



September 28, 2021

Shanghai No.9 Knitting Mill Co., Ltd.
Ivy Wang
Consultant
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K211794
Trade/Device Name: Disposable surgical mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 30, 2021
Received: June 30, 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,

Clarence W. Murray, III, Ph.D.
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

Indications for Use

510(k) Number (if known)

K211794

Device Name

Disposable surgical mask

Indications for Use (Describe)

The Disposable 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.

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510(K) Summary

K211794

Date of Summary prepared: 2021-09-23

A. Applicant:

Name: SHANGHAI NO.9 KNITTING MILL CO., LTD.

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Submission Correspondent:

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B. Device:

Trade Name: Disposable surgical mask

Common Name: Surgical face mask

Model: Ear loops; Non-sterile

Regulatory Information

Classification Name: Surgical Face Mask

Classification: Class II

Product code: FXX

Regulation Number: 878.4040

Review Panel: Surgical Apparel

C. Predicate device:

K203426

Surgical Face Mask (Non-sterile)

Manufactured by Nantong Taiweishi Medical Technology Co., Ltd.

D. Intended Use/Indications for Use:

The Disposable 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.

E. Device Description:

The proposed device(s) are blue color, and flat pleated type mask, utilizing ear loops way for wearing, and they all have nose clips design for fitting the face mask around the nose.

The proposed device(s) are manufactured with three layers, the inner and outer layers are made of Polypropylene non-woven fabric, and the middle layer is made of polypropylene melt-blown cloth. The model of proposed device, ear loops, is held in place over the users' mouth and nose by two elastic ear loops welded to the face mask. The elastic ear loops are made of Elastic materials consisting of Nylon low elastic yarn and Spandex. The nose piece contained in the proposed device(s) is in the layers of face mask to allow the user to fit the face mask around their nose, which is made of Polypropylene and galvanized iron wire plastic materials. The proposed device(s) are sold non-sterile and are intended to be single use, disposable device.

F. Technological characteristics comparison between the subject and predicate devices

Table 1 General Comparison

Device	Proposed Device	Predicate Device	Result	
Manufacturer	SHANGHAI NO.9 KNITTING MILL CO., LTD.	Nantong Taiweishi Medical Technology Co., Ltd.	-	
510K number	K211794	K203426	-	
Name	Disposable surgical mask	Surgical Face Mask (Non-sterile)	Same	
Classification	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same	
Intended use/Indications for Use	The Disposable Surgical Mask is 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) 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	
Model	Ear loop, Flat pleates,3 layers	Ear loop, Flat pleated,3 layers	Same	
Material	Outer layer	Polypropylene non-woven fabric	Spun-bond polypropylene	Same
	Middle layer	Polypropylene melt-blown cloth	Melt blown polypropylene filter	Same
	Inner layer	Polypropylene non-woven fabric	Spun-bond polypropylene	Same
	Nose clip	Polypropylene and Galvanized iron wire	Polyethylene	Different

	Ear loops	Nylon low elastic yarn and spandex	Nylon and Spandex	Same
Color		Blue	Blue	Same
Dimension		175mm+/-8.75mm	175mm+/-5%	Similar
Dimension (Width)		95mm+/-4.75mm	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 2	Level 2	Same
Biocompatibility		ISO10993	ISO10993	Same
Cytotoxicity (ISO10993-5)		Under the conditions of the study, the device is non-cytotoxic.	Under the conditions of the study, the device is non-cytotoxic.	Same
Irritation (ISO10993-10)		Under the conditions of the study, the device is non-irritating.	Under the conditions of the study, the device is non-irritating.	Same
Sensitization (ISO10993-10)		Under the conditions of the study, the device is non-sensitizing	Under the conditions of the study, the device is non-sensitizing	Same
Fluid Resistance Performance ASTM F1862		31 out of 32 pass at 120 mmHg in 1st lot tested; 32 out of 32 Pass at 120 mmHg in 2nd lot tested; 32 out of 32 Pass at 120 mmHg in 3rd lot tested.	32 out of 32 pass at 120 mmHg	Similar
Particulate Filtration efficiency ASTM F2299		99.4%	99.16%	Similar
Bacterial Filtration Efficiency ASTM F2101		99.36%	99.74%	Similar
Differential Pressure (Delta P) EN 14683 Annex C		4.43mmH ₂ O/cm ²	3.7mm H ₂ O/cm ²	Similar
Flammability 16 CFR 1610		Class 1	Class 1	Same

From the comparison we found the name of inner layer, middle layer, out layer and Ear loops of the proposed device is different from the predicate device, but the material is the same. Only the material of the current nose clip is different from the predicate device.

The biocompatibility tests were conducted to both components to ensure their compliance to the ISO10993-5 and ISO10993-10. There is no new risk generated from the difference of the material.

For the Performance testing, the test results are not identical to each other, but they are similar. The predicate device and the proposed device meet the requirement of Level 2 medical mask according to the ASTM F 2100.

G. Summary of non-Clinical performance test

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was similar 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, stand 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;

Table 2 - Performance Testing

Item	Proposed device	Acceptance Criteria (level 2)	Result
Fluid Resistance Performance ASTM F1862	31 out of 32 Pass at 120 mmHg	29 out of 32 Pass at 120mmHg	PASS
Particulate Filtration Efficiency ASTM F2299	99.4%	≥ 98%	PASS
Bacterial Filtration Efficiency ASTM F2101	99.36%	≥ 98%	PASS
Differential Pressure (Delta P) EN 14683 Annex C	4.43mmH ₂ O/cm ²	< 6.0mmH ₂ O/cm ²	PASS
Flammability 16 CFR 1610	Class 1	Class 1	PASS

Table 3 Biocompatibility Comparison

Item	Proposed device	Acceptance Criteria	Result
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic.	Non-Cytotoxic	PASS
Irritation	Under the conditions of the study, the device is non-irritating.	Non-Irritating	PASS
Sensitization	Under the conditions of the study, the device is non-sensitizing	Non-Sensitizing	PASS

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The nonclinical tests performed demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, K203426 Surgical Face Mask (Non-sterile) by Nantong Taiweishi Medical Technology Co., Ltd..