May 23, 2022

Xiamen Blue Star Enterprise Co., Ltd.
% Sam Lin
Official Correspondent
Shanghai Spica Management Consulting Co.,Ltd.
609 Room,No.133 Shengang Avenue, Pudong New District
Shanghai, 201306
China

Re: K220532
Trade/Device Name: Disposable surgical mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 5, 2021
Received: February 24, 2022

Dear Sam Lin:

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
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)*

K220532

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. 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.

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

Type of submission	Traditional
Date prepared	July 5, 2021

Submission sponsor

Manufacturer Name	Xiamen Blue Star Enterprise Co., Ltd.
Address	Room 201, South Building, No.506, Haiming Road, Maxiang Town, Xiang'an District, Xiamen, China
Tel	86-13015920500
Email	13015920500@163.com
Contact Person	Jincong Zhang

Device identification

Trade Name	Disposable surgical mask
Regulation Number	21 CFR 878.4040
Regulation Name	Mask, Surgical
Device Classification	Class II
Product Code	FXX
Panel	General Hospital
Previous Submissions	**None**

Application correspondent

Company Name	Shanghai Spica Management Consulting Co., Ltd.
Address	609 Room, No.133 Shengang Avenue, Pudong New District, Shanghai, China
Tel	86-18717927910
Email	sam@spicagloble.com
Contact Person	Sam Lin

Predicate device information

Sponsor	WUHAN DYMEX HEALTHCARE CO., LTD.
Trade/Device Name	SURGICAL FACE MASK
510(K) number	K182515
Regulation Number	21 CFR 878.4040

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. 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.

Device description

The Disposable surgical masks are single use, three-layer, flat - folded masks with ear loops and nose piece. The Disposable surgical masks are manufactured with three layers, the inner and outer layers are made of non-woven fabric (polypropylene), and the middle layer is made of melt blown polypropylene filter. The ear loops are held in place over the users' mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are not made with natural rubber latex. The nose piece in the layers of facemask is to allow the user to fit the facemask around their nose, which is made of spandex wrapped with metal wire. The surgical face masks will be provided in blue. The surgical face masks are sold non-sterile and are intended to be single use, disposable devices.

Performance Testing - Clinical

Not Applicable.

Performance Testing - Animal

Not Applicable.

Technological Characteristic Comparison

Provided below is a comparison of the subject device with the predicate device.

Table 6A: General Comparison

	Proposed Device	Predicate Device	Differences Discussion
Device name	Disposable surgical mask	SURGICAL FACE MASK	N/A
510(k) number		K182515	N/A
Manufacturer	Xiamen Blue Star Enterprise Co., Ltd.	Wuhan Dymex Healthcare Co., Ltd	N/A
Product regulation	21 CFR 878.4040	21 CFR 878.4040	Same
Classification name	Mask, Surgical	Mask, Surgical	Same
Regulation class	2	2	Same
Product code	FXX	FXX	Same
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. These face masks	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	Same

		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.	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.	
Rx or OTC		OTC	OTC	Same
Model		Ear Loops, Flat Pleated, 3 layers	Ear Loops, Flat Pleated, 3 layers	Same
Material	Outer facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Inner facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose clip	Polyethylene	Malleable polyethylene wire	Similar
	Ear loops	Spandex	Spandex	Same
Color		Blue	Blue	Same
Dimension		17cm X 9.5cm	17.5cm X 9cm	Similar
Sterility		Non-Sterile	Non-Sterile	Same

Level	Level 2	Level 2	Similar
Use	Single Use, Disposable	Single Use, Disposable	Same

Summary of Non-Clinical Testing

Provided below is a summary of the performance testing of the subject devices to demonstrate that the device meets the specification or acceptance criteria of the standards and test methods shown below.

Table 6B: Comparison of Non-clinical testing

Item	Proposed device	Acceptance Criteria	Result
Fluid Resistance Performance ASTM F1862	3 non-consecutive lots tested	29 out of 32 pass at 120 mmHg	Pass
Particulate Filtration Efficiency ASTM F2299	3 non-consecutive lots tested Lot1: 98.43% Lot2: 98.18% Lot3: 98.54%	≥ 98%	Pass
Bacterial Filtration Efficiency ASTM F2101	3 non-consecutive lots tested Lot1: 99.9% Lot2: 99.9% Lot3: 99.9%	≥ 98%	Pass
Differential Pressure (Delta P) MIL-M-36954C	3 non-consecutive lots tested Lot1: 3.5mmH_2O/cm^2 Lot2: 3.1mmH_2O/cm^2	< 5.0mmH_2O/cm^2	Pass

	Lot3: 3.3mmH_2O/cm^2		
Flammability 16 CFR 1610	Class 1	Class 1	Pass
Irritation	Under the conditions of the study, the device is non-irritating	Under the conditions of the study, the device is non-irritating	Pass
Sensitization	Under the conditions of the study, the device is non-sensitizing	Under the conditions of the study, the device is non-sensitizing	Pass
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic.	Under the conditions of the study, the device is non-cytotoxic.	Pass

Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;
- 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)
- ASTM F2299/F2299M-03 (2017) Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres
- ASTM F2101-2019 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus

- Differential Pressure -Determine breathing resistance or differential pressure as directed in EN 14683:2019, Annex C.
- ASTM F2100-2019 Standard Specification for Performance of Materials Used in Medical Face Masks
- ISO 10993-5:2009 Biological evaluation of medical device- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritation and skin sensitization

Conclusion

Based on the indications for use, general information, and non-clinical performance data, "Disposable surgical mask" is as safe, as effective, and performs as well as the legally marketed predicate devices, "SURGICAL FACE MASK (K182515)". Therefore, the subject device is substantially equivalent to the predicate device.