January 15, 2021

Guangdong Kingfa Sci.&Tech.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: K202107
Trade/Device Name: Medical Protective Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 17, 2020
Received: December 28, 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,

For CAPT Elizabeth Claverie, M.S.
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)*
K202107

Device Name
Medical Protective Mask (Model: KF-A F02(N))

Indications for Use *(Describe)*
The Medical Protective Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The Medical Protective Mask is 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.

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 K202107

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.
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Application Correspondent :

Contact Person : Ms. Cassie Lee
Share Info (Guangzhou) Medical Consultant Ltd.
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Tel : +86 20 8266 2446
Email : regulatory@glomed-info.com

2. Subject Device Information

Type of 510(k): Traditional
Classification Name: Mask, Surgical
Common name: Surgical Mask
Trade Name: Medical Protective Mask
Model Name: KF-A F02(N)
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 878.4040
Regulatory Class: II

3. Predicate Device Information

Sponsor: Shandong Shengquan New Material Co., Ltd.
Trade Name: Protective Face Mask for Medical Use
Common name: Surgical Mask
Classification Name: Mask, Surgical
510(K) Number: K201537

Review Panel: General & Plastic Surgery
Product Code: FXX
Regulation Number: 878.4040
Regulatory Class: II

4. Device Description

The Medical Protective Mask is a single use, two-panel, flat–folded mask with ear loops and nose piece. The mask is designed into a C-shape when flat-folded. The C-shaped design allows for an expanded chamber for the mask in use.

The mask materials include four layers, the inner and outer layers are made of spun-bond polypropylene, and the two middle layers are melt-blown polypropylene and non-woven polypropylene filters, respectively.

The elastic ear loops are made of spandex and polyester, which are welded to the facemask to hold the mask in place over the users' mouth and nose. The elastic ear loops are not made with natural rubber latex. The nose piece is a Iron core covered with polypropylene.

The dimensions of each mask are length 162±5 mm and width 102±5 mm. The dimensions of nosepiece is length 90±10 mm and width 5±0.5 mm, and the ear loop is length 185±5 mm and width 5±0.5 mm. The mask is a single use, disposable device, provided non-sterile in white color.

5. Intended Use / Indications for Use

The Medical Protective Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The Medical Protective Mask is 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.

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**	**Verdict**
Company	GUANGDONG KINGFA SCI.&TECH.CO., LTD.	Shandong Shengquan New Material Co., Ltd.	--
510 (k)	K202107	K201537	--
Trade Name	Medical Protective Mask	Protective Face Mask for Medical Use	--
Model	KF-A F02(N)	--	--
Classification Name	Mask, Surgical	Mask, Surgical	Same
Classification	Class II Device, FXX (21	Class II Device, FXX (21	Same

Elements of Comparison	Subject Device	Predicate Device	Verdict
	CFR878.4040)	CFR878.4040)	
Intended use/ Indication for Use	The Medical Protective Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The Medical Protective Mask is 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.	The Protective Face Mask for Medical Use is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The face mask is 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	Spun-bond polypropylene	Same
Middle layer	Polypropylene non-woven fabric	Polypropylene non-woven fabric	Same
	Melt-blown polypropylene	Melt-blown polypropylene	Same
Inner facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
Nose clip	Iron core polypropylene strip	Plastic coated aluminum wire covered with sponge strips	Different Note 1
Ear Loops	Polyester and spandex	Polyester and spandex	Same
Design features	Color: white	Color: White	Same
Mask Style	Expanded chamber flat-folded, ear loops, 4 layers	Expanded chamber flat-folded, ear loops, 4 layers	Same
Specification and Dimension	Length: 16.2±0.5cm Width: 10.2±0.5cm	Length: 16.5±0.8cm Width: 10.5±0.5cm	Same Note 2
OTC use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
Performance Testing	ASTM F2100 Level 2	ASTM F2100 Level 2	Same
Fluid Resistance Performance	Pass at 120 mmHg	Pass at 120 mmHg	Same

