March 26, 2021

Jiangsu Excellence Medical Supplies Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K202905
Trade/Device Name: Disposable Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 25, 2021
Received: February 26, 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,

Ryan Ortega PhD
Acting 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)*

K202905

Device Name
Disposable Face Mask

Indications for Use *(Describe)*

The 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. 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: K202905

1. Date of Preparation: 03/26/2020

2. Sponsor Identification

Jiangsu Excellence Medical Supplies Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Tingting Su (Alternative Contact Person)

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Email: info@mid-link.net

4. Identification of Proposed Device

Common Name: Surgical Mask
Trade Name: Disposable Face Mask
Models: 14.5cm×9.5cm(L1), 17cm×9.5cm(L1), 17.5cm×9.5cm(L1)
14.5cm×9.5cm(L2), 17cm×9.5cm(L2), 17.5cm×9.5cm(L2)

Regulatory Information
Classification Name: Mask, Surgical

Classification: II;
Product Code: FXX;
Regulation Number: 21CFR 878.4040
Review Panel: General Hospital

Indication for use:
The 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. 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, Disposable Face Mask is a three-layer, single-use, flat-pleated mask. The ear loops to secure the mask over the users' mouth and face and includes a nosepiece to provide a firm fit over the nose. The disposable surgical mask is available in four different specifications: 14.5cmx9.5cm, 17cmx9.5cm and 17.5cmx9.5cm. The device is single use and provided non-sterile.

5. Identification of Predicate Device

510(k) Number: K160269
Product Name: Surgical Face Masks (Ear loops and Tie-on) Models: EL 10000, EL 10010, TO 10000, TO 10010
EL 20000, EL 20010, TO 20000, TO 20010
EL 30000, EL 30010, TO 30000, TO 30010

6. Comparison of technological characteristics between the subject and predicate devices

Table 1 Comparison of Disposable Face Mask

ITEM	Proposed Device K202905	Predicate Device K160269	Remark
Product Code	FXX	FXX	Identical
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Identical
Class	II	II	Identical
Indication for Use	The 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. 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	Identical

Design feature	Ear strap		Ear strap/ Tie-on		Same
Dimension	145mm×95mm, 170mm×95mm, 175mm×95mm		175mm×90mm, 180mm×90mm		Similar
ASTM F2100 Level	Level 1		Level 1		Identical
	Level 2		Level 2		Identical
Fluid resistance ASTM F1862	Level 1 Pass at 80mmHg		Level 1 Pass at 80mmHg		Identical
	Level 2 Pass at 120mmHg		Level 2 Pass at 120mmHg		Identical
Particulate efficiency level ASTM F2299	≥95%	≥98%	Pass at 99.6%	Pass at 99.6%	Similar
Bacterial filtration level ASTM F2101	≥95%	≥98%	Pass at >98%	Pass at >98%	Similar
Differential pressure EN 14683	＜ 5.0mm H_2O/ cm^2	＜ 6.0mm H_2O/ cm^2	Passed at 2.0 mmH_2O/cm^2	Passed at 1.6 mmH_2O/cm^2	Similar
Flammability 16 CFR1610	Class 1		Class 1		Identical
Label/Labeling	Complied with 21 CFR part 801		Complied with 21 CFR part 801		Identical
Patient Contacting Material					
ear strap	Spandex and Polyester		Polyester, polyurethane		Different
nose clip	HDPE and Iron		Polyethylene and steel wire		
mask body	$25g/m^2$ PP spunbond non-woven cloth and $25g/m^2$ PP meltblown non-woven cloth		Polypropylene spun bond and Polypropylene melt-blown		
Biocompatibility					
Cytotoxicity	Comply with ISO 10993-5 No Cytotoxicity		Comply with ISO 10993-5 No Cytotoxicity		Identical
Sensitization	Comply with ISO 10993-10 No Sensitization		Comply with ISO 10993-10 No Sensitization		
Irritation	Comply with ISO 10993-10 No Irritation		Comply with ISO 10993-10 No Irritation		

Similar - Dimension

The dimension for the proposed device is different from predicate device. This difference does not affect intended use and will not raise any safety issues. Thus, this difference does not affect substantially equivalence between the proposed device and predicate device.

Similar - Particulate efficiency level

The test result for particulate efficiency for the proposed device is different from predicate device. However, the test result for the proposed device can meet the requirements of level 1/level 2 mask. Thus, this difference does not affect substantially equivalence between the proposed device and predicate device.

Similar - Bacterial filtration level

The test result for bacteria efficiency for the proposed device is different from predicate device. However, the test result for the proposed device can meet the requirements of level 1/level 2 mask. Thus, this difference does not affect substantially equivalence between the proposed device and predicate device.

Similar - Differential pressure

The test result for different pressure for the proposed device is different from predicate device. However, the test result for the proposed device can meet the requirements of level 1/level 2 mask. Thus, this difference does not affect substantially equivalence between the proposed device and predicate 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. Therefore, this difference does not affect substantially equivalence between the proposed device and predicate device.

7. Non-Clinical Test Summary

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- 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)
- 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 F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- 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

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K202905, the Disposable Face Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K160269.