February 12, 2021

Shanghai Jianzhong Medical Packaging Co., Ltd.
℅ Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K202341
Trade/Device Name: Disposable Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 13, 2021
Received: January 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 CAPT Elizabeth Claverie-Williams, MS
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)*
K202341

Device Name
Disposable Surgical Mask

Indications for Use *(Describe)*
The Disposable Surgical 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 and sterile.

Models: 17.5*9.5cm-3ply (sterile), 14.5*9.5cm-3ply (sterile), 14.5*8cm-3ply (sterile)
17.5*9.5cm-3ply (non-sterile), 14.5*9.5cm-3ply (non-sterile), 14.5*8cm-3ply (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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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: K202341

1. Date of Preparation: 02/12/2021

2. Sponsor Identification

Shanghai Jianzhong Medical Packaging 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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P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: +1-360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Disposable Surgical Mask
Common Name: Surgical mask
Models: 17.5*9.5cm-3ply (sterile), 14.5*9.5cm-3ply (sterile), 14.5*8cm-3ply (sterile)
17.5*9.5cm-3ply (non-sterile), 14.5*9.5cm-3ply (non-sterile), 14.5*8cm-3ply (non-sterile)

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 Surgical 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 and sterile.

Models: 17.5*9.5cm-3ply (sterile), 14.5*9.5cm-3ply (sterile), 14.5*8cm-3ply (sterile)
17.5*9.5cm-3ply (non-sterile), 14.5*9.5cm-3ply (non-sterile), 14.5*8cm-3ply (non-sterile)

Device Description:
The proposed device, Disposable Surgical Mask is a three-layer, flat-folded mask with ear strap and nose clip. The ear straps are held in place over the users' mouth and nose by two elastic ear straps welded to the facemask. The color of the surgical mask is blue. The disposable surgical mask is available in three different specifications: 17.5*9.5cm, 14.5*9.5cm and 14.5*8cm. The device is single use and provided non-sterile and 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

ITEM	**Proposed Device K202341**	**Predicate Device K160269**	**Comparison**
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Indication for Use	The Disposable Surgical 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 and sterile. Models: 17.5*9.5cm-3ply (sterile), 14.5*9.5cm-3ply (sterile), 14.5*8cm-3ply (sterile), 17.5*9.5cm-3ply (non-sterile), 14.5*9.5cm-3ply (non-sterile), 14.5*8cm-3ply (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. 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	Similar
Configuration	ear strap nose clip mask body	ear strap/ Tie-on nose clip mask body	Similar
Dimension	17.5*9.5 cm 14.5*9.5 cm 14.5*8 cm	17.5*9 cm 18*9 cm	Different
Level	Level III	Level III	Same
Fluid Resistance	Pass at 160 mmHg	Pass at 160 mmHg	Same
Particulate efficiency level	Pass at >98.01%	Passed at 99.7%	Similar
Bacterial filtration level	Pass at >98.12%	Passed at >99%	Similar
Differential pressure	Pass at <4.6 mmH_2O/cm^2	Passed at 2.5 mmH_2O/cm^2	Similar
Flammability	Class 1	Class 1	Same

Patient Contacting Material				
Ear strap		Polyurethane	Polyester, polyurethane	Similar
Nose clip		Polyvinylchloride coated iron wire	Polyethylene coated steel wire	Different
Mask body	Outer material	Polypropylene	Polypropylene	Same
	Middle material	Polypropylene melt-blown	Polypropylene spun bond and Polypropylene melt-blown	Similar
	Inner material	Polypropylene	Polypropylene	Same
	Pigment	Blue PCTG Pigment	Unknown	Different
Biocompatibility				
Cytotoxicity		No Cytotoxicity	No Cytotoxicity	Same
Sensitization		No Sensitization	No Sensitization	Same
Irritation		No Irritation	No Irritation	Same
Sterilization				
Method		EO sterilized or non-sterile	Non-sterile	Different
SAL		10^{-6}	/	Different

7. Non-Clinical Test Conclusion

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:

- ISO 10993-5:2009 Biological evaluation of medical device- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-7:2008 Biological Evaluation of Medical Device- Part 7: Ethylene Oxide Sterilization Residuals
- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritaion and skin sensitization
- ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials. (Sterility)
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- ASTM F1886 / F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- 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 F2101-2017 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- BS EN 14683 Medical face masks — Requirements and test methods, Annex C: Method for

determination of breathability (differential pressure)

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

Based on the technological comparison and nonclinical tests described above, the subject devices, Disposable Surgical Masks, are as safe, as effective, and perform as well or better than the legally marketed predicate device cleared under K160269.