wen
Tel: +886-2-26982419
Fax: +886-2-26982423
Email: bobwen@makrite.com.tw

Submission Correspondent:
Primary contact: Ms. Ivy Wang
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-58817802
Email: haiyu.wang@sungoglobal.com
Secondary contact: Mr. Raymond Luo
Room 1401, Dongfang Building, 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-68828050
Email: zxfda@sungoglobal.com

B. Device:

Trade Name: Disposable Medical Face Mask
Common Name: Disposable Medical Face Mask
Model: M643BE

Regulatory Information
Classification Name: Surgical Mask
Classification: Class II
Product code: FXX
Regulation Number: 21 CFR 878.4040
Review Panel: Surgical Apparel

C. Identification of Primary Predicate device:

K222809
Anqing Mayfield Medical Limited.
Trade/Device Name: Medical Disposable Face Masks

Regulatory Information
Classification Name: Surgical Mask
Classification: Class II
Product code: FXX Regulation
Regulation Number: 21 CFR 878.4040
Review Panel: Surgical Apparel

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

E. Device Description:

The Disposable Medical Face Mask is blue color, single use, three-layer, flat-folded masks with nose piece and ear loops. The blue colorant is polypropylene (PP) master batch.
The body of the mask is composed of three layers: the inner (3rd layer) and outer (1st layer) layers are made of spun-bond polypropylene, the middle (2nd layer) is made of melt blown polypropylene. The nose piece is made of Iron core coated with polypropylene, ear loop is made of Nylon and Spandex.
Each mask contains ear loops 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 and are intended to be single use, disposable devices.
The mask is designed and manufactured in accordance with ASTM F2100-23 Standard Specification for Performance of Materials Used in Medical Face Masks.

F. Comparison of technological characteristics with the predicate device

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**
Devece Name	Disposable Medical Face Mask	Medical Disposable Face Masks	Similar
510k Number	K240258	K222809	---
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 a single use, disposable device(s), provided non-sterile.	The Medical Disposable 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 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, provided nonsterile.	Similar
Size specification (Dimension)		175×95mm	17.5×9.5cm 14.5×9.5cm	Similar
Color		Blue	Blue	Same
Design Feature		Ear Loops, Flat-pleated, 3 layers	Ear Loops, Flat-pleated, 3 layers	Same
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 core coated with polypropylene	Aluminum with Polypropylene (PP) covering	Different. The proposed device has different material of nose piece and ear loop to the predicate device.
	Ear loop	Nylon, Spandex	Polyester, Spandex	
OTC use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
ASTM F2100 Level		ASTM F2100-23 Level 1	ASTM F2100-19 Level 1	Similar
Fluid Resistance Performance ASTM F1862		32 out of 32 per lot pass at 80 mmHg 3 non-consecutive lots tested	32 out of 32 per lot pass at 80 mmHg 3 non-consecutive lots tested	Same

Particulate Filtration Efficiency	⩾ 80% ASTM F3502-2022a 8.1	⩾ 95% ASTM F2299	Similar. Both masks meet the particulate filtration efficiency requirements for their respective versions of ASTM F2100
Bacterial Filtration Efficiency ASTM F2101	⩾ 95%	⩾ 95%	Same
Differential Pressure (Delta P) EN14683 Annex C	< 5.0mmH_2O/cm²	< 5.0mmH_2O/cm²	Same
Flammability 16 CFR 1610	Class 1	Class 1	Same
Biocompatibility	ISO 10993 Under the conditions of the studies, non-cytotoxic, not an irritant, and not a sensitizer	ISO 10993 Under the conditions of the studies, non-cytotoxic, not an irritant, and not a sensitizer	Same.

Difference Analysis:

The proposed device has same intended use and similar structure, parameters, and performance as the predicate device. The materials of inner layer, middle layer and outer layer of the proposed device are also similar to those of the predicate device.

The proposed device has different materials for the nose piece and ear loops than the predicate device. However, the proposed device meets the requirements of ISO 10993. The results do not show any adverse effect. Thus, this difference will not affect the safety and effectiveness between the proposed device and the predicate device.

The Proposed device has different Sub-micron particulate filtration efficiency because the testing of proposed device has different standards and testing methods than the predicate device. The proposed device has been tested and the test results shown that the proposed device meets the requirements of Particulate Filtration Efficiency in ASTM F2100-23.

G. Summary of Non-Clinical Testing

- Performance testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications. 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:

• 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 Annex C;

• ASTM F1862/F 1862M, 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 are summarized in below table 2.

Table 2: Summary of Performance Testing

Test Methodology	Purpose	Acceptance Criteria for Level 3 Barrier	Result
Bacterial Filtration Efficiency ASTM F2101	Measure bacterial filtration efficiency	≥95%	Passed 3 non-consecutive lots tested, using a sample size of 32/lot Lot 0923: ≥95% Lot 1023: ≥95% Lot 1123: ≥95%
Differential Pressure (mmH_2O/cm^2) EN 14683:2019 Annex C	Determine breathability of the mask	<5.0 mmH_2O/cm^2	Passed 3 non-consecutive lots tested, using a sample size of 32/lot Lot 0923: <5.0 Lot 1023: <5.0 Lot 1123: <5.0
Sub-micron Particulate Filtration Efficiency ASTM F3502-2022a 8.1	Measure initial particle filtration efficiency	≥80%	Passed 3 non-consecutive lots tested, using a sample size of 32/lot Lot 0923: ≥80% Lot 1023: ≥80% Lot 1123: ≥80%
Resistance to Penetration by Synthetic Blood ASTM F1862-17	Evaluate the resistance to penetration by impact of small volume of synthetic blood	32 out of 32 pass at 80 mmHg	Passed 3 non-consecutive lots tested, using a sample size of 32/lot Lot 0923: 32 out of 32 pass at 80 mmHg Lot 1023: 32 out of 32 pass at 80 mmHg Lot 1123: 32 out of 32 pass at 80 mmHg
Flammability 16 CFR Part 1610-2008	Response of materials to heat and flame	Class I	Passed 3 non-consecutive lots tested, using a sample size of 32/lot Lot 0923: Class 1 Lot 1023: Class 1 Lot 1123: Class 1
ISO 10993-5	Evaluate potential for	Under the conditions	Passed

Tests for in vitro cytotoxicity	cytotoxicity	of the study, non-cytotoxic	
ISO 10993-10 Tests for irritation and skin sensitization	Evaluate potential for irritation	Under the conditions of the study, not an irritant	Passed
	Evaluate potential for skin sensitization	Under the conditions of the study, not a sensitizer	Passed

- Biocompatibility of patient-contacting material

The biocompatibility of the subject device was determined via the evaluation according to the ISO 10993-5: 2009 and ISO 10993-10:2010 standards.

H. Summary of Clinical Testing

No clinical study is included in this submission.

I. Conclusion

The conclusions drawn from the nonclinical tests demonstrate 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 K222809.