December 22, 2020

Guangdong Kaidi Garments Co.,Ltd
℅ Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
13th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K202211
Trade/Device Name: Disposable Medical Surgical Face Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 30, 2020
Received: November 30, 2020

Dear Ivy Wang:

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 and Part 809); 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)*
K202211

Device Name
Disposable Medical Surgical Face Masks

Indications for Use *(Describe)*
The Disposable Medical Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), 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

Date of preparation: 2020-12-18

A. Applicant:

GUANGDONG KAIDI GARMENTS CO., LTD
Address: SHENXIYANG INDUSTRIAL ZONE, FENGSHAN STREET, HEPING TOWN, CHAOYANG, SHANTOU, CHINA 515000
Contact Person: Vicky Chen
Tel： +86- 754-83718111

Submission Correspondent:
Primary contact: Ms. Ivy Wang
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1309, Dongfang Building, 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-58817802
Email: haiyu.wang@sungoglobal.com
Secondary contact: Mr. Raymond Luo
Room 1309, Dongfang Building, 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-68828050
Email: fda.sungo@gmail.com

B. Device:

Trade Name: Disposable Medical Surgical Face Masks
Common Name: Disposable Surgical Mask
Model(s): NA

Regulatory Information
Classification Name: Surgical Face Mask
Classification: Class II
Product code: FXX
Regulation Number: 878.4040
Review Panel: Surgical Apparel

C. Predicate device:

K153496
Disposable Surgical Face Mask

D. Indications for use of the device:

The Disposable Medical Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks

are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

E. Device Description:

The Disposable Medical Surgical Face Masks are composed of mask body, nose clip and ear loop. The body of the mask is composed of three layers: the inner and outer layers are made of spun-bond nonwoven fabric， and the middle layer is made of melt blown non-woven fabric. The nose clip is made of PE and iron wire, ear loop is made of Nylon and Spandex.

The size of the disposable surgical mask is 17.5*9.5cm with tolerance±1cm, the length of the ear loop is 18cm. The outer layer of disposable surgical mask will be provided in blue, the inner layer of the disposable surgical mask will be provided in white, and it will be provided with non-sterile and is intended to be single use, disposable devices.

F. Comparison with predicate device

Table 1 General Comparison

Device		**Proposed Device**	**Predicate Device**	**Conclusion**
Manufacturer		GUANGDONG KAIDI GARMENTS CO., LTD	Xiantao Rayxin Medical Products Co., Ltd.	NA
510K number		K202211	K153496	NA
Classification		Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Intended use		The Disposable Medical Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	The Disposable Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	Same
Material	**Outer**	Spun-bond nonwoven fabric	Spun-bond polypropylene	Same
	Middle	Melt blown non-woven fabric	Melt blown polypropylene filter	Same
	Inner layer	Spun-bond nonwoven fabric	Spun-bond polypropylene	Same
	Nose clip	PE and iron wire	Malleable aluminum wire	Different
	Ear loops	Nylon and Spandex	Polyester	Different
Color		Blue	Blue	Same
Dimension		17.5cm+/-1cm	17.5cm+/-1cm	Same

Dimension	9.5cm+/-1cm	9.5cm+/-1cm	Same
OTC use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100	Level 2	Level 2	Same
Biocompatibility	ISO10993	ISO10993	Same
Fluid Resistance	32 out of 32 per lot pass at 120 mmHg, 3 non-consecutive lots tested	32 out of 32 Pass at 120 mmHg	Similar
Particulate Filtration Efficiency	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: 99.68% Lot 2: 99.56% Lot 3: 99.81%	98.46%	Similar
Bacterial Filtration Efficiency	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: 99.9% Lot 2: 99.9% Lot 3: 99.9%	98.7%	similar
Differential Pressure,	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: 3.6 mm H_2O/cm^2 Lot 2: 3.6 mm H_2O/cm^2 Lot 3: 3.7 mm H_2O/cm^2	4.2 mm H2O/cm2	Similar
Flammability	Class1, 3 non-consecutive lots tested, using a sample size of 32/lot.	Class1	Similar

From the comparison we found the material of the current nose clip and the ear loop were different from the predicate device. The biocompatibility tests were conducted to both components to ensure their compliance to the ISO10993-5 and ISO10993-10. There is no new risk generated from the difference of the material.

For the Performance testing, the test results are not identical to each other, but they are similar and they both meet the requirement of Level 2 medical mask according to the ASTM F 2100.

G. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as to the predicate device. 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 Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004:

- 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 F2100, Standard Specification for Performance of Materials Used In Medical Face Masks
- 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 - Performance Testing

Item	**Proposed device**	**Acceptance Criteria (level 2)**	**Result**
Fluid Resistance Performance ASTM F1862	32 out of 32 per lot pass at 120 mmHg, 3 non-consecutive lots tested	29 out of 32 Pass at 120 mmHg	PASS
Particulate Filtration Efficiency ASTM F2299	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: 99.68% Lot 2: 99.56% Lot 3: 99.81%	≥ 98%	PASS
Bacterial Filtration Efficiency ASTM F2101	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: 99.9% Lot 2: 99.9% Lot 3: 99.9%	≥ 98%	PASS
Differential Pressure (Delta P) EN 14683 Annex C	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: 3.6 mm H_2O/cm^2 Lot 2: 3.6 mm H_2O/cm^2 Lot 3: 3.7 mm H_2O/cm^2	< 6.0mmH_2O/cm^2	PASS
Flammability 16 CFR 1610	Class1, 3 non-consecutive lots tested, using a sample size of 32/lot.	Class 1	PASS

Table 3 Biocompatibility Comparison

Item	Proposed device	Acceptance Criteria	Result
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic.	Non-Cytotoxic	PASS
Irritation	Under the conditions of the study, the device is non-irritating.	Non-Irritating	PASS
Sensitization	Under the conditions of the study, the device is non-sensitizing	Non-Sensitizing	PASS

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, K153496 Xiantao Rayxin Medical Products Co., Ltd. Disposable Surgical Face Mask.