August 18, 2021

Jiangsu Xingtong Biotechnology Group Co., Ltd.
℅ James Tsai
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square,
Nanshan District
Shenzhen, Guangdong 518000
China

Re: K211454
Trade/Device Name: Surgical mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 6, 2021
Received: July 12, 2021

Dear James Tsai:

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, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211454

Device Name
Surgical mask

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, and provided as sterile.

Level 3 Surgical mask model (Ear-loop): XT10A1
Level 3 Surgical mask model (Tie-on): XT10B1

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

K211454

1. Administrative Information

Date of Summary prepared	August 5, 2021
Manufacturer information	Company: Jiangsu Xingtong Biotechnology Group Co., Ltd. Company address: No.8, Kele road, Touqiao Area, Beizhou Industrial Park, Guangling Zone, Yangzhou City, China Contact person: Li Hua Tel: +86-0514-87485222 Fax: +86-0514-87481010 E-mail: 920740335@qq.com
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. Address: 1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen Contact person: James Tsai E-Mail: james_tsai@cefda.com; field@cefda.com

2. Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Surgical mask
Classification name:	Surgical Face Mask, Apparel
Review Panel:	General and plastic surgery devices
Product Code:	FXX
Common name	Surgical mask
Device Class:	II
Regulation Number:	878.4040

3. Predicate Device Information

Sponsor:	SAN-M PACKAGE CO., LTD.
Device trade name:	Surgical face mask (Ear loops and Tie-on)
Device Class:	II
510(K) Number:	K160269

Regulation name	Masks, Surgical
Production regulation:	21 CFR §878.4040
Product code:	FXX
Review Panel:	General and plastic surgery devices

4. Device Descriptions

The surgical mask consists of a mask body, a nose piece, and ear loops or ties. The mask body is divided into three layers, the inner and outer layers are made of polypropylene materials; the middle layer is composed of melt-blown cloth (polypropylene); the nose piece is made of polyethylene coated steel wire, the ear loops are made of polyester silk & polyurethane filament, and the ties are made of polypropylene.
The size specification of the surgical mask:
- Mask body for ear-loop type: 17.5cm×9.5cm & 14.5cm×9.5cm;
- Mask body for Tie-on type: 17.5cm×9.5cm

5. Indications 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, provided as sterile.

6. Technological Characteristics Comparison

Comparison item	Proposed Device (Jiangsu Xingtong Biotechnology Group Co., Ltd.)	Predicate Device (K160269, SAN-M PACKAGE CO., LTD.)	Remark
Product name	Surgical mask	Surgical face mask	Similar
Product model	Ear loops: XT10A1; Tie-on: XT10B1	Ear loops: EL 30000; Tie-on: TO 30000	Similar
Product Code	FXX	FXX	Same
Classification	Class II (21 CFR 878.4040)	Class II (21 CFR 878.4040)	Same
Intended use & Indications 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	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	Similar

	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 as sterile.	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.	
Mask features	Ear Loops and Tie-on; Flat Pleated	Ear Loops and Tie-on; Flat Pleated	Same
Layers	3 layers	4 layers	Different
Outer layer	Polypropylene	Polypropylene	Same
Filter media	Melt-blown cloth (polypropylene)	Polypropylene spunbond Polypropylene meltblown	Different
Inner layer	Polypropylene	Polypropylene	Same
Ear loops	-Ear loops: Polyester silk & Polyurethane filament -Ties: Polypropylene	-Ear loops: Polyester, polyurethane -Side tapes: Polyester spunbond (ear loops mask only) -Tie tapes: Polypropylene spunbond or polyester spunbond	Similar
Nose piece	Polyethylene coated steel wire	Polyethylene coated steel wire	Same
Color	Blue	White or Blue	Similar
Dimension	Mask body for ear-loop type: 17.5cm×9.5cm & 14.5cm×9.5cm Mask body for Tie-on type: 17.5cm×9.5cm	Mask body for both ear-loop and tie-on types: 17.5cm×9.0cm & 18.0cm×9.0cm	Different
OTC Use	Yes	Yes	Same
Sterility	Sterile	Non-sterile	Different
Packaging material	Paper plastic bag	Not publicly available	Different
Sterilization method and S.A.L.	Sterilized by ethylene oxide gas, SAL=10^{-6}	Not applied	Different
Shelf life	2 years	No shelf life claim	Different
Use	Single-use, disposable	Single-use, disposable	Same
Performance	Level 3	Level 3	Same

