



June 14, 2022

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

Re: K220550

Trade/Device Name: Disposable Surgical Face Mask (M663BE, M663BT)  
Regulation Number: 21 CFR 878.4040  
Regulation Name: Surgical Apparel  
Regulatory Class: Class II  
Product Code: FXX  
Dated: May 10, 2022  
Received: May 16, 2022

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 (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for  
Brent Showalter, Ph.D.  
Assistant Director  
DHT6B: Division of Spinal Devices  
OHT6: Office of Orthopedic Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K220550

Device Name  
Disposable Surgical Face Mask (M663BE, M663BT)

### Indications for Use (Describe)

The Disposable Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transferring 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

Prepared date: 2022-02-16

### A. Applicant:

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### B. Device:

Trade Name: Disposable Surgical Face Mask

Common Name: Disposable Surgical Mask

Model: M663BE, M663BT

### Regulatory Information

Classification Name: Surgical Face Mask

Classification: Class II

Product code: FXX

Regulation Number: 878.4040

Review Panel: Surgical Apparel

### C. Predicate device:

K210433

Surgical Face Mask

Wuhan Dymex Healthcare Co., Ltd.

### D. Indications for use:

The Disposable Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transferring 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.

### E. Device Description:

The Disposable Surgical Face Mask is blue color, single use, four-layer, flat-folded masks with nose piece and ear loops or ties. The blue colorant is polypropylene (PP) master batch.

The body of the mask is composed of four layers: the inner(4th layer) and outer(1st layer) layers are made of spun-bond polypropylene, the 2nd layer is made of polyethylene film and the 3rd 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, and the ties are made of spun-bond polypropylene.

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

### F. Comparison with predicate device

Table 1 General Comparison

Device		Proposed Device	Predicate Device	Result
<b>Manufacturer</b>		MAKRITE INDUSTRIES, INC.	Wuhan Dymex Healthcare Co., Ltd.	-
<b>510K number</b>		-	K210433	-
<b>Model name</b>		Disposable Surgical Face Mask	Surgical Face Mask	Same
<b>Classification</b>		Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
<b>Intended use</b>		The Disposable Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transferring 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.	The 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
<b>Model</b>		Ear loop, Tie-on, Flat pleated, 4 layers	Ear loop, Tie-on, Flat pleated, 3 layers	Different
<b>Material</b>	<b>Outer layer</b>	Spun-bond polypropylene	Spun-bond polypropylene	Same
	<b>Middle layer</b>	2 <sup>nd</sup> layer: polyethylene film	/	Different

	3 <sup>rd</sup> layer: Melt blown polypropylene	Melt-blown Polypropylene	Same
<b>Inner layer</b>	Spun-bond polypropylene nonwoven fabric	Spun-bond polypropylene	Same
<b>Nose clip</b>	Iron core coated with polypropylene	Malleable polyethylene wire	Different
<b>Ear loops</b>	Nylon, Spandex	Spandex	Different
<b>Ties</b>	Spun-bond polypropylene	Spunbond Polypropylene	Same
<b>Color</b>	Blue	Blue	Same
<b>Dimension (Length)</b>	17.5cm+/-0.45cm	17.5cm+/-0.2cm	Similar
<b>Dimension (Width)</b>	9.5cm+/-0.45cm	9.5cm+/-0.2cm	Similar
<b>OTC use</b>	Yes	Yes	Same
<b>Sterility</b>	Non-Sterile	Non-Sterile	Same
<b>Use</b>	Single Use, Disposable	Single Use, Disposable	Same
<b>ASTM F2100 level</b>	Level 3	Level 3	Same
<b>Fluid Resistance Performance ASTM F1862</b>	32 out of 32 pass at 160 mmHg	32 out of 32 pass at 160 mmHg	Same
<b>Particulate Filtration Efficiency ASTM F2299</b>	≥ 98%	≥ 98%	Same
<b>Bacterial Filtration Efficiency ASTM F2101</b>	≥ 98%	≥ 98%	Same
<b>Differential Pressure (Delta P) EN 14683 Annex C</b>	< 6.0mmH <sub>2</sub> O/cm <sup>2</sup>	< 6.0mmH <sub>2</sub> O/cm <sup>2</sup>	Same
<b>Flammability 16 CFR 1610 16</b>	Class 1	Class 1	Same
<b>Biocompatibility</b>	ISO10993	ISO10993	Same

### G. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specification for the standards and test methods. 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 Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004:

- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization

- 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);
- EN 14683, Medical Face Masks—Requirements and Test Methods;
- ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using A Biological Aerosol of Staphylococcus Aureus;
- ASTM F2299, stand test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres;
- 16 CFR 1610, Standard for the Flammability of clothing textiles;

Table 2 - Performance Testing & Biocompatibility

Test Methodology	Purpose	Acceptance Criteria: ASTM F2100 Level 3	Result
<b>Fluid Resistance</b>	The purpose of the performance testing is to demonstrate the functionality of the subject device.	29 out of 32 pass at 160 mmHg for level 3	Pass 32 out of 32 pass at 160 mmHg, 3 lots
<b>Particulate Filtration Efficiency</b>		≥ 98%	Pass Average 99.929%, 99.947%, 99.978%
<b>Bacterial Filtration Efficiency</b>		≥ 98%	Pass Average 99.8%, 99.9%, 99.8%
<b>Differential Pressure</b>		< 6.0mmH <sub>2</sub> O/cm <sup>2</sup>	Pass Average 3.7mmH <sub>2</sub> O/cm <sup>2</sup> , 3.8mmH <sub>2</sub> O/cm <sup>2</sup> , 3.8mmH <sub>2</sub> O/cm <sup>2</sup>
<b>Flammability</b>		Class 1	Pass, Class 1
<b>Cytotoxicity</b>	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.
<b>Irritation</b>		Non-irritating	Under the conditions of the study, the device is non-irritating.
<b>Sensitization</b>		Non-sensitizing	Under the conditions of the study, the device is non-sensitizing

#### H. Clinical Test Conclusion

No clinical study is included in this submission.

#### I. 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 K210433.