May 17, 2022

Winner Medical Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K220194
Trade/Device Name: Procedure mask/Surgical mask/Face mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 9, 2022
Received: April 20, 2022

Dear Ms. Hong:

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
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

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)*

K220194

Device Name
Procedure mask/Surgical mask/Face mask

Indications for Use *(Describe)*
The Procedure mask/Surgical mask/Face 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, 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

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92. The assigned 510(k) Number: K220194

1. Date of Preparation: 01/18/2022

2. Sponsor Identification

Winner Medical Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
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510(k) Summary

4. Identification of Proposed Device

Trade Name: Procedure mask/Surgical mask/Face mask
Common Name: Surgical Face Mask

Regulatory Information
Classification Name: Mask, Surgical;
Classification: II;
Product Code: FXX;
Regulation Number: 21CFR 878.4040;
Review Panel: General Hospital;

Indications for use:
The Procedure mask/Surgical mask/Face 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, provided non-sterile.

Device Description:
The proposed device is a three-layer, single-use, flat- pleated mask. The inner and outer layers of the mask are made of polypropylene nonwoven, and the middle layer is made of polypropylene melt-blown nonwoven. The proposed devices are available in two types, ear loop and tie-on. The ear loops are made of polyester and spandex, and the ties are made of polypropylene nonwoven. The ear loops/ties are used to secure the mask over the users' mouth and face. The nose clip is made of Iron and polypropylene. Users can adjust the nose piece 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 loop masks are available in two size, 17.5×9.5 cm and 14.5×9 cm; the tie-on mask is available in one size, 17.5×9.5 cm. And the colors for the ear loop mask are blue and black; the color for the tie-on mask is blue. Both the ear loop and tie-on masks are available in level 1 and level 2 masks based on ASTM F2100-19 due to the difference in gram weight of the mask body. The proposed device is provided in non-sterile. All specifications of the proposed device are provided in table 1.

Table 1 Procedure mask/Surgical mask Description

Product name	ASTM F2100-19 level	Ear strap type	Size (cm)	Color	Layers	Sterilization
Procedure mask/Surgical mask/Face mask	Level 1	Ear loop	17.5x9.5	Blue	3	Non-sterile
				Black		
			14.5x9	Blue		
				Black		
		Tie-on	17.5x9.5	Blue		

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	Level 2	Ear loop	17.5x9.5	Blue		
				Black		
			14.5x9	Blue		
				Black		
		Tie-on	17.5x9.5	Blue		

5. Identification of Predicate Device

510(k) Number: K211462
Product Name: Disposable Ear-loop Medical Face Mask
Disposable Tie-On Medical Face Mask
(Select Level 1 and Level 2 masks as predicate device)

6. Summary of Non-Clinical Test

Non clinical tests were conducted to verify that the proposed device met all design specifications as was same/similar to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ASTM F1862/F1862M: 2017 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity);
- 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;
- 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;
- ASTM F2100: 2019 Standard Specification for Performance of Materials Used in Medical Face Masks
- EN 14683:2019+AC: 2019 Annex C Medical face masks - Requirements and test methods
- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;
- ISO 10993-5:2009 Biological evaluation of medical device- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritaion and skin sensitization

Table 2 Comparison of Procedure mask/Surgical mask

Test Methodology	Purpose	Acceptance Criteria	Result
Resistance to Penetration by Synthetic blood	The test was performed in accordance with ASTM F1862/F1862M: 2017 Standard Test Method for Resistance of Medical Face	Level 1: No penetration at 80 mmHg	Level 1: Pass at 80mmHg
		Level 2: No penetration at 120 mmHg	Level 2: Pass at 120mmHg

	Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) to evaluate the effectiveness of the test article from possible exposure to blood and other body fluids.		
Particulate Filtration Efficiency	The test was performed in accordance with 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 to determine the particle filtration efficiency (PFE) of the test article.	Level 1: ≥95%	Blue mask: Pass at 96.05% Black mask: Pass at 96.03%
		Level 2: ≥98%	Blue mask: Pass at 98.78% Black mask: Pass at 98.75%
Bacterial Filtration Efficiency	The test was performed in accordance with 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 to determine the bacterial filtration efficiency (BFE) of the test article.	Level 1: ≥95%	Blue mask: Pass at 98.25% Black mask: Pass at 98.25%
		Level 2: ≥98%	Blue mask: Pass at 98.72% Black mask: Pass at 98.73%
Differential Pressure	The test was performed in accordance with EN 14683:2019+AC: 2019 Annex C Medical face masks - Requirements and test methods to determine the differential pressure of the test article.	Level 1: <5.0 mmH_2O/cm^2	Blue mask: Pass at 3.5 mmH_2O/cm^2 Black mask: Pass at 3.5 mmH_2O/cm^2
		Level 2: <6.0 mmH_2O/cm^2	Blue mask: Pass at 3.5 mmH_2O/cm^2

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			Black mask: Pass at 3.6 mmH_2O/cm^2
Flammability	The test was performed in accordance with 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles to evaluate the flammability of the test article.	Class 1	Class 1
Cytotoxicity	The test was performed in accordance with ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity to evaluate the cytotoxicity of the test article.	The viability should be ≥70% of the blank. And the 50% extract of the test sample should have at least the same or a higher viability than the 100% extract.	The viability was ≥70% of the blank. And the 50% extract of the test sample had a higher viability than the 100% extract. Under the conditions of the study, the proposed device was non-cytotoxic.
Sensitization	The test was performed in accordance with ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization to evaluate the sensitization of the test article.	Non-sensitizing	Under the conditions of the study, the proposed device was non-sensitizing.
Irritation	The test was performed in accordance with ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization to evaluate the irritation of the test article.	Non-irritating	Under the conditions of the study, the proposed device was non-irritating.

