November 17, 2021

Suzhou Letian Protective Products Co., Ltd.
% Ryan Li
RA Manager
Shanghai Mind-link Business Consulting Co., Ltd.
Room A08, Floor 14th, No 699, Jiaozhou Road, Jingan District
Shanghai, 200040
China

Re: K210042
Trade/Device Name: Disposable Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 22, 2021
Received: September 29, 2021

Dear Ryan Li:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210042

Device Name

Disposable Surgical Mask, Blue(Model: LT-0175A, LT-0145A)
Disposable Surgical Mask, White (Model: LT-0175B, LT-0145B)

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. The Disposable Surgical Masks are 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.

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510(K) Summary-K210042

I. SUBMITTER:

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Summary prepared：September 17th, 2021

II. DEVICE

Name of Device: Disposable Surgical Mask
Regulation Number: 21 CFR PART 878.4040
Common Name: Surgical Mask
Classification Name: Surgical Mask
Regulatory Class: II

Product Code: FXX

III. PREDICATE DEVICE

Primary predicate device: Surgical Face Masks (K182514)

IV. REFERENCE DEVICE

Reference device: Face Mask (K210007)

V. DEVICE DESCRIPTION

Disposable Surgical Mask is composed of three layers and is flat-pleated. The mask materials consist of an outer layer (spun-bond polypropylene), a middle layer, between the outer layer and inner layers (melt-blown polypropylene), and an inner layer (spun-bond polypropylene). Each mask contains ear loops to secure the mask over the users' mouth and face and includes a malleable nose piece (High-density Polyethylene) to provide a firm fit over the nose.

There are four models for Disposable Surgical Mask with different colors and sizes. All six models are Ear Loop type in blue or white colors and two sizes including 145mm×90mm and 175×95mm.

VI. AVAILABLE MODELS

REF No.	Product Size	Model Description		Mask Color	
		Mask	Ear Loop	Blue	White
LT-O145A	145×90mm	X	X	X	
LT-O175A	175×95mm	X	X	X	
LT-O145B	145×90mm	X	X		X
LT-O175B	175×95mm	X	X		X

VII. INDICATIONS 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. The Disposable Surgical Face Masks are single use, disposable device, provided non-sterile.

VIII. TECHNOLOGICAL CHARACTERISTICS COMPARISON

The Disposable Surgical Masks are compared with the predicate device (Surgical Face Masks (K182514)):

Device	Subject Device Disposable Surgical Mask (K210042)	Primary Predicate Device Surgical Face Mask (K182514)	Comparison
Intended Use	The Disposable 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. The Disposable Surgical Face Masks are 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
Classification **Product Code**	FXX	FXX	Same
Ear Loop **Model**	Ear Loops	Ear Loops	Same
Outer Facing Layer	Spun-bond polypropylene non-woven fabric	Spun-bond polypropylene	Similar Note 1
Middle Layer	Melt-blown polypropylene	Melt blown polypropylene filter	Similar Note 1
Inner Facing Layer	Spun-bond polypropylene non-woven fabric	Spun-bond polypropylene	Similar Note 1
Nose Piece	High-density polyethylene	Malleable aluminum wire	Similar Note 1
Ear Loops	80% Spandex 20% Polyester	Polyester	Similar Note 1
Color	Blue, white	White	Different Note 1

Style	Flat - Pleated	Flat - Pleated	Same
Multiple Layers	3 Layers	3 Layers	Same
Single Use	Single use	Single use	Same
Sterile	Non-sterile	Non-sterile	Same
Length ×Width	145×95mm (±10mm) 175×95mm (±10mm)	Length: 95 ± 10mm Width:175 ± 10mm	Different Note 2
Fluid Resistance ASTM F1862	32 out of 32 pass at 120mmHg	32 out of 32 pass at 120mmHg	Same
Particulate Filtration Efficiency (PFE) ASTM F2299	Pass at ≥99.5%	Pass at 99.88%	Similar
Bacterial Filtration Efficiency (BFE) ASTM F2101	Pass at ≥99.9%	Pass at 99.6%	Similar
Differential Pressure (Delta P) MIL-M-36954 C	Pass at ＜4.3mmH_2O/cm^2	Pass at 3.0 mmH_2O/cm^2	Similar
Flammability 16 CFR PART 1610	Class 1 Non-Flammable	Class 1 Non-Flammable	Same
Cytotoxicity	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	Same
Irritation	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	Same

Sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	Same

Comparison in Detail(s):
Note 1:

Although the material including outer facing layer, middle layer, inner facing layer, nose piece and ear loops, as well as the color of the subject device and the color is different from the predicate device.

Note 2:

Although LT-O145A and LT-O145B models of the subject device are smaller than the predicate device, these models match the dimension with reference device (K210007, Model: Type A), the barrier protection performance of the subject device is same with the barrier protection performance of predicate device and the reference device, which is the Level 2 barrier protection.

IX. PERFORMANCE DATA

Non-Clinical Performance Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications found in the test methodology and standard using 3 nonconsecutive lots. The test results demonstrated that the Disposable Surgical Masks complies with the following standards:

- ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F1862 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- EN 14683:2019+AC2019(E) Annex C

  ASTM F2299 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- ASTM F2101 Standard Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological

Aerosol of Staphylococcus aureus

- MIL-M- 36954C Military Specification, Mask, Surgical, Disposable
- 16 CFR Part 1610 Standard for the Flammability of Clothing
- ISO10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity of medical devices
- ISO10993-10 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization

Test Methodology	Purpose	Acceptance Criteria	Results
Bacterial Filtration Effciency	The test was performed in accordance with 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 to determine the bacterial filtration efficiency(BFE) of	Level 2≥98%	32/32 Passed at ≥99.9%
Particulate Filtration Efficiency	The test was performed in accordance with ASTM F2299 Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres to determine the particle filtration efficiency (PFE) of	Level 2≥98%	32/32 Pass at ≥99.5%
Differential Pressure	The test was performed in	Level 2<6.0mmH2O/cm^2	32/32 Pass at ＜4.3

(delta-P)	accordance with EN 14683:2019+AC;2019(E) Annex C		mmH2O/cm^2
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	The test was performed in accordance with ASTM F1862/F1862M Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (HorizontalProjection of Fixed Volume at a Known Velocity) to evaluate the effectiveness of the test sample from possible exposure to blood and other body fluids.	Level2: No penetration at 120 mmHg	32/32 Passed at 120mmHg
Flammability	The test was performed in accordance with 16 CFR Part 1610 Standard for the Flammability of Clothing to measure the flammability of masks	Level 2: Class 1	32/32 Passed Class 1 requirement

Clinical Test Conclusion

No clinical study is included in this submission.

X. CONCLUSION

The conclusion drawn from the nonclinical tests demonstrates that the subject device, the Disposable Surgical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device Surgical Face Masks (K182514).