November 9, 2021

Suzhou JaneE Medical Technology Co., Ltd.
Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K212526
Trade/Device Name: Disposable Medical Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 11, 2021
Received: August 11, 2021

Dear Ivy 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 Clarence W. Murray III, PhD
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)*
K212526

Device Name
Disposable Medical Surgical Mask

Indications for Use *(Describe)*
The Disposable Medical Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. They 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(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

A. Applicant

Suzhou JaneE Medical Technology Co., Ltd.
Address: No.339 HuaFeng Road, New District,Suzhou,Jiangsu Province, China , 215129
Contact:Mr.Zhu Li
Title: Registration Specialist
Tel: +86 13951116714
Email: czhuli@sz-dk.cn

Submission Correspondent:
Primary contact: Ms. Ivy Wang
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-58817802
Email: haiyu.wang@sungoglobal.com
Secondary contact: Mr. Raymond Luo
Room 1401, Dongfang Building, 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-68828050
Email: fda.sungo@gmail.com

Device:
Trade Name: Disposable Medical Surgical Mask
Common Name: SURGICAL FACE MASK
Model: Rectangle-earloop

Regulatory Information
Classification Name: Surgical Face Mask
Classification: Class II
Product code: FXX
Regulation Number: 878.4040
Review Panel: Surgical Apparel

B. Predicate device

K203426
Surgical Face Mask(Non-sterile)
Nantong Taiweishi Medical Technology Co., Ltd.

C. Indications for use

The Disposable Medical Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material.They 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(s), provided non-sterile.

D. Device Description

The Disposable Medical Surgical Masks are green color, three-layer, flat-folded masks with nose piece and ear loops. The green colorant is polypropylene (PP) master batch.

The inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter.

The ear loops are held in place over the users' mouth and nose by two ear loops welded to the face mask. The ear loops are not made with natural rubber latex or fiberglass， but 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 Iron core coated with Polyethylene.

The Disposable Medical Surgical Masks are sold non-sterile and are intended to be single use, disposable devices.

E. Comparison with predicate device

Device		Proposed Device	Predicate Device	Comparison
Manufacturer		Suzhou JaneE Medical Technology Co., Ltd.	Nantong Taiweishi Medical Technology Co., Ltd.	-
510K number		K212526	K203426	-
Model name		Disposable Medical Surgical Mask Model: Rectangle-earloop	Surgical Face Mask(Non-sterile)	Same
Classification		Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Intended use		The Disposable Medical Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material.They 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(s), provided non-sterile.	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. 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 Features		Ear loop, Flat pleates,3 layers	Ear loop, Tie-on, Flat pleated,3 layers	Similar
Material	**Outer layer**	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Inner layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose clip	Iron and Polyethylene	Polyethylene	Different
	Ear loops	Nylon and Spandex	Nylon and Spandex	Same

Color	Green	Blue	Different
Dimension (Length)	175mm+/-8mm	175mm+/-5%	Similar
Dimension (Width)	95mm+/-5mm	95mm+/-5%	Similar
OTC use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100 level	Level 3	Level 2	Similar

The proposed device has different material of nose piece and different color to the predicate device, while the proposed device has been tested and the test results shown that the material differences do not affect the safety of the proposed device.

The proposed device is similar in design, intended use, technological characteristics, and is composed of the same or similar components as the predicate device. The product proposed under this premarket notification submission has the same or similar performance characteristics and conform to the same or similar standards. Differences between the Disposable Medical Surgical Mask and predicate devices did not raise any new concerns regarding safety and effectiveness.

F. Summary of Non-Clinical Test

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was same to the predicate device. 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 Masks – Premarket Notification [510(k)] Submission* issued on March 5, 2004:

- 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, 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;

Test Methodology	Purpose	Acceptance Criteria	Results
Fluid Resistance Performance ASTM F1862	The purpose of the performance testing is to	29 out of 32 pass at 160 mmHg for level 3	31 out of 32 pass at 160 mmHg, 3 lots; PASS
Particulate Filtration Efficiency ASTM F2299		≥ 98%	98.8%; 98.8%; 98.8%; PASS

Bacterial Filtration Efficiency ASTM F2101	demonstrate the functionality of the subject device.	≥ 98%	99.8%；99.8%；99.8% PASS
Differential Pressure (Delta P) EN 14683 Annex C		< 6.0mmH_2O/cm^2	2.73mm H_2O cm^2 ； 2.73mm H_2O cm^2 ； 2.73mm H_2O cm^2； PASS
Flammability 16 CFR 1610		Class 1	Class 1; PASS
Cytotoxicity	The purpose of the testing is to demonstrate the safety of the subject device.	Non-cytotoxic	Under the conditions of the study,the device is non-cytotoxic.
Irritation		Non-irritating	Under the conditions of the study,the device is non-irritating.
Sensitization		Non-sensitizing	Under the conditions of the study,the device is non-sensitizing

G. Summary of Clinical Test Conclusion

No clinical study is included in this submission.

H. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K203426.