December 30, 2020

Jiangsu JianYu Health Medical Co., Ltd.
Andy Shu
Regulatory Affairs Specialist
No. 88 Longxi Avenue, Zhulin Town, Jintan District
Changzhou, Jiangsu 213241
China

Re: K201754
Trade/Device Name: JianYu Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 16, 2020
Received: December 29, 2020

Dear Andy Shu:

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 CAPT Elizabeth Claverie, M.S.
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)*

K201754

Device Name
JianYu Surgical Mask

Indications for Use *(Describe)*
JianYu surgical mask is intended to be worn to protect both patients and healthcare workers from transfer of microorganisms, body fluids, and particulate material. The surgical mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. The JianYu surgical mask is a single use, disposable device 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

(as requested by 21 CFR 807.92)

510K Number: **K201754**

Submitter / 510(k) owner: Jiangsu JianYu Health Medical Co., Ltd.
Address: No. 88 Longxi Avenue, Zhulin Town, Jintan District, Changzhou City, Jiangsu, CN 213241
Tel: +86-519-82445588
Fax: +86-519-82442788

Contact Person: Andy Shu
Regulatory Affairs Specialist
E-mail: andy_smiths@sina.com

Date of preparation: June 15th, 2020

Proposed device:

Trade Name:	JianYu Surgical Mask
Common/Classification Name:	Surgical Mask Regulation
Name:	Surgical Apparel
Product Code:	FXX
Review Panel:	General Hospital
Device Class:	Class II
Regulation Number:	878.4040

Legally Marketed Predicate Device:

Trade Name:	Surgical Face Mask (EL30000)
510(k) Number:	K160269
Submitter of 510(k)/holder:	SAN-M PACKAGE CO., LTD.

Device Description:

The JianYu surgical mask is composed of 3-layers and is flat-pleated. The mask materials consist of an outer layer (spunbond polypropylene, blue), filter layer (meltblown polypropylene, white), and inner layer (spunbond polypropylene, white). The three layers of the mask body are collated and sonically welded around the edges. The surgical mask contains ear loops attached by welding to secure the mask over the user's mouth and face and includes a malleable nosepiece to provide a firm fit over the nose. The surgical mask is a single use, disposable device, provided non-sterile.

Intended Use:

JianYu surgical mask is intended to be worn to protect both patients and healthcare workers from transfer of microorganisms, body fluids, and particulate material. The surgical mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. The JianYu surgical mask is a single use, disposable device provided non-sterile.

Comparison of Technological Characteristics between the subject and predicate devices:
JianYu Surgical mask has the same technological characteristics as the predicate device. The design, material, form, fit, function and method of operation are similar.

Element of Comparison	Subject Device K201754	Predicate Device K160269	Comparison
Indications for Use	JianYu surgical mask is intended to be worn to protect both patients and healthcare workers from transfer of microorganisms, body fluids, and particulate material. The surgical mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. The JianYu surgical mask is a single use, disposable device provided non-sterile.	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 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.	Same
Material Composition	Three-layer mask constructed of: Outer layer: spunbond polypropylene Filter layer: meltblown polypropylene Inner layer: spunbond polypropylene Ear loops: spandex Nose clip: malleable aluminum wire/PVC	Outer layer: Polypropylene Filter media: 1. Polypropylene spunbond 2. Polypropylene meltblown Inner layer: Polypropylene Ear loop: Polyester, polyurethane Nose lamps: Polyethylene coated steel wire	Similar
Dimension	Length: 175±5mm, Width: 95±5mm	Length: 175±5mm, Width: 90±3mm	Similar
Mask style	Flat-pleated	Flat-pleated	Same
Design feature	Ear loops	Ear loops	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single use; Disposable	Single use; Disposable	Same
Color	Blue	White or blue	Same
Biocompatibility	The surgical mask was tested with following standards: • AAMI /ANSI/ ISO 10993-5:2009, Under the testing conditions, the subject surgical mask did not show potential cytotoxicity • AAMI /ANSI/ ISO 10993-10:2010, Under the testing conditions, the subject surgical mask did not cause significant irritation or sensitization reaction to the test animals.	The surgical mask was tested in accordance with ISO10993 and passed acceptance criteria.	Same

Product performance specification per ASTM F2100-19 meets Level 3			
Bacterial filtration efficiency (BFE)	Passed at ≥99.9% ASTM F2101	Passed at ≥99% ASTM F2101	Same
Differential pressure	Passed at <6.0 mmH_2O/cm^2 EN14683:2019 Annex C	Passed at 2.5 mmH_2O/cm^2 MIL-M-36954C	Similar
Particulate filtration efficiency (PFE)	Passed at ≥98% ASTM F2299	Passed at 99.7% ASTM F2299	Same
Resistance to penetration by synthetic blood	Passed at 160mmHg ASTM F1862	Passed at 160mmHg ASTM F1862	Same
Flammability	Class 1, 16CFR PART 1610	Class 1, 16CFR PART 1610	Same

Summary of Non-Clinical Performance Testing

Performance tests have been conducted on Surgical mask per ASTM F2100-19, and all testing results met ASTM F2100-19 Level 3 acceptance criteria. Detailed testing conducted as below:

- Bacterial filtration efficiency (BFE)
- Differential pressure
- Particulate filtration efficiency (PFE)
- Resistance to penetration by synthetic blood
- Flammability

Testing standards

Standards No.	Standards Title
ASTM F2100-19	Standard Specification for Performance of Materials Used in Medical Face Masks
ASTM F2101-19	Standard Test Method for Evaluating the Bacteria Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus Aureus
EN14683: 2019	Medical Fask Masks—Requirements and Test Methods
ASTM F2299-17	Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
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)
16CFR PART 1610	Standard for the Flammability of Clothing Textiles
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
AAMI /ANSI/ ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
AAMI /ANSI/ ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Summary of Clinical Performance Testing
Not applicable.

Conclusion
The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K201754, the JianYu Surgical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K160269.