September 20, 2022

Xiantao Junhui Plastic Products Co., Ltd.
℅ Ms. Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Co., Ltd.
14th Floor, 1500# Century Avenue
Shanghai, 200122
China

Re: K221976
Trade/Device Name: Surgical Face Mask (Non-sterile)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 5, 2022
Received: July 5, 2022

Dear Ms. Wang:

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
Brent L. 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.

Submission Number *(if known)*

K221976

Device Name

Surgical Face Mask (Non-sterile)

Indications for Use *(Describe)*

The Surgical Face Mask (Non-sterile) 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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XIANTAO JUNHUI PLASTIC PRODUCTS CO., LTD.
No. 3, Babu Industrial Park, Pengchang Town, Xiantao City, HUBEI, CHINA

510(K) Summary

(As requirement by 21 CFR 807.92)

Date prepared: 15th, June, 2022

A. Applicant:

Name: XIANTAO JUNHUI PLASTIC PRODUCTS CO., LTD.
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B. Device:

Trade Name: Surgical Face Mask (Non-sterile)
Model: Flat type/over-the-ear

Regulatory Information
Common Name: Surgical Face Mask
Classification: Class II
Product code: FXX
Regulation: 21 CFR 878.4040 - Surgical apparel

C. Identification of Primary Predicate device:

K211827
Zhejiang Lanhine Medical Products LTD.
Trade Name: Level 3 Fluid Resistant Procedure/Surgical Mask
Common Name: Surgical Face Mask
Model(s): 15604F, 15704F

XIANTAO JUNHUI PLASTIC PRODUCTS CO., LTD.
No. 3, Babu Industrial Park, Pengchang Town, Xiantao City, HUBEI, CHINA

Regulatory Information:
Common Name: Surgical Face Mask
Classification: Class II
Product code: FXX
Regulation: 21 CFR 878.4040 - Surgical apparel

D. Indications for use of the device:

The Surgical Face Mask (Non-sterile) 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 toreduce the potential exposure to blood and body fluids. This a single use, disposable device(s), provided non-sterile.

E. Device Description:

The Surgical Face Masks (Non-sterile) are blue color, three-layer, flat-pleaded masks with nose piece and ear loops, which are composed of inner layer, middle layer and outer layer. The colorant is blue polypropylene (PP) master batch.

The inner layer and outer layer of the mask are made of spun-bonded non-woven fabric (polypropylene), the middle layer is made of polypropylene melt-blown non-woven fabric. The ear loop of the subject mask is held in place over the users' mouth and nose by two ear loops welded to the face mask. The ear loop is made with nylon 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 galvanized iron wire coated by PE.

The Surgical Face Mask (Non-sterile) is sold non-sterile and are intended to be single use, disposable devices.

The mask is designed and manufactured in accordance with ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks.

F. Comparison of technological characteristics with the predicate device

The Surgical Face Masks are essentially the same as or similar to the predicate device in terms of the indications for use, design and construction, performance characteristics. Provided below table 1 is a comparison of the proposed device with the predicate device.

Table 1 Comparison of Proposed and Predicate Devices

Device	Proposed Device	Predicate Device	Result
510K #	-	K211827	-
Manufacturer	XIANTAO JUNHUI PLASTIC PRODUCTS CO., LTD.	Zhejiang Lanhine Medical Products LTD.	-
Product Name	Surgical Face Mask (Non-sterile)	Level 3 Fluid Resistant Procedure/Surgical Mask	Similar
Level	Level 3	Level 3	Same

XIANTAO JUNHUI PLASTIC PRODUCTS CO., LTD.
No. 3, Babu Industrial Park, Pengchang Town, Xiantao City, HUBEI, CHINA

Product Code	FXX	FXX	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Indications for use	The Surgical Face Mask (Non-sterile) 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 Level 3 Fluid Resistant Procedure/Surgical Masks (model: 15604F, 15704F) 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 a single use, disposable device(s), provided non-sterile.	Same
Design Feature	Ear loops, flat pleated, 3 layers	Ear loops, tie-on, flat pleated, 3 layers	Similar
Color	Blue	Blue	Same
Dimension	175±5mm 95±5mm	17.5cm±0.5cm 9.5cm±0.5cm	Same
Sterility	Non-sterile	Non-sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
Material			
Outer layer	Spun-bonded non-woven fabric (polypropylene)	Non-woven fabric (Polypropylene)	Same
Middle layer	Polypropylene melt-blown non-woven fabric	Melton blown fabric (Polypropylene)	Same
Inner layer	Spun-bonded non-woven fabric (polypropylene)	Non-woven fabric (Polypropylene)	Same
Nose clip	Galvanized iron wire coated by PE	Polypropylene coating iron	Different
Ear loops	Nylon and spandex	Polyurethane	Different
Biocompatibility	ISO 10993	ISO 10993	Same

Difference Analysis:
The proposed device has same intended use, structure, parameter and performance with the predicate device. The materials of inner layer, middle layer and outer layer of the proposed device are also the same as those of the predicate device.

The proposed device has different material of nose clip and ear loops to the predicate device. However, biocompatibility test has been performed on the proposed device according to ISO 10993-5 and ISO 10993-10 and the results does not show any adverse effect. Thus, this difference will not affect the safety and effectiveness between the proposed device and the predicate device.

XIANTAO JUNHUI PLASTIC PRODUCTS CO., LTD.
No. 3, Babu Industrial Park, Pengchang Town, Xiantao City, HUBEI, CHINA

G. 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

Performance testing and biocompatibility testing are summarized in below table 2.

Table 2: Summary of Performance Testing & Biocompatibility testing

Test Methodology	Purpose	Acceptance Criteria for Level 3 Barrier	Result
Bacterial Filtration Efficiency ASTM F2101	Measure bacterial filtration efficiency	≥98%	Passed 3 non-consecutive lots tested, using a sample size of 32/lot Lot 1: ≥98% Lot 2:≥98% Lot 3:≥98%
Differential Pressure (mmH_2O/cm^2) EN 14683:2019 Annex C	Determine breathability of the mask	<6.0 mmH_2O/cm^2	Passed 3 non-consecutive lots tested, using a sample size of 32/lot Lot 1: <6.0 Lot 2: <6.0 Lot 3: <6.0
Sub-micron Particulate Filtration Efficiency ASTM F2299-17	Measure initial particle filtration efficiency	≥98%	Passed 3 non-consecutive lots tested, using a sample size of 32/lot Lot 1: ≥98% Lot 2: ≥98% Lot 3: ≥98%
Resistance to Penetration by	Evaluate the resistance to penetration by	29 out of 32 pass at 160 mmHg	Passed 3 non-consecutive lots tested, using a

Synthetic Blood ASTM F1862-17	impact of small volume of synthetic blood		sample size of 32/lot 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
Flammability 16 CFR Part 1610-2008	Response of materials to heat and flame	Class I	Passed 3 non-consecutive lots tested, using a sample size of 32/lot Lot 1: Class 1 Lot 2: Class 1 Lot 3: Class 1
Cytotoxicity	Assess the potential risk of cytotoxicity of mask material	Non-cytotoxic	Pass Under the condition of this study, the device has no potential toxicity.
Irritation	Assess the potential risk of irritation of mask material	Negligibly irritating	Under the condition of this study, the device is negligibly irritating.
Sensitization	Assess the potential risk of sensitization of mask material	Non-sensitizing	Under the conditions of the study, the device is non-sensitizing

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Surgical Face Mask (Non-sterile) is substantially equivalent to the legally marketed predicate device cleared under K211827.