December 13, 2022

Xiantao Sanda Industrial Co., Ltd
℅ Bryan Wong
Associate
PureFDA
111 Town Square Place, Suite 1203
Jersey City, New Jersey 07310

Re: K222651
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 9, 2022
Received: November 10, 2022

Dear Bryan Wong:

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,

Katherine D. Kavlock -S

for
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)*
K222651

Device Name
Surgical Face Mask

Indications for Use *(Describe)*
The Surgical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The Surgical Face Mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This a single use, disposable device(s), 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

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K222651

1. **Date of Submission**: October 31, 20220

2. Submitter Identification

XIANTAO SANDA INDUSTRIAL CO., LTD

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3. Identification of Proposed Device

Trade/Proprietary Name: Surgical Face Mask
Common name: Surgical Face Mask

Regulatory Information

Classification Name: Mask, Surgical

Classification: Class II

Product Code: FXX;

Review Panel: Orthopedic

4. Identification of Predicate Device

Predicate Device:

510(k) Number: K221222

Product Name: Surgical Face Mask (HNFM0304)
Manufacturer: Shanghai Hua En Industrial CO LTD

5. Device Description

The Surgical Face Masks are blue color, there-layer, flat-pleaded masks with nose piece and ear loops/ties, which are composed of outer layer, middle layer and inner layer.

The outer layer and inner layer of the mask are made of polypropylene, the middle layer is made of melt-blown polypropylene.

The ear loop/ties of the subject mask is held in place over the users' mouth and nose by two ear loops/ties welded to the face mask. The ear loop is made with polyester and spandex. The nose piece in the layers of face mask is to allow the user to fit the mask around their nose, which is made of high density polyethylene.

The Surgical Face Mask is sold non-sterile and are intended to be single use, disposable devices. The mask is designed and manufactured in accordance with ASTM F2100 Standard Specification for Performance of Materials Used in Surgical Face Masks.

6. Intended Use Statement

The Surgical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The Surgical Face Mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This a single use, disposable device(s), provided non-sterile.

7. Non-clinical Test Conclusion

The Surgical Face Mask was tested in accordance with the tests recommended in the FDA guidance document,Guidance for Industry and FDA Staff Surgical Masks – Premarket Notification [510(k)] Submission issued March of 2004. Based upon the guidance document the following testing has beenperformed.

Test Methodology	Purpose	Acceptance Criteria for Level 3 Barrier	Result
Bacterial Filtration Efficiency ASTM F2101	Measure bacterial filtration efficiency	≥98%	Passed
Differential Pressure (mmH_2O/cm^2) EN 14683:2019	Determine breathability of the mask	<6.0 mmH_2O/cm^2	Passed

Annex C			
Sub-micron Particulate Filtration Efficiency ASTM F2299-17	Measure initial particle filtration efficiency	≥98%	Passed
Resistance to by Penetration Synthetic Blood ASTM F1862-17	Evaluate the resistance to penetration by impact of small volume of synthetic blood	29 out of 32 pass at 160 mmHg	Passed
Flammability 16 CFR Part 1610-2008	Response of materials to heat and flame	Class I	Passed

Biocompatibility Testing

The biocompatibility evaluation for the Surgical Face Mask was conducted in accordance with ISO 10993-1:2018 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing within a Risk Management Process, as recognized by FDA. The Surgical Face Mask is classified as a surface contacting device. Specific biocompatibility tests were selected under the guidance of ISO 10993-1:2018 Annex A.

