August 17, 2022

Shanghai Hua En Industrial CO LTD
% Ms. Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, 200122
China

Re: K221838
Trade/Device Name: Surgical Face Mask (HNFM0103)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 23, 2022
Received: June 23, 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,

Brent 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.

510(k) Number *(if known)*
K221838

Device Name
Surgical Face Mask (HNFM0103)

Indications for Use *(Describe)*
The Surgical Face Mask 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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#30, NO988 HUI JI ROAD, XUANQIAO TOWN, PUDONG,SHANGHAI CHINA 201314

510(K) Summary

(As requirement by 21 CFR 807.92)

Date prepared: 16th, June, 2022

A. Applicant:

Name: SHANGHAI HUA EN INDUSTRIAL CO LTD
Address: #30, NO988 HUI JI ROAD, XUANQIAO TOWN, PUDONG,SHANGHAI CHINA 201314
Contact: Lisa Zhao
Title: General Manager
Tel：+86- 15618875177
Email: lisa.zhao@hnind.com

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

B. Device:

Trade Name: Surgical Face Mask
Model: HNFM0103

Regulatory Information
Classification Name: Surgical Face Mask
Classification: Class II
Product code: FXX
Regulation Number: 21 CFR 878.4040
Review Panel: Surgical Apparel

C. Predicate device:

K212471
Medical Face Mask
Haian Medigauze Co., Ltd

Regulatory Information
Classification Name: Surgical Face Mask

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Classification: Class II
Product code: FXX
Regulation Number: 21 CFR 878.4040
Review Panel: Surgical Apparel

D. Indications for use of the device:

The Surgical Face Mask 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.

E. Device Description:

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

The outer facing layer and inner facing layer of the mask are made of spun-bond polypropylene, the middle layer is made of melt blown polypropylene. 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 polypropylene wrapped aluminium.

The Surgical Face Mask 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 Surgical Face Masks.

F. Non-clinical Test Conclusion

The Surgical Face Mask was tested in accordance with the tests recommended in the FDA guidance document, Guidance for Industry and FDA Staff Surgical Masks – Premarket Notification [510(k)] Submission issued March of 2004. Based upon the guidance document the following testing has been performed.

Test Methodology	Purpose	Acceptance Criteria for Level 1 Barrier	Result
Bacterial Filtration Efficiency ASTM F2101	Measure bacterial filtration efficiency	≥95%	Passed
Differential Pressure (mmH_2O/cm^2) EN 14683:2019 Annex C	Determine breathability of the mask	<5.0 mmH_2O/cm^2	Passed
Sub-micron	Measure initial particle	≥95%	Passed

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Particulate Filtration Efficiency ASTM F2299-17	filtration efficiency		
Resistance to Penetration by Synthetic Blood ASTM F1862-17	Evaluate the resistance to penetration by impact of small volume of synthetic blood	29 out of 32 pass at 80 mmHg	Passed
Flammability 16 CFR Part 1610-2008	Response of materials to heat and flame	Class I	Passed

Biocompatibility Testing

The biocompatibility evaluation for the Surgical Face Mask was conducted in accordance with ISO 10993-1:2018 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing within a Risk Management Process, as recognized by FDA. The Surgical Face Mask is classified as a surface contacting device. Specific biocompatibility tests were selected under the guidance of ISO 10993-1:2018 Annex A.

Biocompatibility Evaluation				
Biological Effect		**Standard**	**Result**	
1	Cytotoxicity	ISO 10993-5	Non-cytotoxic	Passed
2	Sensitization	ISO 10993-10	Non-sensitizing	Passed
3	Irritation	ISO 10993-10	Negligibly irritating	Passed

G. Summary of Technological Characteristics

Table 1 Comparison of Proposed and Predicate Devices

Device	**Proposed Device**	**Predicate Device**	**Result**
510K #	-	K212471	-
Manufacturer	SHANGHAI HUA EN INDUSTRIAL CO LTD	Haian Medigauze Co., Ltd	-
Product Name	Surgical Face Mask	Medical face mask	Similar
Level	Level 1	Level 1	Same
Product Code	FXX	FXX	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Indications for use	The Surgical Face Mask 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	The medical face masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate materials in infection control practices to reduce the potential exposure	Same

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	control practices to reduce the potential exposure to blood and body fluids. This a single use, disposable device(s), provided non-sterile.	to blood and body fluids. It is for single-use and provided non-sterile.	
Mask Style	Flat pleated	Flat pleated	Same
Configurations	Ear loop;	Ear loop;	Same
Color	Blue	Blue	Same
Dimension	180mm×95mm	17.5 cm×9.5cm	Similar
Sterility	Non-sterile	Non-sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
Material			
Outer facing layer	Spun-bond Polypropylene	Polypropylene	Same
Middle layer	Meltblown Polypropylene	Meltblown Polypropylene	Same
Inner facing layer	Spun-bond Polypropylene	Polypropylene	Same
Nose clip	Polypropylene wrapped aluminium	Polypropylene coated steel wire	Different
Ear loops	Nylon, spandex	Nylon, spandex	Same
Biocompatibility			
Cytotoxicity	Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic.	Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic.	Same
Irritation	Under the conditions of the study, the proposed device extract was determined to be non-irritating.	Under the conditions of the study, the proposed device extract was determined to be non-irritating.	Same
Sensitization	Under the conditions of the study, the proposed device extract was determined to be non-sensitizing.	Under the conditions of the study, the proposed device extract was determined to be non-sensitizing.	Same

Difference Analysis:

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

H. 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

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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

I. Clinical Test Conclusion

No clinical study is included in this submission.

J. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Surgical Face Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K212471.