October 11, 2022

Luoyang Sunmed Devices Co., Ltd.
% Ms. Grace Liu
Consultant
Shenzhen Joyantech Consulting Co. Ltd
1713A, 17th Floor, Block A, Zhongguan Times Square,
Nanshan District
Shenzhen, Guangdong 518000
China

Re: K222335
Trade/Device Name: Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 2, 2022
Received: August 3, 2022

Dear Ms. Liu:

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,

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K222335

Device Name
Surgical Mask

Indications for Use *(Describe)*
The product is intended to be worn to protect both the patients and healthcare personnel from transfer of microorganisms, body fluids and particulate materials. These masks are intended for adult 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/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 - K222335

1. Contact Details

1.1 Applicant information

Applicant Name	Luoyang Sunmed Devices Co., Ltd.
Address	No. 8 Huaxia Road, Hi-Tech Zone, Luoyang Area of China (Henan) Pilot Free Trade Zone
Contact person	Tian Qian
Phone No.	+86-18637911566
E-mail	qtian@suntech-power.com
Date Prepared	2022-08-02

1.2 Submission Correspondent

卓远天成	Shenzhen Joyantech Consulting Co., Ltd 1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen, Guangdong Province, China
Phone No.	+86-755-86069197
Contact person	Grace Liu; Field Fu;
Contact person's e-mail	grace@cefda.com; field@cefda.com
Website	http://www.cefda.com

2. Device Information

Trade name	Surgical Mask
Common name	Surgical Face Mask
Classification name	Mask, Surgical
Review Panel	General Hospital
Product code	FXX
Device Class	II
Regulation No.	21 CFR 878.4040

3. Legally Marketed Predicate Device

Primary predicate device

Trade Name	Surgical Face Masks (Sterile), Surgical Face Masks (Non-sterile)
510(k) Number	K202843
Product Code	FXX
Manufacturer	B.J.ZH.F.Panther Medical Equipment Co., Ltd.

Additional predicate device

Trade Name	Surgical Face Mask (Non-sterile)
510(k) Number	K212398
Product Code	FXX
Manufacturer	Hubei Kimsoul Industrial Co., Ltd

4. Device Description

The proposed devices are three-layer, flat pleated masks. It has two design styles, i.e. earloop and tie-on. Each mask is composed of a mask body, a nose piece, two ear loops or four tie tapes.

The mask body is manufactured with three layers, the inner layer and the outer layer are made of polypropylene spunbond nonwoven fabric, and the middle layer is made of polypropylene meltblown nonwoven fabric.

The proposed device is held in place over the user's mouth and nose by two elastic ear loops or four tie tapes welded to the mask body. The elastic ear loops are knitted elastic loops (made of nylon and spandex), and the tie tapes are made of polypropylene nonwoven fabric.

The nose piece is enclosed between the layers of face mask to allow the user to fit the face mask around their nose, which is an iron wire with polypropylene covering.

The proposed devices can simultaneously meet the requirements for the performance class of level 2 and level 3 specified in ASTM F2100.

Both of the two design styles are available non-sterile or sterile. They are intended to be single use, disposable devices.

5. Intended Use/Indication for Use

The product is intended to be worn to protect both the patients and healthcare personnel from transfer of microorganisms, body fluids and particulate materials. These masks are intended for adult 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/sterile.

6. Technological Characteristics Comparison

Table 1 Technological Characteristics Comparison Table

Comparison item	Proposed Device (K222335)	First Predicate Device (K202843)	Second Predicate Device (K212398)	Comment
Manufacturer	Luoyang Sunmed Devices Co., Ltd.	B.J.ZH.F.Panther Medical Equipment Co., Ltd.	HUBEI KIMSOUL INDUSTRIAL CO., LTD	None
Product name	Surgical Mask	Surgical Face Masks (Sterile), Surgical Face Masks (Non-sterile)	Surgical Face Mask (Non-sterile)	None
Product Code	FXX	FXX	FXX	Same
Regulation Number	21 CFR § 878.4040	21 CFR § 878.4040	21 CFR § 878.4040	Same
Classification	Class II	Class II	Class II	Same

