October 8, 2021

Jiangxi Hongda Medical Equipment Group Co., Ltd.
Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box. 120-119
Shanghai, 200120
China

Re: K210622
Trade/Device Name: Single-Use Medical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 04, 2021
Received: September 14, 2021

Dear Diana 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 Clarence W. Murray III, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210622

Device Name
Single-use Medical Face Mask

Indications for Use *(Describe)*
The single-use medical 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, provided sterile and non-sterile.

Level 1 mask Models: Sterile Tie-on, Sterile Ear loop, Non-sterile Tie-on, Non-sterile Ear loop
Level 2 mask Models: Sterile Tie-on, Sterile Ear loop, Non-sterile Tie-on, Non-sterile Ear loop
Level 3 mask Models: Sterile Tie-on, Sterile Ear loop, Non-sterile Tie-on, Non-sterile Ear loop

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.

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510(k) Summary K210622

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

The assigned 510(k) Number: K210622

1. Date of Preparation: 10/07/2021

2. Sponsor Identification

Jiangxi Hongda Medical Equipment Group Co., Ltd.
39 South Shengli Road, Jinxian County, Nanchang City, Jiangxi Province, China.

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

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Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device
Trade Name: Single-use Medical Face Mask
Common Name: Surgical Mask

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

Indication for use:

The single-use medical 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, provided sterile and 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 spunbonded 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 held in place over the users' mouth and nose by ear loops/ ties welded to the mask. The nose clip is made of polypropylene and iron. 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. Both the ear loop and tie-on masks are available in level 1, level 2 and level 3 masks based on ASTM F2100-19, which are provided in following table. The difference of the level 1, level 2 and level 3 masks is the gram weight of the melt-blown nonwoven. The gram weight of the melt-blown nonwoven for level 1 is 30g/m^2, and that for level 2 and level 3 masks is 40g/m^2. Level 2 and level 3 masks are exactly the same and are divided into level 2 and level 3 just for marking. The proposed devices are provided in sterile and non-sterile two types.

ASTM F2100-19	Specification	Ear loop	Tie-on	Color	Sterility
Level 1	17.5 × 9.5cm	√		White	Sterile
		√		White	Non-sterile
			√	White	Sterile
			√	White	Non-sterile

Level 2		√		White	Sterile
		√		White	Non-sterile
			√	White	Sterile
			√	White	Non-sterile
Level 3		√		White	Sterile
		√		White	Non-sterile
			√	White	Sterile
			√	White	Non-sterile

5. Identification of Predicate Device

510(k) Number: K160269
Product Name: Surgical Face Masks (Ear loops and Tie-on)

6. Non-Clinical Test Conclusion

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:

- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritation and skin sensitization;
- ISO 10993-5:2009 Biological evaluation of medical device-Part 5: Tests for in vitro cytotoxicity;
- ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials;
- 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 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);
- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;
- EN 14683: 2019 Medical face masks- Requirements and test methods;
- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection;
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials;
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration;
- ISO 10993-7:2008 Biological Evaluation of Medical Device- Part 7: Ethylene Oxide Sterilization Residuals;

Table 1. Summary of the Non-clinical Testing

Models/types	Test Method	Acceptance Criteria	Test Result
Sterile Tie-on Sterile Ear loop Non-sterile Tie-on Non-sterile Ear loop	Resistance to Penetration by Synthetic blood from 3 non-consecutive lots 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 1: No penetration at 80 mmHg; Level 2: No penetration at 120 mmHg; Level 3: No penetration at 160 mmHg	Sterile Tie-on Level 1: Pass at 80 mmHg; Level 2: Pass at 120 mmHg; Level 3: Pass at 160 mmHg
			Sterile Ear loop Level 1: Pass at 80 mmHg; Level 2: Pass at 120 mmHg; Level 3: Pass at 160 mmHg
			Non-sterile Tie-on Level 1: Pass at 80 mmHg; Level 2: Pass at 120 mmHg; Level 3: Pass at 160 mmHg
			Non-sterile Ear loop Level 1: Pass at 80 mmHg; Level 2: Pass at 120 mmHg; Level 3: Pass at 160 mmHg
	Bacterial Filtration Efficiency from 3 non-consecutive lots 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	Level 1: ≥95% Level 2: ≥98% Level 3: ≥98%	Sterile Tie-on Level 1: 98.48% Level 2: 99.84% Level 3: 99.85%
			Sterile Ear loop Level 1: 98.38% Level 2: 99.86% Level 3: 99.89%
			Non-sterile Tie-on Level 1: 98.39% Level 2: 99.82% Level 3: 99.87%
			Non-sterile Ear loop Level 1: 98.67% Level 2: 99.86% Level 3: 99.88%
	Particulate Filtration Efficiency from 3 non-consecutive lots ASTM F2299/F2299M-03	Level 1: ≥95% Level 2: ≥98% Level 3: ≥98%	Sterile Tie-on Level 1: 99.22% Level 2: 99.85% Level 3: 99.88%

