June 10, 2021

Lucky Textile Industrial(Wuxi) Co.,Ltd.
Grace Tai
General Manager Assistant
No.10 Zhuqiao Road, Yixing Economic and
Technological Development Zone ,Yixing, Jiangsu, China
Yixing, Jiangsu 214200
China

Re: K203756
Trade/Device Name: Disposable Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: May 8, 2021
Received: May 13, 2021

Dear Grace Tai:

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, 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)*
K203756

Device Name
Disposable Surgical Mask

Indications for Use *(Describe)*

When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate materials. This device is non sterile and for single use only.

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

510(k) Number: K203756

Date Prepared: June 10,2021

1. Submission Sponsor

Manufacturer information	Company: Lucky Textile Industrial(Wuxi) Co.,Ltd. Company address: No.10 Zhuqiao Road, Yixing Economic and Technological Development Zone ,Yixing, Jiangsu, China. Contact person: Grace Tai Phone: + 8 6 - 5 1 0 - 8 0 1 9 2 8 9 0 Fax: / E-mail: lqsy@luckytextiles.cn

2. Submission correspondent

Name	Lucky Textile Industrial(Wuxi) Co.,Ltd.
Address/Post Code	No.10 Zhuqiao Road, Yixing Economic and Technological Development Zone ,Yixing, Jiangsu, China.
Phone No.	+86-510-80192890
Contact Person	Grace Tai
Email	lqsy@luckytextiles.cn

3. Device Identification

Type of 510(k) submission:	Traditional
Trade Name:	Disposable Surgical Mask
Model:	
Classification name:	Mask, Surgical
Review Panel:	Surgical Apparel
Product Code:	FXX
Device Class:	II
Regulation Number:	21 CFR 878.4040

4. Legally Marketed Predicate Device

Trade Name	Surgical face mask
Regulation number	21 CFR 878.4040
Regulation class	II
Regulation name	Surgical face mask
510(k) Number	K203756
Product Code	FXX
Manufacturer	Lucky Textile Industrial(Wuxi) Co.,Ltd.

5. Device Description

The surgical face masks are single use, 3 layers, flat-pleated style with ear loops and nose piece. The outer layer and inner facing layer of face mask consist of Spun-bond Polypropylene, and the middle layer consists of Melt Blown Polypropylene Filter. Each mask contains ear loops to secure the mask over the user's face and mouth with nose piece to firmly fit over the nose.

6. Intended Use/ Indications for Use

When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate materials. This device is non sterile and for single use only.

7. Technological characteristics comparison

Comparison item	Subject Device: Disposable Surgical Mask(K203756)	Predicate Device: Single-use Surgical Mask (K200847)	Comments
Product Code	FXX	FXX	Same
Regulation Number	21 CFR § 878.4040	21 CFR § 878.4040	Same
Classification	Class II	Class II	Same
Use (OTC/RX)	OTC	OTC	Same
Intended Use &	When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate materials. This device is non sterile and for single use only.	When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and airborne particles. This device is non-sterile and for single use only.	Same

Comparison item	Subject Device: Disposable Surgical Mask (K203756)	Predicate Device: Single-use Surgical Mask (K200847)	Comments
Indications for Use	When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate materials. This device is non sterile and for single use only.	When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and airborne particles. This device is non-sterile and for single use only.	
Design feature	3 Ply, Ear Loops, Flat-Pleated Style	3 Ply, Ear Loops, Flat-Pleated Style	Same
Usage	Single use	Single use	Same
Color	Blue	White	Different Issue 1
Size	9.5cm ± 0.5cm(Width) 17.5cm ± 0.5cm(Length)	9.0cm ± 0.5cm(Width) 17.5cm ± 0.5cm(Length)	Similar Issue 2
Sterilization Status	Non-sterile	Non-sterile	Same
Material	Outer layer: Spun-bond polypropylene	Outer layer: Spun-bond polypropylene	Same
	Middle layer: Melt blown polypropylene filter	Middle layer: Melt blown polypropylene filter	Same
	Inner layer: Spun-bond polypropylene	Inner layer: Spun-bond polypropylene	Same
	Nose piece: Single Galvanize Wire, Coated By PE	Nose piece: Single Galvanize Wire, Coated By PE	Same

Comparison item	Subject Device: Disposable Surgical Mask(K203756)	Predicate Device: Single-use Surgical Mask (K200847)	Comments
	Ear-Piece: Spandex	Ear-Piece: not made with natural rubber latex	Same
ASTM F 2100 Level	Level 3	Level 2	Issue 3
Fluid Resistance Performance ASTM F 1862-13	Lot 1: 32 Out of 32 pass at 160 mmHg Lot 2: 32 Out of 32 pass at 160 mmHg Lot 3: 32 Out of 32 pass at 160 mmHg	30 Out of 32 pass at 120 mmHg	Different Issue 4
Particulate Filtration Efficiency ASTM F 2299	Lot 1:99.8% Lot 2:99.9% Lot 3: 99.9%	99.9%	Same
Bacterial Filtration Efficiency ASTM F 2101	Lot 1: > 99.9% Lot 2: > 99.9% Lot 3: > 99.9%	> 99.9%	Same
Differential Pressure (Delta P) EN 14683:2019+ AC：2019	Lot 1: 3.4 mmH_20/cm^2 Lot 2: 3.5 mmH_20/cm^2 Lot 3: 3.3 mmH_20/cm^2	3.0 mmH_20/cm^2	Same
Flammability 16CFR 1610	Lot 1: Class 1 Lot 2: Class 1 Lot 3: Class 1	Class 1	Same
Cytotoxicity	Comply with ISO 10993-5 Non cytotoxic	Comply with ISO 10993-5 Non cytotoxic	Same
Irritation	Comply with ISO 10993-10 Non irritating	Comply with ISO 10993-10 Non irritating	Same
Sensitization	Comply with ISO 10993-10 Non sensitizing	Comply with ISO 10993-10 Non sensitizing	Same

