April 5, 2022

Guangdong Kingfa Sci.&Tech. Co., Ltd.
Yu Xiaoge
Product Certification Engineer
28 Delong Avenue, Shijiao Town, Qingcheng District
Qingyuan City, Guangdong 511500
China

Re: K213450
Trade/Device Name: Medical surgical mask (Black mask, Level 1 and Level 3)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 25, 2022
Received: March 1, 2022

Dear Yu Xiaoge:

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,

Bifeng Qian, M.D., Ph.D.
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)*
K213450

Device Name
Medical surgical mask (Black mask, Level 1 and Level 3)

Indications for Use *(Describe)*
Medical surgical mask is intended for use by healthcare workers during procedures to protect both patients and healthcare workers against transfer of microorganisms, bodily fluids, and particulate matters. This device is single use and 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.

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510(k) Summary K213450

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: GUANGDONG KINGFA SCI.&TECH. CO., LTD.
Establishment Registration Number: 3016785267
Address: No.28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
Postal Code:511500
Tel: +86 2632 8999
Fax: +0763-3203108
Contact Person (including title): Yu Xiaoge (Product certification engineer)
E-mail: yuxiaoge@kingfa.com.cn

Date of the summary prepared: April 4, 2022

2. Subject Device Information

Common Name: Medical surgical mask
Classification Name: Mask, Surgical
Trade Name: Medical surgical mask (Black mask, Level 1 and Level 3)
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 878.4040
Regulatory Class: II

3. Predicate Device Information

3.1. Predicate Device Information

Sponsor: Guangdong KINGFA Sci.&Tech.Co.,Ltd.
Trade/Device Name: Medical surgical mask
Classification Name: Mask, Surgical
Common Name: Mask, Surgical
510(K) Number: K201622
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 878.4040

Regulation Class: II

3.2. Predicate Device Information

Sponsor: Guangdong KINGFA Sci.&Tech.Co.,Ltd.
Trade/Device Name: Medical surgical mask
Classification Name: Mask, Surgical
Common Name: Mask, Surgical
510(K) Number: K202139
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 878.4040
Regulation Class: II

4. Device Description

The medical surgical mask (model: Black mask, Level 1 and Level 3) is a flat pleated style mask with ear loops, and a nose piece design for fitting the mask around the nose.
The mask is manufactured with three layers, the inner and outer layers are made of polypropylene, and the middle layer is made of melt-blown polypropylene.
Ear loops are held to cover the users' mouth and nose by two polypropylene bands ultrasonically welded to the mask. The elastic ear loops are not made with natural rubber latex.
The nose piece included in the mask is in the middle layer of the mask, to allow the user to fit the mask around their noses. The mask will be provided in black color, the colorant for the masks is Carbon black (CAS No.1333-86-4).
The subject device has 2 kinds of dimensions: 17.5 cm x 9.5 cm and 14.5 cm x 9.5 cm, and 2 kinds of protection performance: Level 1 and Level 3.
The mask is sold non-sterile and intended to be a single-use, disposable device.

5. Intended Use / Indications for Use

Medical surgical mask is intended for use by healthcare workers during procedures to protect both patients and healthcare workers against transfer of microorganisms, bodily fluids, and particulate matters This device is single use and provided non-sterile.

6. 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 1	Predicate Device 2	Verdict
Company	Guangdong KINGFA Sci.&Tech.Co.,Ltd.	Guangdong KINGFA Sci.&Tech.Co.,Ltd.	Guangdong KINGFA Sci.&Tech.Co.,Ltd.	--
Trade Name	Medical surgical mask	Medical surgical mask	Medical surgical mask	--
Classification Name	Mask, Surgical	Mask, Surgical	Mask, Surgical	Same
510(k) Number	K213450	K201622	K202139	--
Product Code	FXX	FXX	FXX	Same
Classification	Class II	Class II	Class II	Same
Intended Use / Indications for Use	Medical surgical mask is intended for use by healthcare workers during procedures to protect both patients and healthcare workers against transfer of microorganisms, bodily fluids, and particulate matters This device is single use and provided non-sterile.	Medical surgical mask is intended for use by healthcare workers during procedures to protect both patients and healthcare workers against transfer of microorganisms, bodily fluids, and particulate matters This device is single use and provided non-sterile.	This product is indicated for infection control practices in the health care industry. When worn properly, the Medical Surgical Mask is intended to protect both patient and wearer from the transfer of microorganisms, body fluids and particulate material.	Same
Material				
Outer facing layer	Polypropylene	Polypropylene	Polypropylene	Same
Middle layer	Polypropylene melt-blown	Polypropylene melt-blown	Polypropylene melt-blown	Same
Inner facing layer	Polypropylene	Polypropylene	Polypropylene	Same
Nose clip	Polypropylene and metallic iron	Polypropylene and metallic iron	Iron core polypropylene strip	Same

