March 31, 2021

Foshan Xinbao Technology Co., Ltd.
% Cassie Lee
Manager
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza,
Shuixi Road, Huangpu District
Guangzhou, Guangdong 510700
China

Re: K202424
Trade/Device Name: Surgical Mask-Model CR02-2, CR02
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 21, 2020
Received: August 25, 2020

Dear Cassie Lee:

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,

Ryan Ortega, PhD
Acting 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)*
K202424

Device Name
Surgical Mask (Model: CR02-2, CR02)

Indications for Use *(Describe)*
The Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These masks are intended for use in infection control practices to reduce potential exposure to blood and body fluids. This is a single use, disposable device, 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 for K202424

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

510(k) Owner's Name: Foshan Xinbao Technology Co., Ltd.
Establishment Registration Number: Applying
Address: No. 20 Changjiang Road, Sanshan New Town, Nanhai District, Foshan City, Guangdong, China
Contact Person: Weishan Peng
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Application Correspondent:
Contact Person: Ms. Cassie Lee
Share Info (Guangzhou) Medical Consultant Ltd.
Address: No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District, Guangzhou, China
Tel: +86 20 8266 2446
Email: regulatory@glomed-info.com

2. Date of the summary prepared: November 26, 2020

3. Revision date: March 4, 2021

4. Subject Device Information

Type of 510(k): Traditional
Classification Name: Mask, Surgical
Common Name: Surgical apparel
Trade Name: Surgical Mask
Model Name: CR02-2, CR02
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 878.4040
Regulatory Class: II

5. Predicate Device Information

Sponsor: San-M Package Co., Ltd.
Trade Name: Surgical Face Masks (Ear Loops And Tie-On)
Classification Name: Mask, Surgical
Common Name: Surgical apparel
510(K) Number: K160269
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 878.4040
Regulation Class: II

6. Device Description

The surgical masks are three-layer, flat-pleated style mask with ear loops and nose clip design for fitting the mask around the nose and mouth. The proposed device is manufactured with three layers, the inner and outer layers are made of spun-bond polypropylene, and the middle layer (Filter layer) is made of melt-blown polypropylene. The ear loops are made of nylon and spandex and the nose clip is made of galvanized iron wire. The masks not made with natural rubber latex materials, and all materials are being used in currently marketed devices. The masks will be provided in blue and the model CR02-2 will be labeled to Level 2, the CR02 will be labeled to Level 3. The masks are single-use, disposable devices, provided non-sterile.

7. Intended Use / Indications for Use

The Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These masks are intended for use in infection control practices to reduce potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.

8. Comparison to predicate device and conclusion

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device		Predicate Device			Remark
Company	Foshan Xinbao Technology Co., Ltd.		San-M Package Co., Ltd.			--
510 (k)	K202424		K160269			--
Trade Name	Surgical Mask		Surgical Face Masks (Ear Loops And Tie-On)			--
Model	CR02-2	CR02	EL 10000	EL 20000	EL 30000	--
Classification Name	Mask, Surgical		Mask, Surgical			Same
Classification	Class II Device, FXX (21 FR 78.4040)		Class II Device, FXX (21 CFR 78.4040)			Same
Intended use	The Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These masks are intended for use in infection control practices to reduce 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
Material						
Outer facing layer	Spun-bond polypropylene		Polypropylene			Same
Middle layer	Melt blown polypropylene		1. Polypropylene spunbond 2. Polypropylene meltblown			Similar Note 1
Inner facing layer	Spun-bond polypropylene		Polypropylene			Same
Nose clip	Galvanized iron wire		Polyethylene coated steel wire			Similar Note 1
Ear loops	Nylon and Spandex		Ear loops: Polyester, polyurethane			Similar Note 1

			Side tapes: Polyester spunbond (ear loops mask only)			
Color	Blue		White, Blue			Same
Mask Style	Flat Pleated		Flat Pleated			Same
Specification and Dimension	Length: 17.5cm±1cm Width: 9.5cm±1cm		Length: 90 ± 3 mm Width:175 ± 5 mm			Similar Note 1
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 3	Level 1	Level 2	Level 3	Same
Fluid Resistance Performance	Pass at 120 mmHg	Pass at 160 mmHg	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Same
Particulate Filtration Efficiency	Pass at ≥98%	Pass at ≥98%	Pass at 99.6%	Pass at 99.6%	Pass at 99.7%	Similar Note 2
Bacterial Filtration Efficiency	Pass at ≥98%	Pass at ≥98%	Pass at >98%	Pass at >98%	Pass at >99%	Similar Note 2
Differential Pressure	Pass at <6.0 mm H_2O/cm^2	Pass at <6.0 mm H_2O/cm^2	Pass at 2.0 mm H_2O/cm^2	Pass at 1.6 mm H_2O/cm^2	Pass at 2.5 mm H_2O/cm^2	Similar Note 2
Flammability	Class 1		Class 1			Same
Biocompatibility						
Cytotoxicity	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.		Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.			Same
Irritation	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.		Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.			Same
Sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.		Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.			Same

Comparison in Detail(s):
Note 1:

Although the “Middle layer”, “Nose clip”, “Ear loops” and “Specification and Dimension” of subject device is little difference with predicate device, it meets the requirement of essential performance standard ISO 10993. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

Note 2:
Although the “Particulate Filtration Efficiency”, “Bacterial Filtration Efficiency” and “Differential Pressure” of subject device is little difference with predicate device, and they all meet the requirements of essential performance standard ASTM F2100. So, the differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

9. Summary of Non-Clinical Performance Testing

Performance Testing summary

Test item	Test method	Pass criteria		Test results /Verdict
		For Level 2	For Level 3	
Bacterial filtration efficiency	ASTM F2101-14 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus according to ASTM F2100:2019	≥ 98%	≥ 98%	Pass
Differential pressure (Delta-P)	EN 14683: 2019, Annex C Medical face masks - Requirements and test methods according to ASTM F2100:2019	<6.0 mm H_2O/cm^2	<6.0 mm H_2O/cm^2	Pass
Sub-micron particulate filtration efficiency at 0.1 μm of Polystyrene Latex Spheres	ASTM F2299-03 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres according to ASTM F2100:2019	≥ 98%	≥ 98%	Pass
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) according to ASTM F2100:2019	Fluid resistant claimed at 120 mm Hg	Fluid resistant claimed at 160 mm Hg	Pass
Flame spread	16 CFR Part 1610 Standard for the Flammability of Clothing according to ASTM F2100:2019	Class 1	Class 1	Pass

Biocompatibility Testing

According to ISO 10993-1: 2018, the nature of body contact for the subject device is Surface Device category, Skin Contact and duration of contact is B-prolonged (>24 h to 30 d). The following tests for the subject device were conducted to demonstrate that the subject device is biocompatible and safe for its intended use:
1) In vitro Cytotoxicity Test per ISO 10993-5: 2009 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity,
2) Skin Sensitization Tests per ISO 10993-10: 2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization,
3) Skin Irritation Tests per ISO 10993-10: 2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization.

10. Summary of Clinical Performance Test

No clinical study is included in this submission.

11. Final Conclusion：

The conclusion drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed device identified in K160269.