November 24, 2020

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: K201622
Trade/Device Name: Medical surgical mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: October 15, 2020
Received: October 22, 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
Assistant Director
DHT4B: Division of Health Technology 4B 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)*
K201622

Device Name
Medical surgical mask (Model: KF-B P05)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary for K201622

1. Submitter's Information

510(k) Owner's Name: Guangdong KINGFA SCI.&TECH.Co.,Ltd.

Address: 28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China

Post Code: 511500

Contact Person: Yu Xiaoge

Tel: +86 2632 8999

Fax: +0763-3203108

Email: yuxiaoge@kingfa.com.cn

Application Correspondent:

Contact Person: Ms. Cassie Lee

Share Info (Guangzhou) Medical Consultant Ltd.

Address: No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District, Guangzhou, China

Tel: +86 20 8266 2446

Email: regulatory@glomed-info.com

2. Date of the summary prepared: June 10, 2020

Revision date: November 24, 2020

3. Subject Device Information

Type of 510(k): Traditional

Classification Name: Mask, Surgical

Common name: Surgical Mask

510(K) Number: K201622

Trade Name: Medical surgical mask

Model Name: KF-B P05

Review Panel: Surgical Apparel

Product Code: FXX

Regulation Number: 878.4040

Regulatory Class: 2

4. Predicate Device Information

Sponsor: Protect U Guard, LLC

Trade Name: Protect U Guard Earloop and Tie-On Mask (Blue, White or Green)

Classification Name: Mask, Surgical

Common name: Surgical Mask

510(K) Number: K153409

Review Panel: Surgical Apparel

Product Code: FXX

Regulation Number: 878.4040

Regulation Class: 2

5. Device Description

The Medical surgical mask is flat pleated style mask, utilizing ear Loops way for wearing, and they all have 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 spun bond polypropylene, only the outer layers' color is blue (colorant: Pigment Blue K6911D /CAS number: 12239-87-1), and the middle layer is made of melt blown polypropylene.

Ear loops, which is held to cover the users' mouth and nose by two polyester and spandex elastic 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±5 mm and width 95±2 mm, and the inner and outer layers' density are 25 gsm, the middle layer is 35 gsm. The dimensions of nosepiece is length 100±5 mm and width 3±0.5 mm, and the ear loop is length 175±10 mm and width 3.5±0.5 mm.

The Medical surgical mask is sold non-sterile and is intended to be single use, disposable device.

6. 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.

7. 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.	Protect U Guard, LLC	--
510 (k)	K201622	K153409	--
Trade Name	Medical surgical mask	Protect U Guard Earloop and Tie-On Mask (Blue, White or	--

Elements of Comparison	Subject Device	Predicate Device	Verdict
		Green)	
Classification Name	Mask, Surgical	Mask, Surgical	Identical
Classification	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Identical
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.	Earloop Mask and Tie-On Mask is intended for use by healthcare workers during procedures to protect both patients and healthcare workers against transfer of microorganisms, bodily fluids, and airborne particles. This device is singleuse and provided non-sterile.	Identical
Material			
Outer facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Identical
Middle layer	Melt blown polypropylene	Melt blown polypropylene	Identical
Inner facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Identical
Nose piece	Polypropylene and metallic iron	Aluminum strip	Similar Note 1
Ear loops	Polyester and spandex elastic band	Urethane elastic fiber	Similar Note 1
Design features	Color: blue	Color: Blue, White and Green	Similar Note 1

Elements of Comparison	**Subject Device**	**Predicate Device**	**Verdict**
Mask Style	Earloop Flat Pleated	Earloop or Tie-On Flat Pleated	Identical
Specification and Dimension	9.5cm x 17.5 cm	9.5cm x 17.7 cm	Identical
OTC use	Yes	Yes	Identical
Sterility	Non-Sterile	Non-Sterile	Identical
Use	Single Use, Disposable	Single Use, Disposable	Identical
Performance Testing (according to ASTM-2100: 2019)	Level 1	Level 1	Identical
Fluid Resistance Performance	Pass at 80 mmHg	Pass at 80 mmHg	Identical
Particulate Filtration Efficiency	99.46%	99.18%	Similar better Note 2
Bacterial Filtration Efficiency	99.2%	99.17%	Similar better Note 2
Differential Pressure	<5.0 mm H_2O/cm^2	3.79 mmH_2O/cm^2	Similar Note 2
Flammability	Class 1	Class 1	Identical
Latex	Not Made With Natural Rubber Latex	Not Made With Natural Rubber Latex	Identical

Elements of Comparison	Subject Device	Predicate Device	Verdict
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.	Identical
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.	Identical
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.	Identical

Comparison in Detail(s):

Note 1:

Although the “Design features”, “Nose piece” and “Ear loops” of subject device is little difference with predicate device, it meet 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 “Fluid Resistance Performance”, “Particulate Filtration Efficiency”, “Bacterial Filtration Efficiency”, “Differential Pressure” and “Specification and Dimension” of subject device is little difference with predicate device, it meet 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.

8. Summary of Non-Clinical Tests Performed:

- Performance Testing summary

Test item (Performance Level 1)	**Test method**	**Pass criteria**	**Test results /Verdict**
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%	99.2% / 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 H_2O/cm^2	<5.0 mm H_2O/cm^2 / Pass
Sub-micron particulate filtration efficiency at 0.1 μm of Polystyrene Latex Spheres	ASTM F2299-03 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by	≥ 95%	99.46% / Pass

	Particulates Using Latex Spheres according to ASTM F2100:2019		
Resistance to penetration by synthetic blood, minimum pressure in mm Hg 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 mm Hg	Fluid Resistant claimed at 80 mm Hg / Pass
Flame spread	16 CFR Part 1610 Standard for the Flammability of Clothing according to ASTM F2100:2019	Class 1	Class 1 / 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 B-prolonged (>24 h to 30 d). The following tests for the subject device were conducted to demonstrate that the subject device is biocompatible and safe for its intended use:

1) In vitro Cytotoxicity Test per ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity,

2) Skin Sensitization Tests per ISO 10993-10:2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization,

3) Skin Irritation Tests per ISO 10993-10:2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization.

9. Summary of Clinical Performance Test

No clinical study is included in this submission.

10. Final Conclusion:

The conclusion drawn from the nonclinical tests demonstrates that the subject device Medical surgical mask in 510(k) K201622, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K153409.