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Verdict
Ear loops	Polypropylene	Polyester and spandex elastic band	Polyester and spandex elastic bands	Different Note 1
Design features	Color: black	Color: blue	Color: blue	Different Note 1
Mask Style	Ear loop flat	Ear loop Flat	Ear loop flat	Same
Specification and Dimension	17.5*9.5; 14.5*9.5 cm; Ear loops:150-185 mm	17.5cmx9.5cm	17.5cmx9.5cm	Different Note 1
OTC use	Yes	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Single Use, Disposable	Same
Product performance (Level 1)				
Performance Testing (according to ASTM-2100: 2019)	Level 1	Level 1	--	Same
Bacterial Filtration Efficiency	Passed at ave.99.3%	99.2%	--	Similar Note 2
Differential Pressure	Passed at ave.3.7 mmH_2O/ cm^2	<5.0 mmH_2O/ cm^2	--	Similar Note 2
Resistance to penetration by synthetic blood	Pass at 80 mmHg	Pass at 80 mmHg	--	Same
Particulate Filtration Efficiency	Passed at ave.98.12%	99.46%	--	Similar Note 2
Flammability	Class 1	Class 1	--	Same
Product performance (Level 3)				
Performance Testing	Level 3	--	Level 3	Same

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Verdict
(according to ASTM-2100: 2019)				
Bacterial Filtration Efficiency	Passed at ave.99.8%	--	>99.9%	Similar Note 2
Differential Pressure	Passed at ave.4.27 mmH2O/ cm^2	--	3.72 mm H2O/ cm^2	Similar Note 2
Resistance to penetration by synthetic blood	Pass at 160 mmHg	--	Pass at 160 mmHg	Same
Particulate Filtration Efficiency	Passed at ave.99.58%	--	99.65%	Similar Note 2
Flammability	Class 1	--	Class 1	Same
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

Comparison in Detail(s):

Note 1:

Although the Ear loops", "Design features" and "Specification and Dimension" of subject device are different from the predicate devices, all of them meet the requirement of safety and essential performance standard ISO 10993-5 and ISO 10993-10. So, the differences between the predicate devices and subject device will not affect the safety and effectiveness of the subject device.

Note 2:

Although the "Bacterial Filtration Efficiency" "Differential Pressure" and "Particulate Filtration Efficiency" of subject device are different from the predicate devices, all of them meet the requirement of safety and essential performance standard ASTM F2100-19. So, the differences between the predicate devices and subject device will not affect the safety and effectiveness of the subject device.

7. Summary of Non-Clinical Performance Testing

Medical surgical mask (Level 1)

Test item (Performance Level 1)	Test method	Pass criteria	Test results
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	≥ 95%	32/32 Passed at ave.99.3% / Pass
Differential pressure (Delta-P)	EN 14683: 2019, Annex C Medical face masks - Requirements and test methods according to ASTM F2100:2019	<5.0 mm H2O/cm2	32/32 Passed at ave.3.7 mmH2O/cm2/ Pass
Particulate Filtration Efficiency	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	≥ 95%	32/32 Passed at ≥ave.98.12% / Pass
Resistance to penetration by synthetic blood, minimum pressure in mmHg 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 80 mmHg	32/32 Passed at 80 mmHg/ Pass
Flame spread	16 CFR Part 1610 Standard for the Flammability of Clothing according to ASTM F2100:2019	Class 1	32/32 Passed ≥3 Seconds burn Time-Class 1 / Pass

Medical surgical mask (Level 3)			
Test item (Performance	**Test method**	**Pass criteria**	**Test results**

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%	32/32 Passed at ≥99.8% / 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 H2O/cm2	32/32 Passed at <4.24 mm H2O/cm2/ Pass
Particulate Filtration Efficiency	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%	32/32 Passed at ≥99.58% / Pass
Resistance to penetration by synthetic blood, minimum pressure in mmHg 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 160mmHg	32/32 Passed at 160 mmHg/ Pass
Flame spread	16 CFR Part 1610 Standard for the Flammability of Clothing according to ASTM F2100:2019	Class 1	32/32 Passed ≥3 Seconds burn Time-Class 1 / Pass

8. Biocompatibility Testing Summary

According to ISO 10993-1: 2018, the nature of body contact for the subject device is direct surface contact with skin and indirect contact with the respiratory tract, and the duration of the contact is A-Limited (<24 h). The following tests for the subject device were conducted to demonstrate that the subject device is biocompatible and safe for its intended use:

Title of the test	Purpose of the test	The source of references (Test method)	Acceptance criteria	Test results
In vitro Cytotoxicity Test	Under the research conditions, determine whether the target device extract is cytotoxic.	ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	Pass
Skin Sensitization Test	Under the research conditions, determine whether the non-polar and polar extracts of the target device are sensitive.	ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	Pass
Skin Irritation Test	Under the research conditions, determine whether the non-polar and polar extracts of the target device are irritating.	ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	Pass

9. Summary of Clinical Performance Test

No clinical study is included in this submission.

10. Final Conclusion

The conclusions drawn from the nonclinical tests that demonstrate that the subject device Medical surgical mask (Black mask, Level 1 and Level 3) is as safe, as effective, and performs as well as or better than the legally marketed device K201622 and K202139.