OTC use	Yes	Yes	Yes	Same
Indications for Use	The product is intended to be worn to protect both the patients and healthcare personnel from transfer of microorganisms, body fluids and particulate materials. These masks are intended for adult 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/sterile.	The Surgical Face Mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.	The masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These masks are intended for adult 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.	Similar
Mask style	Flat-pleated, 3 layers	Flat-pleated, 3 layers	Flat-pleated, 3 layers	Same
Design feature	Ear loop/Tie-on	Ear loop/Tie-on	Ear-loop	Same
Single use	Yes	Yes	Yes	Same
Color	Blue	Blue	White	Same
Specifications and dimensions	1. 145mm×95mm Nose piece: 85mm×3.0mm Ear loop: 155mm×3.5mm Tie tape: N.A. 2. 175mm×95mm: Nose piece: 100mm×3.0mm Ear loop: 190mm×3.5mm Tie tape: 890mm×8.5mm	1. 14.5cm×9cm: Nose clip: 85mm×2.9mm Ear loop: 180mm×3mm Ties: 910mm×10mm 2. 17.5cm×9.5cm: Nose clip: 100mm×2.9mm Ear loop: 180mm×3mm Ties: 910mm×10mm	1. 145mm × 95mm Nose piece: 95mm×2.8mm Ear loop: 160mm×3.5mm Tie tape: N.A. 2. 175mm×95mm Nose piece: 105mm×2.8mm Ear loop: 165mm×3.5mm Tie tape: N.A.	Similar
Sterility	Non-sterile/Sterile	Non-sterile/Sterile	Non-Sterile	Same
Sterilization method	EO (SAL: 10^{-6})	EO (SAL: 10^{-6})	N.A.	Same
ASTM F2100 Level	Level 2, Level 3	Level 2	Level 3	Different
Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Materials				
Outer layer	Polypropylene spunbond nonwoven	Polypropylene spunbond nonwoven	Polypropylene spunbond nonwoven	Same
Middle layer	Polypropylene meltblown nonwoven	Polypropylene meltblown nonwoven	Polypropylene meltblown nonwoven	Same

Inner layer	Polypropylene spunbond nonwoven		Polypropylene spunbond nonwoven	Polypropylene spunbond nonwoven	Same
Nose piece	Iron wire with polypropylene covering		Medical polypropylene and Q235	Polyethylene (PE)	Different
Ear loop	Nylon and spandex		Nylon and spandex	Polyester and Polyurethane	Same
Tie tape	Polypropylene spunbond nonwoven		Polypropylene spunbond nonwoven	N.A.	Same
Performances					
/	Sterile	Non-sterile	Surgical Face Masks (Sterile), Surgical Face Masks (Non-sterile)	Surgical Face Mask (Non-sterile)	/
Fluid Resistance (ASTM F1862)	Pass at 120mmHg and 160mmHg	Pass at 120mmHg and 160mmHg	Pass at 120mmHg	Pass at 160 mmHg	Different
Particulate Filtration Efficiency (ASTM F2299)	Average: 98.38%	Average: >99.99%	Average: 98.98%	Average: 99.6%	
Bacterial Filtration Efficiency (ASTM F2101)	Average: 99.6%	Average: >99.9%	Average: 98.92%	Average: ≥99.9%	
Differential Pressure (Delta P) (EN 14683)	Average: 2.7 mmH_2O/cm^2	Average: 5.5 mH_2O/cm^2	Average: 4.4 mmH_2O/cm^2	Average: 3.7 mmH_2O/cm^2	
Flammability (16CFR 1610)	Class 1	Class 1	Class 1	Class 1	
Biocompatibility	ISO 10993-5 and ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic, non-sensitizing, and non-irritating.		ISO 10993-5 and ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic, non-sensitizing, and non-irritating.	ISO 10993-5 and ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic, non-sensitizing, and non-irritating.	Same

The proposed device has the similar indication for use as the two predicate devices as well as comparable technical and biocompatibility properties and characteristics, and the differences don't raise any additional questions for safety and effectiveness, therefore, the proposed device is substantially equivalent to the predicate device.

