March 8, 2022

Hubei Medlink Healthcare Co., Ltd
Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K214087
Trade/Device Name: Medical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 30, 2021
Received: December 27, 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,

for
Brent 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)*
K214087

Device Name
Medical Face Mask

Indications for Use *(Describe)*
The 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 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.

Description	Size specification	Model No.	Color	Barrier Level
Ear loop mask	17.5*9.5	MFS11	Blue	Level 1
Ear loop mask	16*9.5	MFS12	Blue	Level 1
Ear loop mask	15.5*9.5	MFS13	Blue	Level 1
Ear loop mask	14.5*9.5	MFS14	Blue	Level 1
Ear loop mask	14*9.5	MFS15	Blue	Level 1

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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510(K) Summary

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

Date of summary prepared: 2022-03-01

A. Applicant:

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B. Device:

Trade Name: Medical Face Mask
Common Name: SURGICAL MASK
Model:

Description	Size specification	Model No.	Color	Barrier Level
Ear loop mask	17.5*9.5	MFS11	Blue	Level 1
Ear loop mask	16*9.5	MFS12	Blue	Level 1
Ear loop mask	15.5*9.5	MFS13	Blue	Level 1
Ear loop mask	14.5*9.5	MFS14	Blue	Level 1
Ear loop mask	14*9.5	MFS15	Blue	Level 1

Regulatory Information
Classification Name: Surgical Face Mask
Classification: Class II
Product code: FXX

Regulation Number: 878.4040
Review Panel: Surgical Apparel

C. Predicate device:

K201729
MEDICAL MASK
Zhende Medical Co., Ltd.

D. Indications for use of the device:

The 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 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.

E. Device Description:

The Medical Face Mask is blue color, single use, three-layer, flat-folded masks with nose piece and ear loops. The blue colorant is polypropylene (PP) master batch.
The Medical Face Mask is 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 elastic ear loops welded to the facemask. The elastic ear loops are not made with natural rubber latex.
The nose piece in the layers of facemask is to allow the user to fit the facemask around their nose, which is made of Malleable polyethylene wire.
The medical face masks are available in five sizes, 17.5*9.5cm, 16*9.5cm, 15.5*9.5cm, 14.5*9.5cm, 14*9.5cm.
The medical face masks are sold non-sterile and are intended to be single use, disposable devices.

F. Technological Characteristics Comparison Table

Provided below is a comparison of the subject device with the predicate device
Table 1 General Comparison

Device	Proposed Device	Predicate Device	Result
510K #		K201729	-
Manufacturer	HUBEI MEDLINK HEALTHCARE CO., LTD	Zhende Medical Co., Ltd.	-
Model Name	MEDICAL FACE MASK Ear loops	MEDICAL MASK Ear loops	Similar
Classification	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Intend use	The Medical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate	The Medical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These	Same

		material. The 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.	face masks are intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	
Design Features		Ear Loops, Flat-pleated, 3 layers	Ear Loops, Flat-pleated, 3 layers	Same
Materials	**Outer layer**	Spunbond Polypropylene	Spunbond Polypropylene	Same
	Inner layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
	Filter layer	Melt-blown Polypropylene	Melt-blown Polypropylene	Same
	Nose wire	Malleable polyethylene wire	Malleable polypropylene with iron wire	Different
	Ear loops	Spandex	Polyester, Spandex	Different
Color		Blue	Blue	Same
Dimension (mask body)		17.5*9.5cm 16*9.5cm 15.5*9.5cm 14.5*9.5cm 14*9.5cm	18cm*9.5cm	Different
Dimension (ear loop)		16cm 16cm 16cm 15.5cm 15.5cm	17cm	Different
Dimension (nose wire)		10.5cm 10cm 10cm 9.5cm 9.5cm	Not known	Different
OTC use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
Use		Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100 Level		Level 1	Level 1	Same
Biocompatibility (ISO10993)		Non-Cytotoxic, Non-Sensitizing, Non-Irritating	Non-Cytotoxic, Non-Sensitizing, Non-Irritating	Same
Fluid Resistance Performance ASTM F1862		32 out of 32 per lot pass at 80 mmHg, 3 non-consecutive lots tested	32 out of 32 per lot pass at 80 mmHg, 3 non-consecutive lots tested	Same
Particulate Filtration Efficiency ASTM F2299		⩾ 95%	⩾ 95%	Same

Bacterial Filtration Efficiency ASTM F2101	⩾ 95%	⩾ 95%	Same
Differential Pressure (Delta P) EN 14683 Annex C	< 5.0mmH_2O/cm^2	< 5.0mmH_2O/cm^2	Same
Flammability 16 CFR 1610	Class 1	Class 1	Same

Different Analysis:

The proposed device has different material of nose clamp and ear loop to the predicate device, but the material has been tested and the test results shown that the material differences do not affect the safety of the proposed device.

The proposed device has different dimension (mask body, ear loop and nose clip dimension) to the predicate device. Smaller masks are suitable for user with smaller face. This difference does not affect intended use and will not raise any safety issues. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

G. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was same to the predicate device. 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 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;

Test Methodology	**Purpose**	**Acceptance Criteria: ASTM F2100 Level 1**	**Result**
Fluid Resistance	The purpose of the performance testing is to demonstrate the functionality of the subject device.	29 out of 32 per lot pass at 80 mmHg	Pass 32 out of 32 pass at 80 mmHg, 3 lots
Particulate Filtration Efficiency		⩾ 95%	Pass ＞95%
Bacterial Filtration		⩾ 95%	Pass

Efficiency			＞99%
Differential Pressure		＜5.0mmH_2O/cm^2	Pass ＜4.0mmH_2O/cm^2
Flammability		Class 1	Pass Class 1
Cytotoxicity	The purpose of the testing is to demonstrate the safety of the subject device.	Non-cytotoxic	Under the conditions of the study, the device is non-cytotoxic.
Irritation		Non-irritating	Under the conditions of the study, the device is non-irritating.
Sensitization		Non-sensitizing	Under the conditions of the study, the device is non-sensitizing

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K201729.