Biocompatibility Evaluation				
Biological Effect		**Standard**	**Result**	
1	Cytotoxicity	ISO 10993-5	Non-cytotoxic	Passed
2	Sensitization	ISO 10993-10	Non-sensitizing	Passed
3	Irritation	ISO 10993-10	Negligibly irritating	Passed

8. Summary of Technological Characteristics

Comparison of Proposed and Predicate Devices			
Device	**Proposed Device**	**Predicate Devices**	**Result**
510K #	-	K221222	-
Manufacturer	XIANTAO SANDA INDUSTRIAL CO., LTD	SHANGHAI HUA EN INDUSTRIAL CO LTD	-
Product Name	Surgical Face Mask	Surgical Face Mask	Same
Level	Level 3	Level 3	Same
Product Code	FXX	FXX	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Indications for use	The Surgical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The Surgical Face Mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This a single use, disposable device(s), provided non-sterile.	The Surgical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The Surgical Face Mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This a single use, disposable device(s), provided non-sterile.	Same
Design Feature	Ear loop/tie, flat pleated, 3 layers	Ear loops, flat pleated, 4 layers	Different, Note 1
Color	Blue	Blue	Same
Dimension	Length: 17.5cm±0.5cm Width: 9.5±0.5cm	Length: 180±5mm Width: 95±5mm	Different, Note 2
Sterility	Non-sterile	Non-sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
Material			
Outer layer	Polypropylene SpunBond Non Woven Fabric	spun-bond polypropylene	Same

Second layer	N/A	nylon single way filting net	Different, Note 3
Middle layer	Melt-blown Polypropylene Non Woven Fabric	melt blown polypropylene	Same
Inner layer	Polypropylene SpunBond Non Woven Fabric	spun-bond polypropylene	Same
Nose clip	High Density Polyethylene	polypropylene wrapped aluminium	Different, Note 4
Ear loops	Polyester, Spandex	Nylon, spandex	Different, Note 5
Biocompatibility	ISO 10993-5 Cytotoxicity: Non-cytotoxic	ISO 10993-5 Cytotoxicity: Non-cytotoxic	Same
	ISO 10993-10 Sensitization: Non-sensitizing	ISO 10993-10 Sensitization: Non-sensitizing	
	ISO 10993-10 Irritation: Negligibly irritating	ISO 10993-10 Irritation: Negligibly irritating	

Performance Characteristic Comparison				
Item	**Proposed Device**	**Predicate Device**	**ASTM F2100 Requirements**	**Comparison**
ASTM F2100 Level	Level 3	Level 3	Level 3	Same
Bacterial Filtration Efficiency	≥98%	≥98%	≥98%	Same
Differential Pressure (mmH_2O/cm^2)	<6.0 mmH_2O/cm^2	<6.0 mmH_2O/cm^2	<6.0 mmH_2O/cm^2	Same
Sub-micron Particulate Filtration Efficiency	≥98%	≥98%	≥98%	Same
Resistance to Penetration by Synthetic Blood	32 out of 32 pass at 160 mmHg	32 out of 32 pass at 160 mmHg	29 out of 32 pass at 160 mmHg	Same
Flammability	Class I	Class I	Class I	Same

Difference Analysis:

Note 1:

The different layer number does not raise additional questions for safety and effectiveness. All proposed devices are conducted the test according to ASTM F2100, the test results shown that the proposed device meet the requirements of standard.

Note 2:

The difference in the dimension does not raise additional questions for safety and effectiveness. Proposed devices are conducted the test according to ASTM F2100, the test results shown that the proposed device meet the requirements of standard.

Note 3:

The different layer number does not raise additional questions for safety and effectiveness. All proposed devices are conducted the test according to ASTM F2100, the test results shown that the proposed device meet the requirements of standard.

Note 4

The difference in material of nose clip does not raise additional questions for safety and effectiveness. Proposed devices are conducted the biocompatibility best according to ISO 10993, the test results shown that the proposed device meet the requirements of standard.

Note 5:

The difference in material of ear loops does not raise additional questions for safety and effectiveness. Proposed devices are conducted the biocompatibility best according to ISO 10993, the test results shown that the proposed device meet the requirements of standard.

9. Summary of Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specification. The test results demonstrated that the proposed device complies with the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Mask - Premarket Notification [510(K)] Submission issued on March 5, 2004:

- ISO 10993-05:2009 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, 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, Medical Face Masks - Requirements and Test Methods

- ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus Aureus
- ASTM F2299, 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

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Substantially Equivalent (SE) Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Surgical Face Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K221222.