January 26, 2022

Foshan Nanhai Plus Medical CO LTD
% Olivia Meng
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Service Co., Ltd.
8-9th Floor, R&D Building, No.26 Qinglan Street,
Panyu District
Guangzhou, Guangdong 510006
China

Re: K212610
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 21, 2021
Received: December 27, 2021

Dear Olivia Meng:

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)*
K212610

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 is a single-use, disposable device, provided non-sterile.

Level 2 Surgical Face Mask Models: Tie strap type: 522-001, 522-003, 522-005
Ear loop type: 522-002, 522-004, 522-006
Level 3 Surgical Face Mask Models: Tie strap type: 533-001, 533-003, 533-005
Ear loop type: 533-002, 533-004, 533-006

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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K212610

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. SUBMITTER

Foshan Nanhai Plus Medical CO LTD

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Fax: +86-755-27343466

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Secondary Contact Person:	Suyi Li Regulatory Affairs Manager Foshan Nanhai Plus Medical CO LTD Phone: +86-757-86914198 Fax: +86-755-27343466
Date prepared	Dec 19th , 2021

2. DEVICE

Device Name:	Surgical face mask
Common name:	Mask, Surgical
Model:	522-001, 522-002, 522-003, 522-004, 522-005, 522-006, 533-001, 533-002, 533-003, 533-004, 533-005, 533-006
Regulation number	21 CFR 878.4040
Regulation Class:	2
Product Code:	FXX

3. PREDICATE DEVICE

K160269, Surgical Face Masks (Ear loops and Tie-on)

This predicate has not been subject to a design-related recall.

4. DEVICE DESCRIPTION

The Surgical face mask is designed and manufactured by Foshan Nanhai Plus Medical CO LTD. It is non-sterile and for single use.

The Surgical face mask is a sandwich structure with the inner and outer layer of polypropylene nonwoven. The middle layer is polypropylene melt-blown nonwoven which provides barrier protection to microorganism, body fluid and particulate aerosol transfer. The ear loop is made with polypropylene nonwoven (tie strap type) or spandex elastic (ear loop type). The Surgical face mask is latex free.

It is a self-inhalation filter mask, which works by filtering the air containing harmful substances through the filter material of the mask before being inhaled or exhaled.

Twelve models are included in this submission, the differences listed below:

Model#	Ear Type	ASTM F2100 Level
522-001	Tie strap	Level 2
522-002	Ear loop	
522-003	Tie strap	
522-004	Ear loop	
522-005	Tie strap	
522-006	Ear loop	
533-001	Tie strap	Level 3
533-002	Ear loop	
533-003	Tie strap	
533-004	Ear loop	
533-005	Tie strap	
533-006	Ear loop	

Six models including 522-001, 522-002, 522-003, 522-004, 522-005, 522-006 are level 2 according to ASTM F2100-19. The main parameters of the product are listed as followed:

- Bacterial filtration efficiency (BFE) ≥98%
- Sub-micron particle filtration efficiency ≥98%
- Different pressure: <6.0 mm H_2O/cm^2
- Flammability: class 1
- Resistance to penetration by synthetic blood: 120 mmHg

Six models including 533-001, 533-002, 533-003, 533-004, 533-005, 533-006 are level 3 according to ASTM F2100-19. The main parameters of the product are listed as followed:

- Bacterial filtration efficiency (BFE) ≥98%
- Sub-micron particle filtration efficiency ≥98%
- Different pressure: <6.0 mm H_2O/cm^2
- Flammability: class 1
- Resistance to penetration by synthetic blood: 160 mmHg

5. 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 is a single-use, disposable device, provided non-sterile.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Item	Proposed device	Predicate device	Comparison result
Manufacturer	Foshan Nanhai Plus Medical CO LTD	San-M Package Co., Ltd.	NA
510K Number	K212610	K160269	NA
Product Common Name	Surgical face mask	Surgical Face Masks (Ear loops and Tie-on)	NA
Intended 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 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
Mask style	Flat pleated	Flat pleated	Same
Design feature	Ear loop, tie strap Colors: white or blue No visor option	Ear loop, tie-on Colors: white or blue Visor option: polyester	Similar
Material of outer facing layer	Polypropylene nonwoven	Polypropylene	Same
Material of middle layer	Polypropylene meltblown nonwoven	Polypropylene meltblown and polypropylene spunbond	Similar
Material of inner facing layer	Polypropylene nonwoven	Polypropylene	Same
Nosepiece	Galvanized iron wire wrapped with polyethylene(PE)	Polypropylene coated steel wire	Similar