	(2017) Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres		Sterile Ear loop Level 1: 99.23% Level 2: 99.86% Level 3: 99.88%
			Non-sterile Tie-on Level 1: 99.23% Level 2: 99.87% Level 3: 99.88%
			Non-sterile Ear loop Level 1: 99.23% Level 2: 99.87% Level 3: 99.87%
	Differential Pressure from 3 non-consecutive lots EN 14683:2019 Medical face masks- Requirements and test methods	Level 1 <5.0 mm H_2O/cm^2 Level 2: <6.0 mm H_2O/cm^2 Level 3: <6.0 mm H_2O/cm^2	Sterile Tie-on Level 1: 4.00 mm H_2O/cm^2 Level 2: 4.83 mm H_2O/cm^2 Level 3: 4.90 mm H_2O/cm^2
			Sterile Ear loop Level 1: 3.83 mm H_2O/cm^2 Level 2: 4.77 mm H_2O/cm^2 Level 3: 4.90 mm H_2O/cm^2
			Non-sterile Tie-on Level 1: 4.10 mm H_2O/cm^2 Level 2: 4.90 mm H_2O/cm^2 Level 3: 4.93 mm H_2O/cm^2
			Non-sterile Ear loop Level 1: 4.00 mm H_2O/cm^2 Level 2: 4.90 mm H_2O/cm^2 Level 3: 4.97 mm H_2O/cm^2
	Flammability from 3 non-consecutive lots 16 CFR 1610 Standard for the Flammability of Clothing Textiles Corrections	Class I	Class I
	EO ECH Residual Test ISO 10993-7:2008	EO residual shall not exceed 4mg/device ECH residual shall not exceed 9mg/device	EO residual was less than 4mg/device ECH residual was less than 9mg/device
	Cytotoxicity ISO 10993-5: 2009	The viability should be ≥70% of the blank.	The viability was ⩾70% of the blank. And the 50%

	Biological Evaluation of Medical Devices-Part 5: Tests for in Vitro Cytotoxicity	And the 50% extract of the test sample should have at least the same or a higher viability than the 100% extract.	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.
	Irritation ISO 10993-10: 2010 Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization	Non-irritating	Under the conditions of the study, the proposed device was non-irritating.
	Sensitization ISO 10993-10: 2010 Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization	Non-sensitizing	Under the conditions of the study, the proposed device was non-sensitizing.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technological characteristics

Table 2. Comparison of Technology Characteristics

ITEM	Proposed Device K210622	Predicate Device K160269	Remark
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Indication for Use	The single-use medical 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, provided sterile and 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, provided non-sterile.	Similar
Mask style	Flat-pleated	Flat-pleated	Same
Design feature	Ear loop or tie-on	Ear loop or tie-on	Same
Color	White	Blue, White	Different
Dimension	Mask body: 175×95mm Nose Clip: 80~105mm Ear loop: 140~150mm Ties: 330~400mm	175×90mm 180×90mm	Different
ASTM F2100 Level	Level 1, Level 2, Level 3	Level 1, Level 2, Level 3	Same
Sterility	Non sterile/Sterile Sterilization method: Ethylene Oxide (EO) Packaging material: Paper and Polyethylene film	Non-sterile	Different
EO ECH Residual	EO residue: <4mg/device ECH residue: <9mg/device	The predicate device is non-sterile	
Use	Single Use, Disposable	Single Use, Disposable	Same
Fluid resistance	Level 1: Pass at 80 mmHg Level 2: Pass at 120 mmHg Level 3: Pass at 160 mmHg	Level 1: Pass at 80 mmHg Level 2: Pass at 120 mmHg Level 3: Pass at 160 mmHg	Same
Particulate filtration efficiency	Level 1: Ear loop (Non-sterile): ≥95% Ear loop (Sterile): ≥95% Tie-on (Non-sterile): ≥95%	Level 1: Pass at 99.6% Level 2: Pass at 99.6% Level 3: Pass at 99.7%	Different

