July 8, 2021

Shantou T&K Medical Equipment Factory Co.,Ltd
% Stuart Situ
Director
Landlink Healthcare Technology (Shanghai) Co., Ltd.
Room 1308, Baohua International Plaza,
West Guangzhong Road 555
Shanghai, 200071
China

Re: K210380
Trade/Device Name: Medical surgical mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 26, 2021
Received: May 28, 2021

Dear Stuart Situ:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210380

Device Name
Medical surgical mask

Indications for Use *(Describe)*
The Medical surgical 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
K210380

I. Submitter

Shantou T&K Medical Equipment Factory Co.,Ltd
No.8 Workshop, Wanji South Second Street Shantou, Guangdong CN515065

Establishment Registration Number: 3016710550

Contact person: Wan Li
Position: Manager
Tel.: +86 15992258456
E-mail: triangel.wan@163.com

Preparation date: July.8, 2021

II. Proposed Device

Trade Name of Device:	Medical surgical mask
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 Medical surgical mask is 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 surgical mask is manufactured with three layers. The outer layer is made

of polypropylene (PP) non-woven fabric with blue color. The middle layer is filtration function and is made of polypropylene (PP) melt-blown non-woven fabric. The inner layer contact with face is made of polypropylene (PP) non-woven fabric with white color.
The Medical surgical mask is single use, disposable device, provided non-sterile.

V. Indication for Use

The Medical surgical 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.

VI. Comparison of Technological Characteristics with the Predicate Devices

Table 10-1 General Comparison

Item	Proposed Device (K210380)	Predicate Device (K160269)	Comparison
Trade Name	Medical surgical mask	Surgical Face masks (Ear loops and Tie-on)	Different
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	Class II	Class II	Same
Mask Style	Flat-pleated, ear loops, 3 layers	Flat-pleated, ear loops or tie-on, 4 layers	Different
Indication for Use	The Medical 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	The Surgical face masks 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.	Similar

	single use, disposable device, provided non-sterile.		

Material	Inner layer		Polypropylene	Different
	Middle layer	Polypropylene melt-blown non-woven fabric	1. Polypropylene spun-bond 2. Polypropylene melt blown	Similar
	Outer layer	Polypropylene nonwoven	Polypropylene	Similar
	Ear loops	Ear loops: Spandex Tie bands: Polypropylene nonwoven	Ear loops: Polyester, polyurethane; Side tapes: Polyester spun-bond (ear loops mask only) Ties tapes: Polypropylene spun-bond or polyester spun-bond	Different
	Nose piece	PP、PE, galvanized	Polyethylene coated steel wire	Different
Color		Blue	Blue ,white	Different
Dimension		17.5cmx9.5cm	17.5cmx9.0cm 18.0cmx9.0cm	Similar
OTC Use		Yes	Yes	Same
Sterile		Non-sterile	Non-sterile	Same
For single Use		Yes	Yes	Same
ASTM F2100 Level		Level 3	Level 1: Pass at 80mmHg Level 2: Pass at 120mmHg Level 3: Pass at 160mmHg	Similar

Biocompatibility	Confirm to the requirements of ISO 10993 series standards	Confirm to the requirements of ISO 10993 series standards	Same

V. 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 (3 Lots)
ASTM F1862M-17	Fluid Resistance Performance	29 out of 32 pass at 160mmHg	Pass
ASTM F2299	Particulate Filtration Efficiency	≥98%	Pass
ASTM F2101-19	Bacterial Filtration Efficiency	≥98%	Pass
EN 14683:2019 Annex C	Differential Pressure	< 6.0mmH_2O/cm²	Pass
16 CFR 1610	Flammability	Class I non flammable	Pass

VI. Clinical Testing

No clinical study is included in this submission.

VII.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).