level			
Fluid Resistance Performance	32 Out of 32 pass at 160mmHg (ASTM F1862)	32 Out of 32 pass at 160mmHg (ASTM F1862)	Same
Particulate Filtration Efficiency	Pass at ⩾ 98% (ASTM F2299)	Pass at ⩾ 98% (ASTM F2299)	Same
Bacterial Filtration Efficiency	Pass at ⩾ 98% (ASTM F2101)	Pass at ⩾ 98% (ASTM F2101)	Same
Differential Pressure (Delta-P)	Pass at <6mm H_2O/cm^2 (EN 14683:2019)	Pass at <5mm H_2O/cm^2 (MIL-M36945C)	Different
Flammability	Pass at Class I (16 CFR 1610)	Pass at Class I (16 CFR 1610)	Same
Cytotoxicity ISO 10993-5	Under the conditions of the study, the subject device was non-cytotoxic	Under the conditions of the study, the subject device was non-cytotoxic	Same
Sensitization ISO 10993-10	Under the conditions of the study, the subject device was non-sensitizing	Under the conditions of the study, the subject device was non-sensitizing	Same
Irritation ISO 10993-10	Under the conditions of the study, the subject device was non-irritating	Under the conditions of the study, the subject device was non-irritating	Same

Both of the proposed device and predicate device conform to ASTM F2100, the difference is the versions of the standard, the proposed device was tested by the latest version, and this difference will not raise any new safe and effective issue.

From the comparison table and the gaps analysis above, the differences in the materials, layers, sizes, sterility status and packaging material will not raise any new issue for safety and effectiveness. Physical performance tests and biocompatibility evaluation have been carried out on the finished devices; EO sterilization validation has also been provided to prove the product sterility and performance; Accelerated aging test validates the shelf life of the proposed device.

In summary, the performance and biocompatibility testing of the subject device meet all the requirements of standards of ASTM F2100 and ISO 10993-5 &-10. So, the differences between the predicate device and subject device will not raise any new issue of safety and effectiveness of the subject device.

7. Summary of Non-clinical Testing

The following performance data of proposed device was provided in support of the substantial equivalence determination:

Biocompatibility testing

The biocompatibility evaluation for the proposed device was conducted in accordance with the International Standard ISO 10993-1: 2018 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process," as recognized by FDA. The outer layer, inner layer and ear loops or tie-on are considered to be contacted with patient's intact face skin for duration of less than 24 hours. And the biocompatibility evaluation included the following tests:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

Physical performance testing

Physical performance was conducted, and the results show that the proposed device complies with the following standards:

- ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks

Ethylene oxide Sterilization Validation

The proposed device is also provided for sterility, sterilization validation is performed and the results show that the proposed device complies with the following standards:

- ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]
- ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ASTM F88-2015 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1929-2015 Standard test method for detecting seal leaks in porous medical packaging by dye penetration

Summary

Based on the non-clinical performance data as documented above in the device development, the proposed device has a safety and effectiveness profile that is similar to the predicate device, the testing results are summarized in the following table:

Name of Test Methodology (standard)	Purpose	Acceptance Criteria	Results
			Sterile mask
ASTM F	Fluid Resistance	29 out of 32	Lot 1# pass at 160mmHg;

1862-17	Performance	pass at 160 mmHg	Lot 2# pass at 160mmHg; Lot 3# pass at 160mmHg
ASTM F2101-19	Bacterial Filtration Efficiency Performance	≥ 98%	Lot 1# 99.7%-99.9%; Lot 2# 99.7%-99.9%; Lot 3# 99.7%-99.9%
EN 14683: 2019	Differential Pressure (Delta-P)	< 6.0mm H_2O/cm^2	Lot 1# 2.3-4.6; Lot 2# 2.3-4.5; Lot 3# 2.0-3.9
ASTM F2299-2007	Particulate Filtration Efficiency Performance	≥ 98%	Lot 1# 99.2%-99.8%; Lot 2# 99.0%-99.7%; Lot 3# 99.3%-99.7%
16 CFR Part 1610	Flammability	Class I	Lot 1# Class I; Lot 2# Class I; Lot 3# Class I
ISO 10993-5	Cytotoxicity	Non-cytotoxic	Under the conditions of the study, the subject device was non-cytotoxic
ISO 10993-10	Sensitization	Non-sensitizing	Under the conditions of the study, the subject device was non-sensitizing
ISO 10993-10	Irritation	Non-irritating	Under the conditions of the study, the subject device was non-irritating

8. Brief discussion of clinical tests

No clinical tests were performed.

9. Conclusions

The conclusion drawn from the nonclinical tests demonstrates that the subject device in this 510(K) submission, the surgical mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K160269.