June 10, 2021

Hunan Triplex Precision Medical Devices Co., Ltd
℅ Amber Pang
Director
Landlink Healthcare Technology (Shanghai) Co., Ltd.
Room 703, 705, Building 1, West Guangzhong Road 555,
Shanghai, 200072
China

Re: K210767
Trade/Device Name: Surgical Masks, Model:FE-1
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: March 9, 2021
Received: March 15, 2021

Dear Amber Pang:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210767

Device Name
Surgical Masks

Indications for Use *(Describe)*
The 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(s), 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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Section 3-510(k) Summary

I. Submitter

Hunan Triplex Precision Medical Devices Co., Ltd.
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Preparation date: Jun. 01, 2021

II. Proposed Device

Trade Name of Device:	Surgical Masks
Common name:	Surgical Mask
Regulation Number:	21 CFR 878.4040
Regulatory Class:	Class II
Product code:	FXX
Review Panel	General Hospital

III. Predicate Devices

510(k) Number:	K160269
Trade name:	Surgical Face masks (Ear loops and Tie-on)
Common name:	Surgical Mask
Classification:	Class II
Product Code:	FXX
Manufacturer	San-M Package Co., Ltd.

IV. Device Description

The Surgical Masks are Flat Pleated type mask, utilizing Ear Loops way for wearing, and they all have Nose Piece design for fitting the face mask around the nose. The

Medical Procedure Masks are manufactured with three layers. The outer layer is made of double spun-bonded polypropylene (PP) non-woven fabric. The middle layer with filtration function is made of melt blown polypropylene (PP) non-woven fabric. The inner layer which contacts with face is made of double spun-bonded polypropylene (PP) non-woven fabric.
The Surgical Masks are single use, disposable device, provided non-sterile.

V. Indication for Use

The 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(s), provided non-sterile.

VI. Comparison of Technological Characteristics with the Predicate Devices

Table 10-1 General Comparison

Item	**Proposed Device**	**Predicate Device (K160269)**
Trade Name	Surgical Masks	Surgical Face masks (Ear loops and Tie-on)
Product Code	FXX	FXX
Regulation No.	21 CFR 878.4040	21 CFR 878.4040
Class	Class II	Class II
Mask Style	Flat-pleated, ear loops, 3 layers	Flat-pleated, ear loops or tie-on, 4 layers
Indication for Use	The 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(s),	The Surgical facemasks are intended to be worn to protect the patient and healthcare personnel from transfer of microorganisms, blood fluid, and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluid. This is a single-use, disposable devices

		provided non-sterile.	provided non-sterile.
Material	Inner layer	White double spun-bond polypropylene	Polypropylene
	Middle layer	Melt blown polypropylene filter	1. Polypropylene spun-bond 2. Polypropylene melt blown
	Outer layer	Blue double spun-bond polypropylene	Polypropylene
	Ear loops	85% Polyester +15% Spandex 3.0 Latex – free white elastic band	Ear loops: Polyester, polyurethane; Side tapes: Polyester spun-bond (ear loops mask only) Ties tapes: Polypropylene spun-bond or polyester spun-bond
	Nose piece	Iron wire covered by polypropylene	Polyethylene coated steel wire
Color		Blue	Blue ,white
Dimension		17.5cmx9.5cm	17.5cmx9.0cm 18.0cmx9.0cm
OTC Use		Yes	Yes
Sterile		Non-sterile	Non-sterile
For single Use		Yes	Yes
ASTM F2100 Level		Level 3	Level 1, Level 2, Level 3
Biocompatibility		Confirm to the requirements of ISO 10993 series standards	Confirm to the requirements of ISO 10993 series standards

VII. Non-Clinical Testing

Non clinical performance tests were conducted to verify that the proposed device met all design specifications. The below table shows the test results of test article, which demonstrated that the proposed device complies with the standards of ASTM F2100-19:

Methodology	Purpose	Acceptance Criteria	Results
ASTM F1862M-17	Fluid Resistance Performance	29 out of 32 pass at 160mmHg	Pass at 160mmHg
ASTM F2299	Particulate Filtration	≥98%	Pass

	Efficiency		
ASTM F2101-19	Bacterial Filtration Efficiency	≥98%	Pass
EN 14683:2019 Annex C	Differential Pressure	< 6.0mmH2O/cm²	Pass
16 CFR 1610	Flammability	Class I non flammable	Pass

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusion

The conclusion drawn from the non-clinical performance testing data demonstrates that the subject device is as safe, as effective, and performs as well as or better than the predicate device, Surgical Face masks (K160269).