Elements of Comparison	Subject Device	Predicate Device	Verdict
Particulate Filtration Efficiency	99.1%	99.22%	Similar Note 3
Bacterial Filtration Efficiency	99.9%	≥9.89%	Similar Note 3
Differential Pressure	On average of 5.04 mm H_2O/cm^2	Pass at 4.2 mmH_2O/cm^2	Similar Note 3
Flammability	Class 1	Class 1	Same
Latex	Not Made With Natural Rubber Latex	Not Made With Natural Rubber Latex	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 “Nose clip” of subject device is slightly difference with predicate device, it meets the requirement 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 “Specification and Dimension” of subject device is slightly difference with predicate device. The differences between the predicate device and subject device is minimal, there may be some measurement errors, it will not affect the safety and effectiveness of the subject device.

Note 3:

Although the “Particulate Filtration Efficiency”, “Bacterial Filtration Efficiency” and “Differential Pressure” of subject device is little difference with predicate device, it meets the requirement of essential performance standard ASTM 2100. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

7. Summary of Non-Clinical Performance Testing

Medical Protective Mask (Model: KF-A F02(N)) has been evaluated the safety and performance by lab bench testing as following:

- Performance Testing summary

Title of the test	**Purpose of the test**	**The source of references (Test method)**	**Acceptance criteria**	**Test results /Verdict**
Bacterial filtration efficiency	In order to verify whether the subject equipment meets the performance requirements of ASTM F2100 level 2, Bacterial filtration efficiency: ⩾ 98%	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%	99.1% / Pass
Differential pressure (Delta-P)	In order to verify whether the subject equipment meets the performance requirements of ASTM F2100 level 2, Differential pressure (Delta-P): <6.0 mm H_2O/cm^2	EN 14683: 2019, Annex C Medical face masks - Requirements and test methods according to ASTM F2100:2019	<6.0 mm H_2O/cm^2	On average of 5.04 mm H2O/cm2 / Pass
Sub-micron particulate filtration efficiency at 0.1 μm of Polystyrene Latex Spheres	In order to verify whether the subject equipment meets the performance requirements of ASTM F2100 level 2, Sub-micron particulate filtration efficiency at 0.1 μm of Polystyrene Latex Spheres: ⩾ 98%	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%	99.9% / Pass
Resistance to penetration by	In order to verify whether the subject	ASTM F1862/F1862M-17 Standard Test Method for	Fluid resistant claimed	Fluid Resistant

synthetic blood, minimum pressure in mm Hg for pass result	equipment meets the performance requirements of ASTM F2100 level 2, Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result: Fluid resistant claimed at 120 mm Hg	Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) according to ASTM F2100:2019	at 120 mm Hg	claimed at 120 mm Hg / Pass
Flame spread	In order to verify whether the subject equipment meets the performance requirements of ASTM F2100 level 2, Flame spread: Class 1	16 CFR Part 1610 Standard for the Flammability of Clothing according to ASTM F2100:2019	Class 1	Class 1 / Pass
Shelf-life	In order to verify that the subject equipment still meets the requirements of ASTM F2100 level 2 after 2 years of aging	ASTM F 1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices ASTM F2100 − 19, Standard Specification for Performance of Materials Used in Medical Face Masks	Meets the requirements of ASTM F2100 level 2	Pass

- Biocompatibility Testing

According to ISO 10993-1:2009, the nature of body contact for the subject device is Surface Device category, Skin Contact and duration of contact is A-Limited (≤24h). 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	Under the research	ISO 10993-10:2010	Under the conditions	Pass

Test	conditions, determine whether the non-polar and polar extracts of the target device are sensitive.	Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization	of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	
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

8. Summary of Clinical Performance Test

No clinical study is included in this submission.

9. Date of the summary prepared: January 13, 2021

10. Final Conclusion:

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K202107, the Medical Protective Mask (Model: KF-A F02(N)) is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K201537.