	Tie-on (Sterile): ≥95% Level 2: Ear loop (Non-sterile): ≥98% Ear loop (Sterile): ≥98% Tie-on (Non-sterile): ≥98% Tie-on (Sterile): ≥98% Level 3: Ear loop (Non-sterile): ≥98% Ear loop (Sterile): ≥98% Tie-on (Non-sterile): ≥98% Tie-on (Sterile): ≥98%		
Bacterial filtration efficiency	Level 1: Ear loop (Non-sterile): ≥95% Ear loop (Sterile): ≥95% Tie-on (Non-sterile): ≥95% Tie-on (Sterile): ≥95% Level 2: Ear loop (Non-sterile): ≥98% Ear loop (Sterile): ≥98% Tie-on (Non-sterile): ≥98% Tie-on (Sterile): ≥98% Level 3: Ear loop (Non-sterile): ≥98% Ear loop (Sterile): ≥98% Tie-on (Non-sterile): ≥98% Tie-on (Sterile): ≥98%	Level 1: Pass at 98% Level 2: Pass at 98% Level 3: Pass at 99%	Different
Differential pressure	Level 1: Ear loop (Non-sterile):＜5mmH_2O/cm^2 Ear loop (Sterile): ＜5mmH_2O/cm^2 Tie-on (Non-sterile): ＜5mmH_2O/cm^2 Tie-on (Sterile): ＜5mmH_2O/cm^2 Level 2: Ear loop (Non-sterile): ＜6mmH_2O/cm^2 Ear loop (Sterile): ＜6mmH_2O/cm^2 Tie-on (Non-sterile): ＜6mmH_2O/cm^2 Tie-on (Sterile): ＜6mmH_2O/cm^2 Level 3: Ear loop (Non-sterile): ＜6mmH_2O/cm^2 Ear loop (Sterile): ＜6mmH_2O/cm^2 Tie-on (Non-sterile): ＜6mmH_2O/cm^2	Level 1: Pass at 2.0 mmH_2O/cm^2 Level 2: Pass at 1.6 mmH_2O/cm^2 Level 3: Pass at 2.5 mmH_2O/cm^2	Different

	Tie-on (Sterile): ＜6mmH_2O/cm^2		
Flammability	Level 1: Class 1 Level 2: Class 1 Level 3: Class 1	Level 1: Class 1 Level 2: Class 1 Level 3: Class 1	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Shelf Life	3 years	Unknown	Different
Patient Contacting Material			
Outer facing layer	Polypropylene Spunbonded Nonwoven	Polypropylene	Different
Middle layer	Polypropylene Melt-blown Nonwoven	1. Polypropylene spunbond 2. Polypropylene meltblown	
Inner facing layer	Polypropylene Spunbonded Nonwoven	Polypropylene	
Nose Clip	Polypropylene and iron	Polyethylene coated steel wire	
Ear loops/Ties	Ear loops: Polyester and spandex Ties: Polypropylene Spunbonded Nonwoven	Ear loops: Polyester, polyurethane Ties: Polypropylene spunbond or polyester spunbond	
Biocompatibility			
Cytotoxicity	Under the conditions of the study, the proposed device was non-cytotoxic.	Under the conditions of the study, the subject 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 subject device was non-sensitizing.	
Irritation	Under the conditions of the study, the proposed device was non-irritating.	Under the conditions of the study, the subject device was non-irritating.	

Similar – Indication for Use

The indication for use of the proposed device is the same as that of the predicate device, although the proposed device is provided in both sterilized and non-sterilized types. In addition, the performance test and biocompatibility test were also conducted on the sterile and non-sterile masks and the test results demonstrated that the devices can meet the requirements of ASTM F2100-19 and do not raise any adverse effects. Thus, this difference will not affect the safety and effectiveness of the proposed device.

Different – Color

The proposed device is white and the predicate device is provided in two colors, including white mask. And 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.

Different – Dimension

The dimension for the proposed device is different from predicate device. The specification of the proposed device is the common specification of the mask. And, this difference does not affect intended use and will not raise any safety issues. Thus, this difference will not affect the safety and effectiveness of the proposed device.

Different –Sterility

The final product status of the proposed device is different from predicate device. The predicate device is non-sterilized, while the proposed device is provided in two states, sterile and non-sterile. Sterilization will affect the safety and effective of the mask. The performance testing of the proposed device has been conducted on the final product and the results show that the proposed device meets the requirements of ASTM F2100-19. For sterile masks, the EO residue testing has been conducted on the final sterile product per ISO 10993-7: 2008 and the results show that the proposed sterile device meets the requirement of EO residue less than 4mg/device and ECH residue less than 9mg/device. Thus, although there are differences between the proposed device and predicate device, the differences will not affect the safety and effectiveness of the proposed device.

Different –Particulate filtration efficiency

The test result for particulate filtration efficiency for the proposed device is different from the predicate device. However, the PFE test result for the proposed device meets the requirements of ASTM F2100-19. Thus, this difference will not affect the safety and effectiveness of the 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 BFE test result for the proposed device meets the requirements of ASTM F2100-19. Thus, this difference will not affect the safety and effectiveness of the proposed device.

Different - Differential pressure

The test result for different pressure for the proposed device is different from the predicate device. However, the different pressure test result for the proposed device meets the requirements of ASTM F2100-19. Thus, this difference will not affect the safety and effectiveness of the proposed device.

Different - Shelf Life

Shelf life will affect the safety and effectiveness of mask. However, the performance testing of the proposed device after three years of accelerated aging has been conducted and the test results show that

the proposed device after three years of aging meets the requirements of ASTM F2100-2019. Thus, this difference will not affect the safety and effectiveness of the proposed device.

Different - Patient Contacting Material

The patient contact material for the propose device is different from predicate device. However, biocompatibility test has been conducted on the propose device and the test result does not show any adverse effect. Thus, this difference will not affect the safety and effectiveness of the proposed device.

9. Conclusion

The proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K160269.