July 29, 2024

Guangdong Kingfa Sci. & Tech. Co., LTD.
Xiaoge Yu
Manager
No.28, Delong Ave., Shijiao Town, Qingcheng District
Qingyuan, Guangdong 511545
China

Re: K233723
Trade/Device Name: Medical surgical mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 26, 2024
Received: June 27, 2024

Dear Xiaoge Yu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D
Assistant Director
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233723

Device Name

Medical surgical mask

Indications for Use *(Describe)*

The medical surgical mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.

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
[AS REQUIRED BY 21CFR807.92]

I. Submitter

GUANGDONG KINGFA SCI. & TECH.CO., LTD.
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Preparation date: July 25, 2024

II. Proposed Device

Device Trade Name:	Medical surgical mask
Common name:	Medical surgical mask
Regulation Number:	21 CFR 878.4040
Regulatory Class:	Class II
Product code:	FXX
Review Panel:	General Hospital

III. Predicate Devices

510(k) Number:	K202843
Trade name:	Surgical Face Masks (Sterile), Surgical Face Masks (Non-sterile)
Common name:	Surgical Face Mask
Classification:	Class II
Product Code:	FXX
Manufacturer	B.J.ZH.F.Panther Medical Equipment Co., Ltd

IV. Device description

The medical surgical mask is flat pleated style mask, utilizing ear loops way for wearing, and has nose piece design for fitting the medical surgical mask around the nose.

The medical surgical mask is manufactured with three layers, the inner and outer layers are made of polypropylene, only the outer layers' color is blue, and the middle layer is made of melt blown polypropylene.

Ear loops, which is held to cover the users' mouth and nose by two polypropylene bands ultrasonic welded to the medical surgical mask. The elastic ear loops are not

made with natural rubber latex.
The nose piece contained in the medical surgical mask is in the middle layer of medical surgical mask to allow the user to fit the medical surgical mask around their noses, which is made of metallic iron wire coated with polypropylene resin.
The dimensions of each medical surgical mask are length 175±8.75 mm and width 95±4.75 mm.
The dimension of nose piece is length ⩾ 80 mm.
The medical surgical mask can be provided in sterile and non-sterile two types, and is intended to be a single use, disposable device.

V. Indication for use

The medical surgical mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.

VI. Comparison of technological characteristics with the predicate device

Table 1 Comparison of medical surgical mask

Item	Proposed device (K233723)	Predicate device (K202843)	Discussion
Trade name	Medical surgical mask	Surgical Face Masks (Sterile), Surgical Face Masks (Non-sterile)	-
Product code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Classification	Class II	Class II	Same
Indication for use	The medical surgical mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.	The Surgical Face Mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.	Same
Mask Style	Ear loop, flat	Ear loop/Tie-on, Flat	Different Note 1
Specification and Dimension	17.5cmx9.5cm;	17.5cmx9.5cm; 14.5cmx9cm;	Different Note 1
OTC use	Yes	Yes	Same
Sterility	Sterile/Non-sterile	Sterile/Non-sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
Shelf life	3 years	/	Different Note 4
Material			
Outer facing layer	Polypropylene	Spun-bonded nonwoven polypropylene	Different Note 2

Middle layer	Polypropylene melt-blown	Melt-blown nonwoven polypropylene	
Inner facing layer	Polypropylene	Spun-bonded nonwoven polypropylene	
Nose clip	Polypropylene and metallic iron	Medical polypropylene and Q235	
Ear loops	Polyester and polyurethane	Nylon and spandex	
Design features	Color: blue	Color: blue	Same
Product performance			
Performance Testing (according to ASTM-2100)	Level 2	Level 2	Same
Bacterial Filtration Efficiency	Average >99.9%	Average 98.92%	Similar Note 3
Differential Pressure	Average 4.6 mmH_2O/cm^2	Average 4.4 mmH_2O/cm^2	Similar Note 3
Resistance to penetration by synthetic blood	pass at 120 mmHg	pass at 120 mmHg	Same
Particulate Filtration Efficiency	Average 99.73%	Average 98.98%	Similar Note 3
Flammability	Class 1	Class 1	Same

Biocompatibility	ISO 10993-5 and ISO 10993-10. Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic, non-sensitizing, and non-irritating.	ISO 10993-5 and ISO 10993-10. Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic, non-sensitizing, and non-irritating.	Same

Note 1:

The “Mask style”, “Specification and Dimension” of proposed device are covered by the predicate devices. The proposed devices have more “Mask style” and “Specification and Dimension”.

Note 2:

Although the “Material” of proposed device is different from the predicate devices, non-clinical performance tests and the biocompatibility tests have been performed on the proposed device according to ASTM F2100, ISO 10993-5 and ISO 10993-10. The results do not show any adverse effect.

Note 3:

Although the “Bacterial Filtration Efficiency” “Differential Pressure” and “Particulate Filtration Efficiency” of proposed device are different from the predicate devices, all of them meet the requirement of safety and essential performance standard ASTM F2100. Therefore, the differences between the predicate devices and proposed device will not affect the safety and effectiveness of the proposed device.

Note 4:

Shelf life is 3 years according to accelerated aging testing conducted for the proposed device. Therefore, this difference will not affect the safety and effectiveness between the proposed device and the predicate device.

VII. 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:

- ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks
- ISO 10993-5:2009, 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 Sensitization
- 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
- ISO 10993-7:2008 Biological Evaluation of Medical Device- Part 7: Ethylene Oxide Sterilization Residuals

Table 2 Summary of Non-Clinical Performance Testing

Test Method	Purpose	Acceptance Criteria	Results
Bacterial Filtration Efficiency ASTM F2101	Measure bacterial filtration efficiency	⩾98%	Pass
Differential Pressure(mmH_2O/cm^2) EN14683:2019 Annex C	Determine breathability of the mask	<6.0 mmH_2O/cm^2	Pass
Sub-micron Particulate Filtration Efficiency ASTM F2299-17	Measure initial particle filtration efficiency	⩾98%	Pass
Resistance to Penetration by Synthetic Blood ASTM F1862-17	Evaluate the resistance to penetration by impact of small volume of	29 out of 32 pass at 120 mmHg	Pass

	synthetic blood		
Flammability 16 CFR Part 1610-2008	Response of materials to heat and flame	Class 1	Pass
In vitro Cytotoxicity ISO 10993-5	Verify that the proposed device extract is non-cytotoxic.	The extract is non-cytotoxic under the study conditions.	Pass
Skin Irritation ISO 10993-10	Verify that the proposed device extract is non-irritating.	The polar and non-polar extracts are non-irritating under the study conditions.	Pass
Skin Sensitization ISO 10993-10	Verify that the proposed device extract is non-sensitizing.	The polar and non-polar extracts are non-sensitizing under the study conditions.	Pass

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the proposed device in 510(K) submission, the medical surgical mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K202843.