December 13, 2021

Jiande Chaomei Daily Chemicals Co., Ltd
Sam Lin
Official Correspondent
Shanghai Spica Management Consulting Co., Ltd.
609Room, NO.133 Shengang Avenue, Pudong New District
Shanghai, 200120
China

Re: K202794
Trade/Device Name: Surgical Face Mask: F-Y1-A
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 26, 2021
Received: November 26, 2021

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 Clarence W. Murray III, PhD
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)*
K202794

Device Name
Surgical face mask: F-Y1-A

Indications for Use *(Describe)*
The Surgical Face Masks are is 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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Type of submission Traditional

Date prepared May 1, 2021

Submission sponsor

Manufacturer Name	Jiande Chaomei Daily Chemicals Co., Ltd.
Address	Shangshan Village, Yancunqiao Town, Jiande City, Zhejiang Province, China
Tel	86-18858158190
Email	zhuliping@cmmask.com
Contact Person	Zhu Lipin

Device identification

Classification Name	Mask, Surgical
Trade Name	Surgical face mask: F-Y1-A
Device Classification	Class II
Regulation Number	21 CFR 878.4040
Panel	General Hospital
Product Code	FXX
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	86-15626132181
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 Surgical Face Masks are is 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 Surgical Face Masks are single use, three-layer, flat –folded masks with ear loops and nose piece. The Surgical Face Masks are manufactured with three layers, the inner and outer layers are made of spunbond 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 PVC 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.

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	Surgical face mask: F-Y1-A	SURGICAL FACE MASK	N/A
510(k) number	K202794	K182515	N/A
Manufacturer	Jiande Chaomei Daily Chemicals 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	Class II	Class II	Same
Product code	FXX	FXX	Same
Indications for use	The Surgical Face Masks are is 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.	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(s), provided non-sterile	Same

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 piece	PVC wrapped with metal wire	Malleable polyethylene wire	Similar
	Ear loops	Low elastic spandex yarn	Spandex	Similar
Color		Blue	Yellow	Similar
Dimension(Width)		17.5cm±0.5cm	17.5cm±0.2cm	Same
Dimension(Length)		9.0cm±0.2cm	9.5cm±0.2cm	Same
Sterility		Non-sterile	Non-sterile	Same
Use		Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100 Level		Level 2	Level 2	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: 99.64% Lot2: 99.70% Lot3: 99.63%	≥ 98%	Pass
Bacterial Filtration Efficiency ASTM F2101	3 non-consecutive lots tested Lot1: 99.6% Lot2: 99.8% Lot3: 99.4%	≥ 98%	Pass
Differential Pressure (Delta P) MIL-M-36954C	3 non-consecutive lots tested Lot1: 3.4mmH_2O/cm² Lot2: 3.2mmH_2O/cm² Lot3: 3.4mmH_2O/cm²	< 5.0mmH_2O/cm²	Pass
Flammability 16 CFR 1610	Class 1, 3 non-consecutive lots tested	Class 1	Pass
Irritation ISO 10993-10	Under the conditions of the study, the device is non-irritating	Under the conditions of the study, the device is non-irritating	Pass

Sensitization ISO 10993-10	Under the conditions of the study, the device is non-sensitizing	Under the conditions of the study, the device is non-sensitizing	Pass
Cytotoxicity ISO 10993-5	Under the conditions of the study, the device is non-cytotoxic.	Under the conditions of the study, the device is non-cytotoxic.	Pass

Performance Testing - Clinical

NOT Applicable.

Performance Testing - Animal

NOT Applicable.

Conclusion

The conclusions drawn from the non-clinical test demonstrate that “Surgical face mask: F-Y1-A (K202794)” is as safe, as effective, and performs as well as the legally marketed predicate devices, “SURGICAL FACE MASK (K182515)”.