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7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Technological Characteristics Comparison

Table 3 Comparison of Procedure mask/Surgical mask

ITEM	Proposed Device		Predicate Device K211462		Remark
Product Code	FXX		FXX		Same
Regulation No.	21 CFR 878.4040		21 CFR 878.4040		Same
Class	II		II		Same
Indications for Use	The Procedure mask/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, provided non-sterile.		The Disposable Ear-loop Medical Face Mask/Disposable Tie-On 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. 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 nonsterile.		Same
Mask style	Flat pleated		Flat pleated		Same
Design feature	Ear loop / Tie-on		Ear loop / Tie-on		Same
Dimension	Ear loops: Body: 175 mm×95 mm, nose clip: 110mm, Ear-loop: 178mm Body: 145 mm×90 mm, nose clip: 85mm, Ear-loop: 145mm Tie-on: Body: 175 mm×95 mm, nose clip: 110mm, Ear-loop: 900mm		Ear loops: Body: 175 mm×95 mm, nose clip: 125mm, Ear-loop: 175mm Tie-on: Body: 175 mm×95 mm, nose clip: 125mm, Tie strings: 910mm		Different
ASTM F2100 Level	Level 1	Level 2	Level 1	Level 2	Same
Fluid Resistance	Pass at 80mmHg	Pass at 120 mmHg	Pass at 80mmHg	Pass at 120 mmHg	Same

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Particulate filtration efficiency		Blue mask: Pass at 96.05% Black mask: Pass at 96.03%	Blue mask: Pass at 98.78% Black mask: Pass at 98.75%	Pass at 98.2%	Pass at 99.3%	Different
Bacterial filtration efficiency		Blue mask: Pass at 98.25% Black mask: Pass at 98.25%	Blue mask: Pass at 98.72% Black mask: Pass at 98.73%	Pass at 98.9%	Pass at 99.4%	Different
Differential pressure		Blue mask: Pass at 3.5 mmH_2O/cm^2 Black mask: Pass at 3.5 mmH_2O/cm^2	Blue mask: Pass at 3.5 mmH_2O/cm^2 Black mask: Pass at 3.6 mmH_2O/cm^2	Passed at 3.6mmH_2O/cm^2	Pass at 4.0mmH_2O/cm_2	Different
Flammability		Class 1		Class 1		Same
Label/Labeling		Complied with 21 CFR part 801		Complied with 21 CFR part 801		Same
Materials						
Ear loop		Polyester and spandex		Nylon and Spandex		Different
Tie strings		38 /m^2 polypropylene nonwoven		35g/ m^2 PP non-woven cloth		
Nose clip		Iron and polypropylene		Aluminum wire		
Mask body	Outer material	25g/m^2 polypropylene nonwoven	30g/m^2 polypropylene nonwoven	23g/ m^2 PP non-woven cloth		
	Middle material	25g/m^2 polypropylene melt-blown nonwoven	30g/m^2 polypropylene melt-blown nonwoven	22g/ m^2 PP non-woven cloth	25g/m^2 PP non-woven cloth	33g/m^2PP non-woven cloth
	Inner material	25g/m^2 polypropylene nonwoven	30g/m^2 polypropylene nonwoven	20g/ m^2 PP non-woven cloth		
Colors		Blue; Black		Blue		Different
Biocompatibility						
Cytotoxicity		Under the conditions of the study, the proposed device was non-cytotoxic.		Under the conditions of the study, the proposed device was non-cytotoxic.		Same
Sensitization		Under the conditions of the study, the proposed device was non-sensitizing.		Under the conditions of the study, the proposed device was non-sensitizing.		Same
Irritation		Under the conditions of the study, the proposed device was		Under the conditions of the study, the proposed device was non-irritating.		Same

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	non-irritating.		
Sterilization			
Method	Non-sterile	Non-sterile	Same

Different - Dimension (mm)

The dimension for the proposed device is different from the predicate device. The mask body of the proposed device is provided in two dimensions: ear loop masks - 17.5×9.5 cm and 14.5×9 cm; tie-on mask - 17.5×9.5 cm. While the predicate device is only provided in one dimension, 17.5×9.5 cm. However, the difference in dimension of mask body does not affect indications for use and will not raise any safety issues. The dimensions of the nose clip, ear loop and ties for the proposed device are different from the predicate device. However, these difference does not affect the protective performance of masks. The nose clip is just to fix the mask on the bridge of the nose and keep it from falling off. And the ear loop and ties are also designed to attach masks to the user's mouth and nose. Thus, this difference will not affect the safety and effectiveness of the proposed device.

Different - Particulate 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 1 / level 2 mask based on ASTM F2100-19. Thus, this difference will not affect the safety and effectiveness of proposed 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 1 / level 2 mask based on ASTM F2100-19. Thus, this difference will not affect the safety and effectiveness of proposed 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 1 / level 2 mask based on ASTM F2100-19. Thus, this difference will not affect the safety and effectiveness of proposed device.

Different - Materials

The material for the proposed device is different from predicate device. However, biocompatibility test has been performed on the proposed device and the results does not show any adverse effect. Thus, this difference in materials will not affect the safety and effectiveness of the proposed device.

Different - Colors

The color of proposed device is provided in blue and black, while the predicate device is blue. However,

the biocompatibility test has been conducted and test results did not show any adverse effects. Thus, this difference will not affect the safety and effectiveness of the proposed device.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device K211462.