7. Summary of Non-clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications as

similar to the predicate device. The tests were conducted according to the following standards, and the results conducted on the representative models, the sterile earloop masks and non-sterile earloop masks with the largest size, demonstrated that the proposed device complies with the following standards (see Table 2 and 3):

- ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- 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
- ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- EN 14683:2019+AC:2019 Medical Face Masks - Requirements and Test Methods
- ASTM F2299/F2299M-03(R2017) Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- 16 CFR 1610 Standard for the Flammability of Clothing Textiles
- 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
- ISO 11737-2:2019 Sterilization of medical devices - Microbiological methods - Part 2 Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ISO 10993-7:2008 Biological evaluation of medical devices Part 7 Ethylene oxide sterilization residuals
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Device
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F1886M-2016 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

Table 2 Summary of Performance Testing

Test	**Purpose**	**Acceptance Criteria** per ASTM F2100-19 (AQL=4.0%)	**Results** (Statistics of three lots, 32 per lot)	
			Sterile erarloop mask, 175*95mm	Non-sterile erarloop mask, 175*95mm
Fluid Resistance (ASTM F1862)	Verify the fluid resistance of the proposed device can meet the requirements for Level 2 and 3 specified in ASTM F2100-19.	Level 2: Pass at 120 mmHg	96 out of 96 pass at 120 mmHg	96 out of 96 pass at 120 mmHg
		Level 3: Pass at 160 mmHg	96 out of 96 pass at 160 mmHg	94 out of 96 pass at 160 mmHg[1]
Bacterial filtration efficiency (BFE) (ASTM F2101)	Verify the bacterial filtration efficiency of the proposed device can meet the requirements for Level 2 and 3 specified in ASTM F2100-19.	Level 2: ≥98%	99.4%~99.7% (Average: 99.6%)	>99.9% (Average: >99.9%)
		Level 3: ≥98%		
Particulate filtration efficiency (PFE) (ASTM F2299)	Verify the particulate filtration efficiency of the proposed device can meet the requirements for Level 2 and 3 specified in ASTM F2100-19.	Level 2: ≥98%	97.64%~99.11% [2] (Average: 98.38%)	99.88%~>99.9977% (Average: >99.99%)
		Level 3: ≥98%		
Differential pressure (Delta-P) (EN 14683)	Verify the differential pressure of the proposed device can meet the requirements for Level 2 and 3 specified in ASTM F2100-19.	Level 2: <6.0 mmH_2O/cm^2	(2.4~3.4) mmH_2O/cm^2 (Average: 2.7 mmH_2O/cm^2)	(4.3~5.9) mmH_2O/cm^2 (Average: 5.5 mmH_2O/cm^2)
		Level 3: <6.0 mmH_2O/cm^2		
Flammability (16 CFR 1610)	Verify the flammability of the proposed device can meet the requirements for Level 2 and 3 specified in ASTM F2100-19.	Level 2: Class 1	Class 1	Class 1
		Level 3: Class 1		

Note:

1 Two samples (one sample per lot in two lots among the three lots) don't meet the acceptance criteria.

2 Only one data (97.64%) doesn't meet the acceptance criteria.

Table 3 Summary of Biocompatibility Testing

Test	Purpose	Acceptance Criteria	Result
In vitro Cytotoxicity (ISO 10993-5)	Verify that the proposed device extract is non-cytotoxic.	The extract is non-cytotoxic under the research conditions.	Pass
Skin Irritation (ISO 10993-10)	Verify that the proposed device extract is non-irritating.	The polar and non-polar extracts are non-irritating under the research conditions.	Pass
Skin Sensitization (ISO 10993-10)	Verify that the proposed device extract is non-sensitizing.	The polar and non-polar extracts are non-sensitizing under the research conditions.	Pass

8. Clinical testing

Clinical testing was not performed for the proposed device.

9. Conclusion

The nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed device (K202843 and K212398).