Discuss of Comments:

Issue 1: The composition of colorants are Phthalocyanine Blue BGS (CAS No.147-14-8) and Pigment Violet 23 (CAS No. 6358-30-1), we provided the MSDS of color additive used in our manufacturing process.

Issue 2: The width dimension of subject is a little longer than that of predicate device, this difference does not affect the safety and effectiveness.

Issue 3: Subject device comply with ASTM F 2100 Level 3, and we have done corresponding performance tests.

Issue 4:The test result of Fluid Resistance Performance meets the requirement of ASTM F 2100 Level 3.

8. Summary of Non-clinical Testing

Non-clinical tests were conducted and conformed to the following standards and the requirements state in the Guidance for Industry and FDA Staff: Surgical Masks - Premarket Notification [510(k)] Submission issued on March 05, 2004.

Standards: List as Applicable

- ASTM F2100-19 Standard Specification For Performance of Materials used in Medical Face Masks.
- ASTM F1862-13 Standard Test Method For Resistance of Medical Face Masks to Penetration by Synthetic Blood.
- ASTM F2299-03 Stand Test Method For Determining The Initial Efficiency Of Materials Used In Medical Face Masks To Penetration By Particulates Using Latex Spheres.
- ASTM F 2101-19 Standard Test Method For Evaluating The Bacterial Filtration Efficiency (BFE) Of Surgical face mask Materials, Using A Biological Aerosol Of Staphylococcus Aureus.
- 16 CFR 1610 Standard For The Flammability Of Clothing Textiles.
- ISO 10993-5: 2009 Biological Evaluation Of Medical Devices – Part 5: Tests For In Vitro Cytotoxicity.
- ISO 10993-10: 2010 Biological Evaluation Of Medical Devices – Part 10: Tests For Irritation And Skin Sensitization.

Table 2: Performance Characteristic Comparison

Test Methodology	Purpose	Acceptance Criteria	Results
Fluid Resistance Performance (ASTM F1862)	The test method is used to evaluate the resistance of medical face masks to penetration by the impact of a small volume(~2 mL) of high-velocity stream of synthetic blood. The pass/fail determinations are based on visual detection of synthetic blood penetration.	29 Out of 32 pass at 160 mmHg	Lot 1: 32 Out of 32 pass at 160 mmHg Lot 2: 32 Out of 32 pass at 160 mmHg Lot 3: 32 Out of 32 pass at 160 mmHg **Pass**
Particulate Filtration Efficiency （ASTM F2299）	The purpose of this test method is to measure the initial partical filtration efficiency of materials using monodispersed aerosols containing suspended latex spheres particulates of 0.1μm diameter.	≥ 98%	Lot 1:99.8％ Lot 2:99.9％ Lot 3: 99.9％ **Pass**
Bacterial Filtration Efficiency (ASTM F2101)	The purpose of this test method is to determine the bacterial filtration efficiency of the mask as specified in ASTM F2101.	≥ 98%	Lot 1: > 99.9% Lot 2: > 99.9% Lot 3: > 99.9% **Pass**
Differential Pressure (EN 14683:2019)	The purpose of this test s to measure the differential pressure between the inside and outside of the mask.	< 6.0 mmH_20/cm^2	Lot 1: 3.4 mmH_20/cm^2 Lot 2: 3.5 mmH_20/cm^2 Lot 3: 3.3 mmH_20/cm^2 **Pass**
Flammability (16 CFR 1610)	The purpose of this test method is to determine the flammability charateristics of the mask as specified in 16 CFR Part 1610. Materials in the construction of medical face masks shall meet the requirements for Class 1, normal flammability specified in 16 CFR Part 1610.	Class 1	Lot 1: Class 1 Lot 2: Class 1 Lot 3: Class 1 **Pass**

Table 3: Biocompatibility Comparison

Test Methodology	Purpose	Acceptance Criteria	Results
Cytotoxicity	The purpose of the test is to determine the biological reactivity of a mammalian cell culture (mouse fibroblast L929cells) in response to the test article.	Non-Cytotoxic	Under the conditions of the study, non-cytotoxicity effect
Irritation	To evaluate the potential skin irritation caused by the extraction of the test article extract contacting with the skin surface of rabbits.	NonSensitizing	Under the conditions of the study, non-irritation
Sensitization	To evaluate the potential of test article extracts to cause skin sensitization in the guinea pig according to GPMT method.	Non-Irritating	Under the conditions of the study, non-sensitization

9. Brief discussion of clinical tests

No clinical tests were performed, or discuss as applicable.

10. Conclusions

The conclusion drawn from the nonclinical tests demonstrates that the subject device in this 510(k) submission K203756, the Disposable Surgical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K200847.