August 28, 2021

Tianchang Kanghui Protective Products CO LTD
% Ivy Wang
Consultant
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K211255
Trade/Device Name: Surgical Mask (model: KH8001& KH8002)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 18, 2021
Received: August 18, 2021

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); 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,

Clarence W. Murray, III, PhD
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)*
K211255

Device Name
Surgical Mask (model: KH8001& KH8002)

Indications for Use *(Describe)*
The Surgical Mask (model: KH8001& KH8002) 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. This 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.

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510(K) Summary

K211255

Document prepared date: 8/25/2021

A. Applicant

Name: TIANCHANG KANGHUI PROTECTIVE PRODUCTS CO., LTD.
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Submission Correspondent:
Primary contact: Ms. Ivy Wang
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B. Device:

Trade Name: Surgical Mask
Common Name: Surgical Face
Mask Model: KH8001,KH8002

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

C. Predicate device:

510K	Device name	ASTM F2100-19 Level	Manufacturer
K203685	Disposable Surgical Face Masks	Level 3, Level 2	Xiantao Zhongyi Safety & Protection Products Co., Ltd

D. Indications for use of the device:

The Surgical Masks (model: KH8001& KH8002) 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 a single use, disposable devices, provided non-sterile.

E. Device Description:

The proposed devices (model: KH8001& KH8002) are White color, and Flat Pleated type mask, utilizing Ear Loops way for wearing, and they all has Nose clips design for fitting the face mask around the nose.

The proposed devices 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 model of proposed device, ear loops, is held in place over the users' mouth and nose by two elastic ear loops welded to the face mask. The elastic ear loops are made of polyester fiber and spandex. The nose piece in the proposed devices is made of Galvanized wire with polypropylene and is contained within the layers of face mask to allow the user to fit the face mask around their nose. The proposed devices are sold non-sterile and are intended to be single use, disposable devices.

F. Technical Characteristic Comparison

Table 1 Summary of Technological Characteristics

Device		Proposed Device	Predicted Device	Comparison
Manufacturer		TIANCHANG KANGHUI PROTECTIVE PRODUCTS CO.,LTD.	Xiantao Zhongyi Safety & Protection Products Co., Ltd	-
510K number		K211255	K203685	-
Classification		Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Indications for use		The Surgical Masks (model: KH8001& KH8002) 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 a single use, disposable device(s), provided non-sterile.	The Disposable Surgical Face Masks (model: ZYD- 02 & ZYD-03) 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 a single use, disposable device(s), provided non-sterile.	Similar
	Outer	spun-bond polypropylene	Spun-bond polypropylene	Same

Material	**Middle**	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Inner	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose clip	Galvanized wire with polypropylene	Polypropylene and Iron	Different
	Ear loops	polyester fiber and spandex	Spandex	Different
Color		White	Blue	Different
Dimension (Length)		17.5+/-0.3cm	17.5 cm +/- 0.5 cm	Similar
Dimension (Width)		9.0+/-0.3cm	9.5 cm +/- 0.5 cm	Similar
OTC use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
Use		Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100 level		Level 2, Level 3	Level 2, Level 3	Same
Fluid Resistance Performance		32 out of 32 pass at 120mmHg; 32 out of 32 pass at 160mmHg;	32 out of 32 pass at 120mmHg; 32 out of 32 pass at 160mmHg;	Same
Particulate Filtration Efficiency		≥ 98%	≥ 98%	Same
Bacterial Filtration Efficiency		≥ 98%	≥ 98%	Same
Differential Pressure (Delta P)		< 6.0mmH_2O/cm^2	< 6.0mmH_2O/cm^2	Same
Flammability 16 CFR 1610		Class 1	Class 1	Same
Biocompatibility		Meet ISO10993: Non-Cytotoxic; Non-Irritating;	Meet ISO10993: Non-Cytotoxic; Non-Irritating; Non-Sensitizing;	Same

	Non-Sensitizing;		

From the comparison we found the material of the current nose clip and the ear loop, as well as the mask color and dimension 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. 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&3 medical mask according to the ASTM F 2100-19, Standard Specification for Performance of Materials Used In Medical Face Masks.

G. Performance Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was similar to the predicate device. Provided below in Table 2 is the summary of the non-clinical testing that was performed per specification of the standard and test methodology using 3 non-consecutive lots with 32 samples for each lot listed below. The results of the performance testing demonstrated the subject device met the acceptance criteria of the standard and the test methodologies summarized below. The test results demonstrated that the proposed device complies with 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: Summary of Non-Clinical Testing

Test Methodology	Purpose	Acceptance Criteria	Results
ASTM F2101-19, Differential Pressure, mm H2O/cm2	Measuring the pressure of dropping across a medical face mask material.	< 6.0mmH_2O/cm^2	Level 3: Passed at 3.1 mmH_2O/cm^2 Level 2: Passed at 3.3 mmH_2O/cm^2
ASTM F1862-17, Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)	Testing the efficiency of resistance to penetration by synthetic blood.	Level 3: 29 out of 32 pass at 160 mmHg; Level 2: 29 out of 32 pass at 120 mmHg	Level 3: 32 out of 32 passed at 160 mmHg; Level 2: 32 out of 32 passed at 120 mmHg
ASTM F2101-19, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using A Biological Aerosol of Staphylococcus Aureus	Testing the effectiveness of medical face mask material in preventing the passage of aerosolized bacteria.	>98%	Level 3: passed at 99.8% Level 2: passed at 99.9%
ASTM F2299-17, Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by	Testing the efficiency of the filter material in capturing aerosolized particles smaller than one micron.	>98%	Level 3: passed at 99.5% Level 2: passed at 99.6%

particulates using latex spheres			
16 CFR 1610, Standard for the Flammability of clothing textiles	Testing the characteristics of a material that pertain to its relative ease of ignition and relative ability to sustain combustion.	Class 1	Met Class 1
ISO 10993-5:2009, Biological Evaluation of Medical Devices, Part 5: Tests for In-Vitro Cytotoxicity	Assess the biological response of mammalian cells in vitro in contact with a device or extracts of a device	Non-Cytotoxic under the conditions of the study	Passed, Non-Cytotoxic under the conditions of the study
ISO 10993-10:2010, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Sensitization	Assess medical devices and their constituent materials for their potential to produce skin irritation or sensitization in animal models	Non-Irritating and Non-Sensitizing under the conditions of the study	Passed, Non-Irritating and Non-Sensitizing under the conditions of the study
ISO 10993-10:2010, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Sensitization	Assess medical devices and their constituent materials for their potential to produce skin irritation or sensitization in animal models	Non-Irritating and Non-Sensitizing under the conditions of the study	Passed, Non-Irritating and Non-Sensitizing under the conditions of the study

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K211255, Surgical Mask, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K203685.