April 26, 2022

Hubei Mediunion Medical Products Co., Ltd.
Jason Sheen
Vice President
No.1 ChuangYe Road, Zhongling Industrial Zone,
Pengchang Town
Xiantao, Hubei 433000
China

Re: K220487
Trade/Device Name: Disposable Medical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 9, 2022
Received: February 22, 2022

Dear Jason Sheen:

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,

Brent L. Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K220487

Device Name
Disposable Medical Face Mask

Indications for Use *(Describe)*
The Disposable Medical Face Mask 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 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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Section 3-510(k) summary

I Submitter

Device submitter: Hubei Mediunion Medical Products Co., Ltd.
No.1 ChuangYe Road, Zhongling Industrial Zone, Pengchang Town, Xiantao city, Hubei province, China

Contact person: Jason Sheen
Vice President
Phone: 0086-574-27882323
E-mail: jason@cehcare.com

Date Prepared: April 25, 2022

II Proposed Device

Trade/Device Name:	Disposable medical face mask
Regulation Number:	21 CFR 878.4040
Regulation Name:	Surgical Apparel
Regulatory Class:	Class II
Product code:	FXX

III Predicate Devices

510(k) Number:	K202211
Trade/Device Name:	Disposable Medical Surgical Face Masks
Regulation Number:	21 CFR 878.4040
Regulation Name:	Surgical Apparel
Classification:	Class II
Product Code:	FXX
Manufacturer	Guangdong Kaidi Garments Co.,Ltd

IV Device description

The Disposable medical face mask is designed for single-use and should be disposed of properly after one wear.

The Disposable medical face mask is divided into three layers, the inner and outer layers of the mask are made of Spunbond polypropylene, and the middle layer is made of Meltblown polypropylene. The mask contains ear loops or ear straps to secure the mask over the users' mouth and face and includes a nose clip to provide a firm fit over the nose. Ear loops are made of Nylon and Spandex, and tie strings are made of PP non-woven cloth,the nose clip is made of Metal strip covered with PP covering.

This is a single use, disposable device(s), provided non-sterile.

V Indication for use

The Disposable Medical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The Disposable medical face 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(s), provided non-sterile.

VI Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was same/similar to the predicate devices. The test results demonstrated that the proposed device complies with the following standards:

- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;
- 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: 2019 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- ASTM F2100: 2019 Standard Specification for Performance of Materials Used in Medical Face Masks
- EN 14683: 2019, Annex C, Medical face masks- Requirements and test methods
- ISO 10993-5:2012 Biological evaluation of medical device- Part 12: Sample preparation and reference materials
- ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization

VII Clinical Test Conclusion

No clinical study is included in this submission.

VIII Summary of Technological characteristics

Table 1 Comparison of Disposable Medical face Mask

Item	Subject device	Predicate device	Discussion
Product name	Disposable medical face mask	Disposable Medical Surgical Face Masks	NA
510K number		K202211	NA
Product Code	FXX	FXX	identical
Intended use	The Disposable Medical Face Mask is intended to be worn to protect both the	The disposable medical surgical face masks are	identical

	patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The Disposable Medical Face 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(s), provided non-sterile.	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),provide non-sterile.	
ASTM F2100Level	Level 2	Level 2	identical
Design feature	ear loop or tie-on	ear loop	Similar
Color	Blue	Blue	identical
Dimension	175mmx95mm	175mmx95mm	identical
Sterility	Non-Sterile	Non-Sterile	identical
Use	Single Use, Disposable	Single Use, Disposable	identical
Particulate filtration efficiency	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: 99.926% Lot 2: 99.93% Lot 3: 99.936%	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: 99.68% Lot 2: 99.56% Lot 3: 99.81%	Similar
Bacterial filtration efficiency	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: ≥99% Lot 2: ≥99% Lot 3: ≥99%	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: 99.9% Lot 2: 99.9% Lot 3: 99.9%	Similar
Differential pressure	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: ＜5 mm H_2O/cm^2	3 non-consecutive lots tested, using a sample size of 32/lot. Lot 1: 3.6 mm H_2O/cm^2	Similar

		Lot 2: ＜5 mm H_2O/cm^2 Lot 3: ＜5 mm H_2O/cm^2	Lot 2: 3.6 mm H_2O/cm^2 Lot 3: 3.7 mm H_2O/cm^2	
Flammability		Class1, 3 non-consecutive lots tested, using a sample size of 32/lot.	Class1, 3 non-consecutive lots tested, using a sample size of 32/lot.	identical
Fluid resistance		pass at 120 mmHg	32 out of 32 per lot pass at 120 mmHg, 3 non-consecutive lots tested	Similar
Label/Labeling		Complied with 21 CFR part 801	Complied with 21 CFR part 801	identical
Patient Contacting Material	Inner and Outer layers	Spunbond polypropylene	Spun-bond nonwoven fabric	Different
	Middle layer	Meltblown polypropylene	Melt blown non-woven fabric	Different
	Nose clip	Iron wire covered with PP covering or aluminum wire covered with PP covering	PE and iron wire	Different
	Ear loops	Urethane elastic fiber or spunbond polypropylene	Nylon and Spandex	Different
Biocompatibility		ISO 10993-5 and ISO10993-10; Under the conditions of thestudy, the proposed deviceextract was determined to benon-cytotoxic, non-sensitizing,and non-irritating.	ISO 10993-5 and ISO10993-10; Under the conditions of thestudy, the proposed deviceextract was determined to benon-cytotoxic, non-sensitizing,and non-irritating.	identical

Different - Patient Contacting Material

The patient contacting material for the proposed device is different from the two predicate devices. However, biocompatibility test has been performed on the proposed device and the results does not show any adverse effect. Thus, this difference will not affect the safety and effectiveness between the proposed device and the two predicate devices.

IX Conclusion

The proposed device has the same the intended use as the predicate device. It presents similar technological characteristics as the predicate device including the performance

parameters and biocompatibility. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.