December 15, 2021

Hubei Kimsoul Industrial Co., Ltd
Grace Liu
Consultant
Shenzhen Joyantech Consulting Co. Ltd
1713A, 17th Floor, Block A, Zhongguan Times Square,
Nanshan District
Shenzhen, Guangdong 518000
China

Re: K212398
Trade/Device Name: Surgical Face Mask (Non-sterile)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: October 16, 2021
Received: Nov 1, 2021

Dear Grace Liu:

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, 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)*
K212398

Device Name
Surgical Face Mask (Non-sterile)

Indications for Use *(Describe)*
The masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These masks are intended for adult 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K212398

1. Contact Details

1.1 Applicant information

Applicant Name	HUBEI KIMSOUL INDUSTRIAL CO., LTD
Address	NO. 1, Industrial Zone, Guohe Town, Xiantao City, Hubei Province, China
Contact person	Faming Zhang
Phone No.	+86-177 0727 3453
E-mail	zhangfaming@ks-nonwoven.com.cn
Date Prepared	2021-10-16

1.2 Submission Correspondent

卓远天成	Shenzhen Joyantech Consulting Co., Ltd 1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen, Guangdong Province, China
Phone No.	+86-755-86069197
Contact person	Grace Liu; Field Fu;
Contact person's e-mail	grace@cefda.com; field@cefda.com
Website	http://www.cefda.com

2. Device Information

Trade name	Surgical Face Mask (Non-sterile)
Common name	Surgical Face Mask
Model	2020, 2030
Classification	Ⅱ
Classification name	Mask, Surgical
Product code	FXX
Regulation No.	21 CFR 878.4040

3. Legally Marketed Predicate Device

Trade Name	Ear-Friendly Mask
510(k) Number	K211105
Product Code	FXX
Manufacturer	RAY Co., Ltd

4. Legally Marketed Reference Device

Trade Name	Disposable Surgical Mask

510(k) Number	K202341
Product Code	FXX
Manufacturer	Shanghai Jianzhong Medical Packaging Co., Ltd.

5. Device Description

The proposed device is a three-layer, flat pleated mask. Each mask is composed of a mask body, a nose piece and two ear loops. The mask body is manufactured with three layers, the inner layer and the outer layer are made of polypropylene spunbond nonwoven fabric, and the middle layer is made of polypropylene meltblown nonwoven fabric. It is held in place over the user's mouth and nose by two elastic ear loops welded to the mask body. The elastic ear loops are made of polyester and polyurethane, not made from natural rubber latex. The nose piece is in the layers of face mask to allow the user to fit the face mask around his nose, which is made of polyethylene.

The proposed device is provided non-sterile and is intended to be a single use, disposable device.

6. Intended Use/Indication for Use

The masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These masks are intended for adult 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.

7. Technological Characteristics Comparison

Table 1 Substantial Equivalence Comparison

Item	Proposed Device (K212398)	Predicate Device (K211105)	Reference Device (K202341)	Comment
Product name	Surgical Face Mask (Non-sterile)	Ear-Friendly Mask	Disposable Surgical Mask	/
Manufacturer	HUBEI KIMSOUL INDUSTRIAL CO., LTD	RAY Co., Ltd	Shanghai Jianzhong Medical Packaging Co., Ltd.	/
Product Code	FXX	FXX	FXX	Same
Regulation Number	21 CFR § 878.4040	21 CFR § 878.4040	21 CFR § 878.4040	Same
Classification	Class Ⅱ	Class Ⅱ	Class Ⅱ	Same
OTC use	Yes	Yes	Yes	Same
ASTM Level	Level 3	Level 3	Level 3	Same
Indications for use	The masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate	When properly worn, the Ear-Friendly Masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body	The Disposable Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body	Similar

	material. These masks are intended for adult 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.	fluids and particulate material. This device is non sterile and for single use only.	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, provided non-sterile and sterile. Models: 17.5*9.5cm-3ply (sterile), 14.5*9.5cm-3ply (sterile), 14.5*8cm-3ply (sterile) 17.5*9.5cm-3ply (non-sterile), 14.5*9.5cm-3ply (non-sterile), 14.5*8cm-3ply (non-sterile)	
Design feature	Ear-loop	Ear-loop	Ear-loop	Same
Mask style	3-ply, Flat Pleated	3-ply, Flat Pleated	3-ply, Flat Pleated	Same
Use	Single Use, Disposable	Single Use, Disposable	Single Use, Disposable	Same
Color	White	White	Blue	Same
Specifications and Dimensions	2020: (145±5) mm × (95±5) mm 2030: (175±5) mm × (95±5) mm	Length: (175±10) mm Width: (95±10) mm	17.5*9.5 cm 14.5*9.5 cm 14.5*8 cm	Different
Sterility	Non-Sterile	Non-Sterile	Non-Sterile, Sterile	Same
Materials				
Outer layer	Spunbond polypropylene	Spunbond polypropylene	Polypropylene	Same
Middle layer	Meltblown polypropylene filter	Meltblown polypropylene filter	Polypropylene melt-blown	Same
Inner layer	Spunbond polypropylene	Spunbond polypropylene	Polypropylene	Same
Nose piece	Polyethylene (PE)	Single Galvanize wire, coated By PE	Polyvinylchloride coated iron wire	Different
Ear loop	Polyester and Polyurethane	Elastic non-woven Fabric (Made With PE&PP mixed)	Polyurethane	Different
Performance				
Fluid	Pass at 160 mmHg	Pass at 160 mmHg	Pass at 160 mmHg	Same

