September 13, 2021

Fujian Kang Chen Daily Necessities CO., LTD
Shuyan Wang
Administrative Director
No.55 Houdun Road, houmao Industrial Zone, Fengze District
Quanzhou, Fujian 362000
China

Re: K203455
Trade/Device Name: Disposable Medical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 5, 2021
Received: August 9, 2021

Dear Shuyan 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 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)*
K203455

Device Name
Disposable Medical mask

Indications for Use *(Describe)*
The Disposable Medical mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. The Disposable Medical mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.

Model: k0450, blue color, and Level 2 barrier level per ASTM F2100.

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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510k Summary

Prepared Date:09/13/2021

510k Number: 203455

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter Information

Sponsor : FUJIAN KANG CHEN DAILY NECESSITIES CO.,LTD

Address: No.55 Houdun Road, houmao Industrial Zone, Fengze District, Quanzhou City, Fujian Province, China.

Contact Person: Shuyan Wang (Administrative Director)

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2. Subject Device Information

Type of 510(k):	Traditional
Common Name:	Surgical mask
Trade Name:	Disposable Medical Mask
Model:	k0450
Classification Name:	Surgical Apparel
Review Panel:	General Hospital
Product Code:	FXX
Regulation Number:	21 CFR 878.4040
Regulation Class:	II

3. Predicate Device Information

Sponsor:	Qiqihar Hengxin Medical Supplies,Ltd.
Common Name:	Surgical Mask
Trade Name:	Single-Use Surgical Face Mask with Ear Loop

510(k) number:	K201691
Model:	L

Classification Name:	Surgical Apparel
Review Panel:	General Hospital
Product Code:	FXX
Regulation Number:	21 CFR 878.4040
Regulation Class:	II

4. Indications for Use

The Disposable Medical mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. The Disposable Medical mask intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.

Model: k0450, blue color, and Level 2 barrier level as ASTM F2100.

5. Device Description

Disposable Medical Mask are non-sterile, single use, 3 layers, flat-pleated style with ear loops and nose clip. The outer layer and inner facing layer of face mask consist of Spunbond Polypropylene, and the middle layer consists of Melt Blown Polypropylene Filter. Each mask contains ear loops to secure the mask over the users' mouth and face and includes a nose clip to provide a firm fit over the nose. The mask is a single use, disposable device, provided non-sterile.

6. Test Summary

Surgical face mask has been evaluated the safety and effectiveness by lab bench testing according to the following standards:

- ASTM F2299 Standard Test Method for Determining the Initial Efficiency of Materials Used in Surgical face masks to Penetration by Particulates Using Latex Spheres.
- ASTM F1862 Standard test method for resistance of Surgical face masks to penetration by synthetic blood (Horizontal projection of fixed volume at a known velocity).
- ASTM F 2101-19 Standard Test Method For Evaluating The Bacterial Filtration Efficiency (BFE) Of Surgical face mask Materials, Using A Biological Aerosol Of Staphylococcus Aureus.
- 16 CFR Part 1610 STANDARD FOR THE FLAMMABILITY OF CLOTHING TEXTILES
- ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks

During use, the Non-Woven Face Mask will directly contact with user's skin, so we have it tested to demonstrate conformance to the following standards.

- ISO 10993-5, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

7. Summary of Comparison and Technological Characteristics

Table 1 - General Comparison

Elements of Comparison	Subject Device	Predicate Device	Results
Product Name	Disposable Medical Mask (Model: k0450)	Single-Use Surgical Mask with Ear Loop (Model:L)	--
510(k) Number	K203455	K201691	
General Comparison			

Elements of Comparison		Subject Device	Predicate Device	Results
Indication for Use		The Disposable Medical mask is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. The Disposable Medical mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile. Model: k0450, blue color, and Level 2 barrier level as ASTM F2100.	The Single-Use surgical mask with Ear Loop is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids and particulate material. The Single-Use Mask with Ear Loop 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. Model:M and L, blue color, and Level 2 barrier level as ASTM F2100	Same
Model		3 layers, Ear Loops, Flat-Pleated Style	3 layers, Ear Loops, Flat-Pleated Style	
Material	Outer facing layer	Spun-bond polypropylene	Spun-bond non-woven fabric	Different Note 1

Elements of Comparison		Subject Device	Predicate Device	Results
	Middle layer	Melt blown polypropylene filter	Melt blown non-woven fabric	Different Note 2
	Inner facing layer	Spun-bond polypropylene	Spun-bond non-woven fabric	Different Note 3
	Nose clip	aluminum wire coated by polyethylene.	Malleable aluminum wire	Different Note4
	Ear loops	Spandex	Polyester	Different Note 5
Color		Blue	Blue	Same
Dimension (Width)		9.5cm ± 0.5cm	9.0cm ± 1.0cm	Different Note 6
Dimension (Length)		17.5cm ± 0.5cm	18.0cm ± 1.0cm	
Sterility		Non-Sterile	Non-Sterile	Same
Use		Single Use	Single Use	Same
ASTM F2100 Level		Level2	Level 2	Same
Fluid Resistance Performance (mmHg)		32 out of 32 pass at 120 mmHg	31 Out of 32 pass at 120 mmHg	Similar
Particulate Filtration Efficiency Performance (%)		99.9%	≥ 99%	Same
Bacterial Filtration Efficiency Performance (%)		99.9%	≥ 99%	Same
Flammability class		Class 1	Class 1	Same
Differential Pressure (Delta-P) (mm H2O/cm2)		＜5.0 mmH_2O/cm^2	< 5.0 mmH_20/cm^2	Same

Note1: Although their are differences in the material of the outer facing layer, the difference does not raise any issues of safety and effectiveness based on the results obtained in the biocompatibility studies and performance studies.

Note2: Although their are differences in the material of the middle layer, the difference does not raise any issues of safety and effectiveness based on the results obtained in the biocompatibility studies and performance studies.

Note3: Although their are differences in the material of the inner facing layer, the difference does not raise any issues of safety and effectiveness based on the results obtained in the biocompatibility studies and performance studies.

Note4: Although their are differences in the material of the nose clip, the difference does not raise any issues of safety and effectiveness based on the results obtained in the biocompatibility studies and performance studies.

Note5: Although their are differences in the material of the ear loops, the difference does not raise any issues of safety and effectiveness based on the results obtained in the biocompatibility studies and performance studies.

Note 6: Although their are differences in the dimension that do not raise any issues of safety and effectiveness based on the results obtained in the biocompatibility studies and performance studies.

8. Non-clinical Tests Performed on the Proposed Device

The proposed device was tested and conformed to 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.

Test purpose	**Test Method**	**Pass Criteria**	**Results**
Fluid Resistance Performance (mmHg)	ASTM F1862	29 Out of 32 pass at 120 mmHg	32 out of 32 pass at 120 mmHg
Particulate Filtration Efficiency Performance (%)	ASTM F2299	≥ 98%	99.9%
Bacterial Filtration Efficiency	ASTM F2101	≥ 98%	99.9%

Performance (%)			
Flammability class	16 CFR 1610	Class 1	Class 1
Differential Pressure (Delta-P) (mm H_2O/cm^2)	ASTM F2100-19	< 5.0 mmH_20/cm^2	＜5.0 mmH_2O/cm^2

9. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K203455, the Disposable Medical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K201691.