August 18, 2021

Macheng Thimble Technology Investment Co., Ltd
% Ivy Wang
Consultant
Shanghai Sungo Management Consulting Company Limited
13th Floor, 1500# Central Avenue
Shanghai 200122
China

Re: K211631
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: May 27, 2021
Received: May 27, 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, 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

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)*
K211631

Device Name
Surgical Face Mask

Indications for Use *(Describe)*
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 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

510(k) Number：K211631
Date Prepared:2021/8/18

A. Applicant:

Manufacturer: Macheng thimble Technology Investment Co., Ltd
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B. Device:

Proprietary Name: Surgical Face Mask
Common Name: Surgical Face Mask
Model(s): Ear loops

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

C. Predicate device:

510(k) Number: K203426
Sponsor: Nantong Taiweishi Medical Technology Co., Ltd.
Trade Name: Surgical Face Mask（non-sterile）
(Note: Predicate device has NOT been subject to any Medical Device Recalls, including design-related recall.)

D. Device Description:

The Surgical Face Masks are blue, flat pleated masks with ear loops to hold the device in place over the user's mouth and nose and a nose piece to fit the mask to the face. The proposed device(s) are manufactured with three layers, 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 polyester. They are not made

with natural rubber latex. The nose piece contained in the proposed device(s) is in the layers of face mask and is made of malleable aluminum wire. The proposed device(s) are sold non-sterile and are intended to be single use, disposable device.

E. Indications use of the device:

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 a single use, disposable device(s), provided non-sterile.

F. Comparison with predicate device

Table 1 General Comparison

Device		**Proposed Device**	**Predicate device**	**Comparison**
Manufacturer		MACHENG THIMBLE TECHNOLOGY INVESTMENT CO., LTD	Nantong Taiweishi Medical Technology Co., Ltd.	-
510K number		K211631	K203426	-
Device name		Surgical Face Mask	Surgical Face Mask（non-sterile）	-
Classification		Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Indications for use		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 a single use, disposable device(s), provided non-sterile.	The Disposable 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(s), provided non-sterile.	Same
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	Malleable aluminum wire	Polyethylene	Different
	Ear loops	Polyester	Nylon and Spandex	Different
Color		Blue	Blue	Same
Dimension (length)		17.5cm+/-0.5cm	175mm+/-5%	Similar
Dimension (Width)		9.5cm+/-0.5cm	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&3	Level 2	Similar
Biocompatibility	Meet ISO10993 ,proved non-cytotoxicity, non-irritating and non-sensitizing	Meet ISO10993 ,proved non-cytotoxicity, non-irritating and non-sensitizing	Same

From the comparison we found the material of the current nose clip and the ear loop were 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.
The level of the proposed device is different from the predicate device, the main performance for level 2 and level 3 surgical face mask is the requirement of Fluid Resistance, the performance has conducted and the result meet the the requirement of Level 2 and level 3 medical mask according to the ASTM F 2100.

Table 2 performance testing comparison

Item	Proposed device	Predicate device	Result
Fluid Resistance Performance ASTM F1862	32 out of 32 per lot pass at 120 mmHg, 3 non-consecutive lots tested; 32 out of 32 per lot pass at 160 mmHg for 2 non-consecutive lots tested; 30 out of 32 per lot pass at 160 mmHg for 1 lot tested.	32 out of 32 pass at 120 mmHg	Pass
Particulate Filtration Efficiency ASTM F2299	99.65%	99.16%	Pass
Bacterial Filtration Efficiency ASTM F2101	99.76%	99.74%	Pass
Differential Pressure (Delta P) EN 14683 Annex C	4.2 mmH_2O/cm^2	3.7 mmH_2O/cm^2	Pass
Flammability 16 CFR 1610	Class 1	Class 1	Pass

G. Non-Clinical Test Conclusion

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 3 – Biocompatibility Testing

Test Method	**Purpose**	**Acceptance Criteria**	**Result**
Cytotoxicity	The purpose of the biocompatibility testing is to demonstrate the biocompatibility of the subject device.	Non-Cytotoxic	PASS Under the conditions of the study, the device is non-cytotoxic.
Irritation		Non-Irritating	PASS Under the conditions of the study, the device is non-irritating.
Sensitization		Non-Sensitizing	PASS Under the conditions of the study, the device is non-sensitizing

Table 4 – Performance Testing

Test Method	**Purpose**	**Acceptance Criteria**	**Result**
Fluid Resistance Performance ASTM F1862	The purpose of the performance testing is to	29 out of 32 pass at 120 mmHg for Level 2 29 out of 32 pass at 160 mmHg for Level 3	PASS 32 out of 32 per lot pass at 120 mmHg, 3 non-consecutive lots tested; 32 out of 32 per lot pass at 160 mmHg for 2 non-consecutive lots tested; 30 out of 32 per lot pass at 160 mmHg for 1 lot tested.
Particulate Filtration Efficiency ASTM F2299		≥ 98%	PASS 3 non-consecutive lots tested, using a sample size of 32/lot. Lot1: 99.79% Lot2: 99.58% Lot3: 99.6%

Bacterial Filtration Efficiency ASTM F2101	demonstrate the functionality of the subject device.	≥ 98%	PASS 3 non-consecutive lots tested, using a sample size of 32/lot. Lot1: 99.56% Lot2: 99.9% Lot3: 99.84%
Differential Pressure (Delta P) EN 14683 Annex C		< 6.0mmH_2O/cm^2	PASS 3 non-consecutive lots tested, using a sample size of 32/lot. Lot1: 5.2 mmH_2O/cm^2 Lot2: 3.8 mmH_2O/cm^2 Lot3: 3.8 mmH_2O/cm^2
Flammability 16 CFR 1610		Class 1	PASS 3 non-consecutive lots tested, using a sample size of 32/lot. Class 1

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device Nantong Taiweishi Medical Technology Co., Ltd. Surgical Face Mask（non-sterile）.