October 24, 2021

Anhui Tiankang Medical Technology Co., Ltd.
Eva Li
Consultant
Shanghai Sungo Management Consulting Company Limited
Room 1309, Dongfang Building, 1500#Century Ave
Shanghai, Shanghai 200122
China

Re: K212368
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 30, 2021
Received: July 30, 2021

Dear Eva Li:

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 Clarence W. Murray III, Ph.D.
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)*

K212368

Device Name
Surgical Face Mask

Indications for Use *(Describe)*

The 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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Anhui Tiankang Medical Technology Co.,Ltd.
No. 228 Weiyi Road, Economic Development Zone, Tianchang City, Anhui, China

510(k) Summary

A. 510(k) Number: K212368

B. Sponsor

Anhui Tiankang Medical Technology Co.,Ltd.
Address: No. 228 Weiyi Road, Economic Development Zone, Tianchang City, Anhui, China
Contact Person: Zhang Yong
Tel：+86-13705505106

C. Date Prepared: September 23, 2021

D. Submission Correspondent

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E. Subject Device

Trade Name: Surgical Face Mask Model(s):

Model#	Description
WKKZ.R.LEVEL1-001 WKKZ.R.LEVEL2-001 WKKZ.R.LEVEL3-001	Ear loop, Flat pleated, 3 layers
WKKZ.J.LEVEL1-001 WKKZ.J.LEVEL2-001 WKKZ.J.LEVEL3-001	Tie-on, Flat pleated, 3 layers

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

F. Predicate device:

K110455
Kimberly-Clark KC100 Mask Kimberly-Clark

G. Indications For Use:

The 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.

H. Device Description:

The Surgical Face Masks are single use, three-layer, flat –folded masks with ear loops/tie coverall and nose clamp.
The Surgical Face Masks are manufactured with three layers, the inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter.
The ties/ear loops are held in place over the users' mouth and nose by two ties/ear loops welded to the facemask. The loops are made of Nylon and spandex and the ties are made of polypropylene nonwoven.
The nose clamp in the layers of facemask is to allow the user to fit the facemask around their nose, which is made of PP coated steel wire.
The Surgical Face Masks will be provided in blue. The Surgical Face Masks are sold non- sterile and are intended to be single use, disposable devices.

I. Comparison of Technological Characteristics

Table 1 General Comparison

Device		Proposed Device	Predicate Device	Comparison
Manufacturer		Anhui Tiankang Medical Technology Co.,Ltd.	Kimberly-Clark	
510(K) number		K212368	K110455	
Model Name		Surgical Face Mask	Kimberly-Clark KC100 Mask	Similar
Classification		Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Indications For Use		The 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 Kimberly-Clark KC100 Procedure Mask(s) is 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. The Kimberly-Clark KC100 Procedure Mask(s) is a single use, disposable devices, provided non- sterile.	Same
Description		Ear loop, Tie-On, Flat pleated, 3 layers	Ear Loops, Tie-On, Flat Pleated, 3 layers	Same
Material	Outer facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Inner facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose clamp	PP coated steel wire	N/A	Different
	Ear loops Ties	Nylon and spandex; PP nonwoven	Polyester/lycra knitted	Different
Color		Blue	Variety (include blue)	Similar
Dimension		175±5mm	165±19mm	Similar

（length）				
Dimension （width）		95±2.85mm	102±19mm	Similar
OTC use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
Use		Single use, Disposable	Single use, Disposable	Same
ASTM F2100 Level		Level 1 Level 2 Level 3	Level 1	Similar
Biocompatibility	Cytotoxicity ISO 10993-5	Non-cytotoxic under the conditions of the study	Non-cytotoxic under the conditions of the study	Same
	Skin Sensitivity ISO 10993-10	Non-sensitizer under the conditions of the study	Non-sensitizer under the conditions of the study	Same
	Skin Irritation ISO 10993-10	Non-irritating under the conditions of the study	Non-irritating under the conditions of the study	Same

The proposed device has different material of nose clamp and ear loop/ties to the predicate device, but the material has been tested and the test results shown that the material differences do not affect device performance. The subject device conducted testing to demonstrate compliance with ASTM F2100 with the different models meeting the Level 1, Level 2, and Level 3 criteria, while the predicate device met the ASTM F2100 Level 1 criteria.

J. Summary of Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the subject device met all design specifications. The test results demonstrated that the subject 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:

Table 2: Non-clinical performance testing

Item	Purpose	Acceptance Criteria		Results
Synthetic Blood Penetration ASTM F1862	Demonstrate resistance to liquid penetration	≥ 29 samples out of 32 pass (AQL 4%)	Level 1 pass at 80mmHg	Pass
			Level 2 pass at 120mmHg	Pass
			Level 3 pass at 160mmHg	Pass
Particulate Filtration Efficiency ASTM F2299	Demonstrate particulate filtration	29 out of 32 pass	Level 1 pass at ≥95%	Pass
			Level 2 pass at ≥98%	Pass
			Level 3 pass at ≥98%	Pass
Bacterial Filtration Efficiency ASTM F2101	Demonstrate bacterial filtration	29 out of 32 pass	Level 1 pass at ≥95%	Pass
			Level 2 pass at ≥98%	Pass
			Level 3 pass at ≥98%	Pass
Differential Pressure (Delta P) EN 14683 Annex C	Demonstrate breathability	29 out of 32 pass	Level 1 pass at ≤ 5.0 mmH_20/cm^2	Pass
			Level 2 pass at ≤ 6.0 mmH_20/cm^2	Pass
			Level 3 pass ≤ 6.0 mmH_20/cm^2	Pass
Flammability 16 CFR 1610	Demonstrate flame resistance	Class I		Pass
Cytotoxicity ISO 10993-5	Demonstrate cytotoxic biocompatibility	Under the conditions of the study, the device is non-cytotoxic.		Pass
Skin Irritation ISO 10993-10	Demonstrate non-irritability	Under the conditions of the study, the device is non-irritating.		Pass

Skin Sensitization ISO 10993-10	Demonstrate non-sensitization	Under the conditions of the study, the device is non-sensitizing	Pass

- 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;

K. Summary of Clinical Performance Tests

No clinical study is included in this submission.

L. Conclusion

Based on the nonclinical tests performed, the subject Surgical Face Masks are as safe, as effective, and perform as well as or better than the legally marketed predicate device, Kimberly-Clark KC100 Mask cleared under K110455.