Attachment	Ear loops: Spandex elastic Tie strap: Polypropylene nonwoven	Ear loops: Polyester, polyurethane Side tapes: Polyester spunbond (ear loops mask only) Tie tapes: Polypropylene spunbond or polyester spunbond	Similar
Dimension (Length × Width)	17.5 cm × 9.5 cm	17.5 cm × 9.0 cm 18.0 cm × 9.0 cm	Similar
OTC use	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Same
Single use	Yes	Yes	Same
ASTM F 2100 level	Level 2 Level 3	Level 1 Level 2 Level 3	Similar
Flammability	For 3 non-consecutive lots, 32 out of 32 pass. Level 2: Class 1 Level 3: Class 1	Level 1: Class 1 Level 2: Class 1 Level 3: Class 1	Similar
Bacterial Filtration Efficiency	For 3 non-consecutive lots, 32 out of 32 pass. Level 2: average at 99.66% Level 3: average at 99.58%	Level 1: > 98% Level 2: > 98% Level 3: > 99%	Similar
Differential Pressure	For 3 non-consecutive lots, 32 out of 32 pass. Level 2: 4.4 mm H_2O/cm^2 Level 3: 5.06 mm H_2O/cm^2	Level 1: pass at 2.0 mm H_2O/cm^2 Level 2: pass at 1.6 mm H_2O/cm^2 Level 3: pass at 2.5 mm H_2O/cm^2	Similar
Sub-Micron Particle Filtration Efficiency	For 3 non-consecutive lots, 32 out of 32 pass. Level 2: average at 99.54% Level 3: average at 99.67%	Level 1: 99.6% Level 2: 99.6% Level 3: 99.7%	Similar
Resistance to Penetration by Synthetic Blood	For 3 non-consecutive lots, ≥29 out of 32 pass (which met the requirements). Level 2: at 120 mmHg Level 3: at 160 mmHg	Level 1: pass at 80 mmHg Level 2: pass at 120 mmHg Level 3: pass at 160 mmHg	Similar
Biocompatibility			
Cytotoxicity	Under the conditions of the study, show potential cytotoxicity.	Under the conditions of the study, not cytotoxic.	Different
Irritation	Under the conditions of the study, not an irritant.	Under the conditions of the study, not an irritant.	Same
Sensitization	Under conditions of the study, not a sensitizer.	Under conditions of the study, not a sensitizer.	Same
Acute systemic toxicity	Under the conditions of the study, no systemic toxicity from the device.	--	Similar

The differences between the Surgical face mask and its predicate device do not raise new issues of safety and effectiveness. The non-clinical data support the safety of the device and the performance testing report demonstrate that the Surgical face mask should perform as intended in the specified use conditions.

7. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Level 2 product:

Test item		Test purpose	Acceptance criteria	Results
Performance test	Flammability	Testing the characteristics of a material that pertain to its relat ive ease of ignition and relative ability to sustain combustion.	Class 1 ASTM F2100	Pass
	Bacterial Filtration Efficiency	Testing the effectiveness of medical face mask material in preventing the passage of aerosolized bacteria.	Level 2: ≥ 98% ASTM F2100	Pass
	Different Pressure, mm H_2O/cm^2	Measuring the pressure of dropping across a medical face mask material.	Level 2: < 6.0 ASTM F2100	Pass
	Sub-Micron Particle Filtration Efficiency	Testing the efficiency of the filter material in capturing aerosolized particles smaller than one micron.	Level 2: ≥ 98% ASTM F2100	Pass
	Resistance to Penetration by synthetic blood	Testing the efficiency of resistance to penetration by synthetic blood.	Level 2: pass at 120 mmHg ASTM F2100	Pass
Biocompatibility	Cytotoxicity	Determining the cytotoxicity of proposed device.	Grade ≤ 2 ISO 10993-5	Fail
	Sensitization	Determining whether the proposed device has sensitization potential.	Sensitization classification grade < 3 ISO 10993-10	Pass
	Skin Irritation	Determining whether the proposed device has irritation potential.	Reaction score is 1,0 or less ISO 10993-10	Pass
	Acute systemic toxicity	Determining whether the proposed device has systemic toxicity potential.	Less than 2 animals appear clinical abnormal and body weight loss ≤ 10% ISO 10993-11	Pass

Level 3 product:

Test item		Test purpose	Acceptance criteria	Results
Performance test	Flammability	Testing the characteristics of a material that pertain to its relati ve ease of ignition and relative a bility to sustain combustion.	Class 1 ASTM F2100	Pass
	Bacterial Filtration Efficiency	Testing the effectiveness of medical face mask material in preventing the passage of aerosolized bacteria.	Level 3: ≥ 98% ASTM F2100	Pass
	Different Pressure, mm H_2O/cm^2	Measuring the pressure of dropping across a medical face mask material.	Level 3: < 6.0 ASTM F2100	Pass
	Sub-Micron Particle Filtration Efficiency	Testing the efficiency of the filter material in capturing aerosolized particles smaller than one micron.	Level 3: ≥ 98% ASTM F2100	Pass
	Resistance to Penetration by synthetic blood	Testing the efficiency of resistance to penetration by synthetic blood.	Level 3: pass at 160 mmHg ASTM F2100	Pass
Biocompatibility	Cytotoxicity	Determining the cytotoxicity of proposed device.	Grade ≤ 2 ISO 10993-5	Fail
	Sensitization	Determining whether the proposed device has sensitization potential.	Sensitization classification grade < 3 ISO 10993-10	Pass
	Skin Irritation	Determining whether the proposed device has irritation potential.	Reaction score is 1,0 or less ISO 10993-10	Pass
	Acute systemic toxicity	Determining whether the proposed device has systemic toxicity potential.	Less than 2 animals appear clinical abnormal and body weight loss ≤ 10% ISO 10993-11	Pass
Simulated transportation		Determining the ability of shipping units to withstand the distribution environment.	No damage on packaging and products after DC 13 procedure of ASTM D4169.	Pass

8. SUMMARY of CLINICAL TESTING

Clinical testing is not applicable to the subject device.

9. CONCLUSION

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