November 7, 2023

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

Re: K231155
Trade/Device Name: Biodegradable Medical surgical mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 7, 2023
Received: September 27, 2023

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,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*

K231155

Device Name

Biodegradable Medical surgical mask

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.

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Section 3-510(k) summary

I. Submitter

GUANGDONG KINGFA SCI. & TECH.CO., LTD.
No. 28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province 511545, China

Contact person: Xiaoge Yu
Position: Manager
Tel.: +86-13570952157
E-mail: yuxiaoge@kingfa.com.cn

Preparation date: January 10, 2023

II. Proposed Device

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

III. Predicate Devices

510(k) Number:	**K201622**
Trade name:	Medical surgical mask
Common name:	Medical surgical mask
Classification:	Class II
Product Code:	FXX
Manufacturer	GUANGDONG KINGFA SCI. & TECH.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 provided non-sterile and is intended to be a single use, disposable device.

V. Indication 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.

VI. Comparison of technological characteristics with the predicate devices

Table 1 Comparison of Medical surgical mask

Item	Proposed device	Predicate device (K201622)	Discussion
Trade name	Biodegradable Medical surgical mask	Medical surgical mask	-
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	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.	Same
Mask Style	Ear loop flat	Ear loop flat	Same
OTC use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Biodegradation Properties	Biodegradable	None	Different Note 1
Use	Single Use, Disposable	Single Use, Disposable	Same
Material			
Outer facing layer	Polylactic acid	Spun-bond polypropylene	Different Note 1

Middle layer	Melt-blown polylactic acid	Melt blown polypropylene	
Inner facing layer	Polylactic acid	Spun-bond polypropylene	
Product performance			
Performance Testing (according to ASTM-2100)	Level 1	Level 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:

Although the "Biodegradation Properties" and "Material" of proposed device are 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.

Biodegradability is not a medical claim and therefore was not reviewed by FDA.

VII. 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 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

Table 2 Summary of Non-Clinical Performance Testing

Test Method	Purpose	Acceptance Criteria	Results
Bacterial Filtration Efficiency ASTM F2101	Measure bacterial filtration efficiency	⩾95%	Pass
Differential Pressure(mmH_2O/cm^2) EN14683:2019 Annex C	Determine breathability of the mask	<5.0 mmH_2O/cm^2	Pass
Sub-micron Particulate Filtration Efficiency ASTM F2299-17	Measure initial particle filtration efficiency	⩾95%	Pass
Resistance to Penetration by Synthetic Blood ASTM F1862-17	Evaluate the resistance to penetration by impact of small volume of synthetic blood	29 out of 32 pass at 80 mmHg	Pass
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 research 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 research	Pass

		conditions.	
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 research 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 K201622.