Resistance				
Bacterial Filtration Efficiency	Pass at ≥98%	Pass at ≥98%	Pass at >98.12%	Same
Particulate Filtration Efficiency	Pass at ≥98%	Pass at ≥98%	Pass at >98.01%	Same
Differential Pressure (Delta-P)	Pass at <6.0 mmH_2O/cm^2	Pass at <6.0 mmH_2O/cm^2	Pass at <4.6 mmH_2O/cm^2	Same
Flammability	Class 1	Class 1	Class 1	Same
Biocompatibility	Under the conditions of the studies employed, the device is non-cytotoxic, non-sensitizing, and non-irritating.	Under the conditions of the studies employed, the device is non-cytotoxic, non-sensitizing, and non-irritating.	No Cytotoxicity, No Sensitization and No Irritation	Same

The proposed device has the same indication for use as the predicate device. The proposed device provides an additional dimension [Model 2020, size: (145±5) mm × (95±5) mm], which is different from the predicate device, but the reference device of the same dimension have been approved by FDA in K202341. The results of performance testing including biocompatibility evaluation performed on the final finished device demonstrates that the proposed device can meet the requirements of ASTM F2100 and ISO 10993. Therefore, the differences in the mask dimensions and materials don't raise any additional questions for safety and effectiveness, and the proposed device is substantially equivalent to the predicate device.

8. Summary of Non-clinical Testing

8.1 Biocompatibility testing

The biocompatibility tests were conducted to demonstrate the safety of the proposed device as similar to the predicate device. The test results demonstrated that the proposed device complies with ISO10993-1 (as shown in Table 2).

Table 2 Summary of Biocompatibility Tests

Test	Purpose	Acceptance Criteria	Result
In vitro Cytotoxicity (ISO 10993-5)	Verify that the proposed device extract is non-cytotoxic.	The extract is non-cytotoxic under the research conditions.	Pass
Skin Irritation (ISO 10993-10)	Verify that the proposed device extract is non-irritating.	The polar and non-polar extracts are non-irritating under the research conditions.	Pass
Skin Sensitization	Verify that the proposed device extract is non-sensitizing.	The polar and non-polar extracts are non-sensitizing under the research	Pass

(ISO 10993-10)		conditions.	

8.2 Performance testing - Bench

The performance tests were conducted to demonstrate the effectiveness of the proposed device as similar to the predicate device. The test results demonstrated that the proposed device complies with the following standards (as shown in Table 3).

- ASTM F2100-20 Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- 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
- ASTM F2299/F2299M-03 (R2017) Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- EN 14683:2019+AC:2019 Medical Face Masks - Requirements and Test Methods
- 16 CFR 1610 Standard for the Flammability of Clothing Textiles

Table 3 Summary of Performance Tests

Test	Purpose	Acceptance Criteria per ASTM F2100-20 (AQL=4.0%)	Results (Statistics of three lots, 32 per lot)
Fluid Resistance (ASTM F1862)	Verify the fluid resistance of the proposed device can meet the requirements for Level 3 specified in ASTM F2100-20.	Pass at 160 mmHg	96 out of 96 pass at 160 mmHg
Bacterial filtration efficiency (BFE) (ASTM F2101)	Verify the bacterial filtration efficiency of the proposed device can meet the requirements for Level 3 specified in ASTM F2100-20.	≥98%	99.8%~>99.9% (Average: ≥99.9%)
Particulate filtration efficiency (PFE) (ASTM F2299)	Verify the particulate filtration efficiency of the proposed device can meet the requirements for Level 3 specified in ASTM F2100-20.	≥98%	99.0%~99.8% (Average: 99.6%)
Differential pressure (Delta-P)	Verify the differential pressure of the proposed device can meet the requirements for	＜6.0 mmH_2O/cm^2	(2.8~4.5) mmH_2O/cm^2 (Average: 3.7 mmH_2O/cm^2)

(EN 14683)	Level 3 specified in ASTM F2100-20.		
Flammability (16 CFR 1610)	Verify the flammability of the proposed device can meet the requirements for Level 3 specified in ASTM F2100-20.	Class 1	96 out of 96 pass at Class 1

9. Clinical Testing

No clinical study is included in this submission.

10. Conclusions

The nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed device (K211105).