November 13, 2021

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

Re: K212264
Trade/Device Name: Surgical Face mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: October 12, 2021
Received: October 12, 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,

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)*

Device Name

Indications for Use *(Describe)*

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 K212264

A. Applicant

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Date Prepared: November 8, 2021

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B. Device

Trade Name: Surgical Face Mask
Model(s):

Model#	Description
Earloop17.5*9.5cm	Ear loop, Flat pleated, 3 layers

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

C. Predicate device:

K110455
Kimberly-Clark KC100 Mask
Kimberly-Clark

D. Intended Use/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 sterile.

E. Device Description:

The Surgical Face Masks are single use, three-layer, flat –folded masks with ear loops 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 ear loops are held in place over the users' mouth and nose by two ear loops welded to the facemask. The loops are made of Nylon and spandex.

The nose clip in the layers of facemask is to allow the user to fit the facemask around their nose, which is made of Polypropylene.

The Surgical Face Masks will be provided in blue. The Surgical Face Masks are sold sterilized and are intended to be single use, disposable devices.

F. Technological Characteristics Comparison

Table 1 General Comparison

Device	Proposed Device	Predicate Device	Comparison
Manufacturer	Nantong Taiweishi Medical Technology Co., Ltd.	Kimberly-Clark	
510(K) number	K212264	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
Intend use/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 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, Flat pleated, 3 layers	Ear Loops, Tie-On, Flat Pleated, 3 layers	Similar
Material	Outer facing layer	Spun-bond polypropylene	nonwoven polyester blends and polypropylene materials.	Different*1
	Middle layer	Melt blown polypropylene filter		
	Inner facing layer	Spun-bond polypropylene		
	Nose clip	Polypropylene	nonwoven polyester	Different*1
	Ear loops	Nylon, Spandex	knitted polyester/lycra or nonwoven polyester.	Different*1
Color		Blue	Variety (include blue)	Similar
Dimension （length）		175±5%(mm)	165±19mm	Similar
Dimension （width）		95±5%(mm)	102±19mm	Similar
OTC use		Yes	Yes	Same
Sterility		Sterile	Non-Sterile	Different*2
Use		Single use, Disposable	Single use, Disposable	Same
ASTM F2100 Level		Level 2	Level 1	Similar*3
Biocompatibility		Non-Cytotoxic	Non-Cytotoxic	Same
		Non-Irritating	Non-Irritating	
		Non-Sensitizing	Non-Sensitizing	

***1 Different Discussion:**

The proposed device has different material of mask body, nose clip and ear loop to the predicate device.

***2 Different Discussion:**

The proposed device is sterile, the predicated device is non-sterile. The proposed device was implemented the performance test and biocompatibility test on the sterilized device.

***3 Similar Discussion：**

The proposed device passes the Level 2 Acceptance Criteria, the predicate device passes the level 1 Acceptance Criteria. The test and the acceptance is following:

	ASTM F2100-19	
	Level 1	Level 2
BFE% ASTM F2101	≥95	≥98
PFE% ASTM 2299	≥95	≥98
Synthetic Blood ASTM 1862	Pass at 80 mmHg	Pass at 120 mmHg
Differential pressure EN 14683	＜5.0 mmH_20/cm^2	＜6.0 mmH_20/cm^2
Flammability 16CFR Part 1610	Class 1	Class 1
Sampling: AQL 4% for BFE, PFE, Delta P; 32 masks for Synthetic Blood(Pass=≥29 passing, Fail=≤2passing Flammability：all samples burn time is 3.5 seconds or more ACCEPTABLE（3.5 sec is a pass		

G. Summary of Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications. 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 Face 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;
- ANSI/AAMI/ISO 11135:2014 Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices

Table 2-performance Testing

Item	Acceptance Criteria (level 2)	Result of LOT-WK20201006	Result of LOT-WK20201204	Result of LOT-WK20201208
Synthetic Blood Penetration ASTM F1862	29 out of 32 pass at 120mmHg	32 out of 32 pass at 120mmHg	32 out of 32 pass at 120mmHg	32 out of 32 pass at 120mmHg
Particulate Filtration Efficiency ASTM F2299	⩾98%	⩾99%	⩾99%	⩾99.9%
Bacterial Filtration Efficiency ASTM F2101	⩾98%	⩾99%	⩾99%	⩾99.9%
Differential Pressure(Delta P) EN 14683 Annex C ASTM F2100-19	＜6.0 mmH_20/cm^2	＜6.0	＜6.0	＜6.0
Flammability 16 CFR 1610 (*IBE=Test article ignited, but extinguished)	Class I	Class I	Class I	Class I

Table3 Biocompatibility Testing

Item	Proposed device	Acceptance Criteria	Result
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic.	Non-Cytotoxic	No cytotoxic potential.
Irritation	Under the conditions of the study, the device is non-irritating.	Non-Irritating	The Primary Irritation Indexes for the test article extracts were both calculated to be 0.0
Sensitization	Under the conditions of the study, the device is non-sensitizing	Non-Sensitizing	Not considered a sensitizer

H. Summary of Clinical Performance Test

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, Kimberly-Clark KC100 Mask cleared under K110455.