January 17, 2022

Guangzhou Quantum Laser Intelligent Equipment Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K212994
Trade/Device Name: Medical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: May 18, 2021
Received: September 20, 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, PhD
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)*

K212994

Device Name
Medical face mask

Indications for Use *(Describe)*

The 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 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: K212994

1. Date of Preparation: 12/23/2021

2. Sponsor Identification

Guangzhou Quantum Laser Intelligent Equipment Co., Ltd.
Building B27 Huachuang Animation Industrial Park, Jinshan Village, Shiqi Town, Panyu District, Guangzhou, Guangdong, China

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jinlei Tang (Alternative Contact Person)

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Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Medical Face Mask
Common Name: Mask

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

Intended Use/Indications for Use:
The 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 non-sterile.

Device Description:
The Medical Face Masks are single use, flat-pleated, ear loop masks that are provided in blue. The medical face masks are available in three types, which are Level 1, Level 2 and Level 3 based on ASTM F2100-19, depending on marketing reasons. However, Level 1, Level 2 and Level 3 masks are exactly the same. The outer and inner layers of the mask are made of spunbond polypropylene. The middle filter layer is made of meltblown polypropylene filter. The ear loops are made of nylon and spandex. The ear loops are held in place over the users' mouth and nose by two elastic ear straps. The nose clip is made of PE and galvanized iron wire. 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. The proposed devices are provided in non-sterile.

5. Identification of Predicate Device

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

6. Summary of Technological characteristics

Table 1 Comparison of Medical Face Mask

ITEM	Proposed Device	Predicate Device K160269	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 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 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.	Same
Mask style	Flat-pleated	Flat-pleated	Same
ASTM F2100 Level	Level 1, Level 2, Level 3	Level 1, Level 2, Level 3	Same
Design feature	Ear loop	Ear loop and Tie-on	Different
Color	Blue	Blue, White	Different
Dimension	Mask body: 175mm×95mm Nose Clip: 100±5mm Ear loop: 170±5mm	175×90mm 180×90mm	Different
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
Particulate filtration efficiency	Pass at 99.2%	Level 1: Pass at 99.6% Level 2: Pass at 99.6% Level 3: Pass at 99.7%	Different
Bacterial filtration efficiency	Pass at 99.2%	Level 1: Pass at 98% Level 2: Pass at 98% Level 3: Pass at 99%	Different
Differential pressure	Pass at 3.8 mm H_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
Flammability	Class 1	Class 1	Same
Fluid resistance	Pass at 160 mmHg	Level 1: Pass at 80 mmHg Level 2: Pass at 120 mmHg Level 3: Pass at 160 mmHg	Different

Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Patient Contacting Material			
Outer facing layer	Spunbond Polypropylene	Polypropylene	Different
Middle layer	Meltblown Polypropylene Filter	1. Polypropylene spunbond 2. Polypropylene meltblown	
Inner facing layer	Spunbond Polypropylene	Polypropylene	
Nose clip	PE and Galvanized iron wire	Polyethylene coated steel wire	
Ear loop	Nylon and Spandex	Polyester, polyurethane	
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.	

Different - Design feature

The proposed masks are ear-loop masks. The design features of the masks for the proposed device can be covered by the design features of the predicate device. Thus, this difference will not affect the safety and effectiveness of the proposed device.

Different - Color

The proposed device is blue and the predicate device is provided in two colors, the color of the proposed device can be covered by the predicate device. In addition, 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 the predicate device. However, the difference does not affect the indication for use and will not raise safety issues. Thus, this difference 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. The proposed devices are available in Level 1, Level 2 and Level 3 based on ASTM F2100-19, depending on marketing reasons. However, Level 1, Level 2 and Level 3 masks are exactly the same. Therefore, the particulate filtration efficiency test was conducted on Level 3 masks and the test result can meet the requirements based on 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. The proposed devices are available in Level 1, Level 2 and Level 3 based on ASTM F2100-19, depending on marketing reasons. However, Level 1, Level 2 and Level 3 masks are exactly the same. Therefore, the bacterial filtration efficiency test was conducted on Level 3 masks and the test result can meet the requirements based on ASTM F2100-19. Thus, this difference will not affect the safety and effectiveness of the proposed device.

Different - Differential pressure

The test result for differential pressure for the proposed device is different from the predicate device. The proposed devices are available in Level 1, Level 2 and Level 3 based on ASTM F2100-19, depending on marketing reasons. However, Level 1, Level 2 and Level 3 masks are exactly the same. Therefore, the differential pressure test was conducted on Level 3 masks and the test result can meet the requirements of the standard ASTM F2100-19 which was recognized by FDA. Thus, this difference will not affect the safety and effectiveness of the proposed device.

Different - Fluid resistance

The test result for fluid resistance for the proposed device is different from the predicate device. The proposed devices are available in Level 1, Level 2 and Level 3 based on ASTM F2100-19, depending on marketing reasons. However, Level 1, Level 2 and Level 3 masks are exactly the same. Therefore, the fluid resistance test was conducted on Level 3 masks and the test result can meet the requirements based on ASTM F2100-19. Thus, this difference will not affect the safety and effectiveness of the proposed device.

Different - Patient Contacting Material

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

7. 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 devices. The test results demonstrated that the proposed device complies with the following standards:

- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;
- 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, Annex C, Medical face masks- Requirements and test methods
- 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 irritation and skin sensitization
- ISO 10993-1:2018 Biological evaluation of medical devices — Part 1 Evaluation and testing within a risk management process.

Performance Characteristics	Test Method	Test result	Acceptance Criteria	Conclusion
Fluid Resistance Performance	ASTM F1862/F1862M: 2017	Pass at 160 mmHg	No penetration at 160 mmHg	Meet the requirement
Particulate Filtration Efficiency	ASTM F2299/F2299M-03 (2017)	Pass at 99.2%	≥98%	Meet the requirement
Bacterial Filtration Efficiency	ASTM F2101: 2019	Pass at 99.2%	≥98%	Meet the requirement
Differential Pressure (Delta-P)	EN 14683: 2019, Annex C	Pass at 3.8 mm H_2O/cm^2	<6.0 mmH_2O/cm^2	Meet the requirement
Flammability class	16 CFR Part 1610	Class 1	Class 1	Meet the requirement

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the medical face mask is as safe, as

effective, and performs as well as or better than the legally marketed predicate device cleared under K160269.