November 20, 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: K202139
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, 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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K202139

Device Name
Medical Surgical Mask (Model: KF-B P05(L3))

Indications for Use *(Describe)*
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.

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

# K202139

prepared 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

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**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

**Date of preparation: October 15, 2020**

**2. Subject Device Information**

Type of 510(k): Traditional

Classification Name: Mask, Surgical

Trade Name: Medical surgical mask

Model Name: KF-B P05(L3)

Review Panel: General Hospital

Product Code: FXX

Regulation Number: 878.4040

Regulatory Class: 2

**3. Predicate Device Information**

Sponsor: H&H RESEARCH COMPANY

Trade Name: The New Medical Mask

Classification Name: Mask, Surgical

510(K) Number: K093179

Review Panel: General Hospital Product Code: FXX

Regulation Number: 878.4040

Regulation Class: 2

**4. Device Description**

The Medical surgical mask is a flat style face mask with ear loops and nose clip for fitting around the nose and mouth. The Medical surgical mask has three layers: the inner and outer layers are made of polypropylene nonwoven and the middle layer is made of polypropylene melt-blown. The outer layer is blue, and the colorant material is identified as Pigment Blue K6911D /CAS number: 12239-87-1. The face mask is held in place over the users' nose and mouth by two polyester and spandex elastic bands as ear loops welded to the face mask. The nose clip is made of iron-cored polypropylene, which allows the users to fit the mask around their nose area.

The dimensions of each mask are 175±5 mm in length and 95±2 mm in width. The density of the inner and outer layer is 25 gsm, and the density of the middle layer is 35 gsm. The dimensions of nosepiece are 100±5 mm in length and 3±0.5 mm in width. The ear loop is 175±10 mm in length and 3.5±0.5 mm in width. The Medical surgical mask is sold non-sterile and is intended to be single use, disposable device.

**5. Intended Use / Indications for Use**

The Medical surgical mask is indicated for infection control practices in the health care facilities. 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.

**6. Comparison to predicate device and conclusion**

| Elements of Comparison | Subject Device | Predicate Device | Verdict |
|---|---|---|---|
| Company | GUANGDONG KINGFA SCI.&TECH.CO., LTD. | H&H RESEARCH COMPANY | -- |
| 510 (k) | K202139 | K093179 | -- |
| Trade Name | Medical surgical mask | The New Medical Mask | -- |
| Classification Name | Mask, Surgical | Mask, Surgical | Identical |
| Classification | Class II Device, FXX (21CFR878.4040) | Class II Device, FXX (21CFR878.4040) | Identical |
| Intended use/ Indications for Use | 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. | This product is indicated for infection control practices in the health care industry. When worn properly, The New Medical Mask is intended to protect both patient and wearer from the transfer of microorganisms, body fluids and particulate material. | Identical |
| Material | | | |
| Outer facing layer | Polypropylene | Polypropylene | Identical |
| Middle layer | Polypropylene melt-blown | Polypropylene | Similar Note 1 |
| Inner facing layer | Polypropylene | Polypropylene | Identical |
| Nose clip | Iron core polypropylene strip | Adhesive tape | Different Note 1 |
| Ear Loops | Polyester and spandex elastic bands | Non-latex elastic ear bands | Different Note 1 |
| Design features | Color: blue | Color: blue | Identical |
| Mask Style | Ear loop flat style | Ear loop flat style | Identical |
| Specification and Dimension | 17.5cm×9.5cm | Length: 7.1 inches (18 cm)<br>Width: 3.9 inches (10 cm) | Similar Note 1 |

| | | | |
|---|---|---|---|
| OTC use | Yes | Yes | Identical |
| Sterility | Non-Sterile | Non-Sterile | Identical |
| Use | Single Use, Disposable | Single Use, Disposable | Identical |
| Protection level | Level 3 | Level 3 | Identical |
| Fluid Resistance Performance | Pass at 160 mmHg | Pass at 160 mmHg | Identical |
| Particulate Filtration Efficiency | 99.65% | 99.9% | Similar Note 2 |
| Bacterial Filtration Efficiency | >99.9% | >99.9% | Identical |
| Differential Pressure | On average of 3.72 mm $H_2O/cm^2$ | Pass at 2.7 mm$H_2O/cm^2$ | Similar Note 2 |
| Flammability | Class 1 | Class 1 | Identical |
| Latex | Not Made with Natural Rubber Latex | Not Made with Natural Rubber Latex | Identical |
| 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 |

**Note 1:**

Although the "Middle layer", "Nose clip", "Ear Loops" and "Specification and Dimension" 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 "Particulate 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 Tests Performed**

| Test Performance | 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 | ≥ 98% | 99.65% / 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 $H_2O/cm^2$ | 3.72 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 Particulates Using Latex Spheres according to ASTM F2100:2019 | ≥ 98% | 99.9% / Pass |
| 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 160 mm Hg | Fluid Resistant claimed at 160 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 |

**8. Summary of Clinical Tests Performed**

Not applicable.

**9. Conclusion**

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K202139, the Medical surgical mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K093179.