August 18, 2021

Hebei Titans Hongsen Medical Technology Co., LTD
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd
Rm. 912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
China

Re: K212097
Trade/Device Name: Disposable medical surgical mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 30, 2021
Received: July 6, 2021

Dear Ray 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 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)*

K212097

Device Name

Disposable medical surgical mask

Indications for Use *(Describe)*

The Disposable medical surgical 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 surgical 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.

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.

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510(k) Summary – K212097

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Preparation:2021/08/18

2. Sponsor Identification

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Disposable medical surgical mask
Common Name: Mask, Surgical

Regulatory Information
Classification Name: Mask, Surgical
Classification: II
Product Code: FXX
Regulation Number: 878.4040
Review Panel: General Hospital

Indication for use Statement:

The Disposable medical surgical 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 surgical 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.

Device Description:

The Disposable medical surgical 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 surgical 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.

The proposed device(s) are ***Blue color***, and ***Flat Pleated*** type mask, utilizing ***Ear Loops'*** way for wearing, and they all have ***Nose Piece*** design for fitting the facemask around the nose.

The proposed device(s) are manufactured with three layers, the inner and outer layers are made of polypropylene spunbond fabric, and the middle layer is made of polypropylene meltblown fabric.

The Disposable medical surgical mask is held in place over the user's mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are made with nylon and spandex.

The nose piece contained in the proposed device(s) is in the layers of the facemask to allow the user to fit the facemask around their nose, which is made of polypropylene coated steel wire.

The proposed device(s) are sold non-sterile and are intended to be single-use, disposable devices.

5. Identification of Predicate Device(s)

510(k) number: K202511
Device Name: Disposable Medical Surgical Mask
Manufacturer: Improve Medical (HuNan) Co., Ltd.

6. Technological Characteristics Comparison

Table 1 General Comparison

ITEM	Proposed Device K212097	Predicate Device K202511	Remark
	ASTM F2100 Level 3	ASTM F2100 Level 3	

Indication for use		The Disposable medical surgical 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 surgical 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.	The Disposable Medical Surgical 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 non-sterile.	SAME
Basic Design		Ear Loops, Flat Pleated, 3 layers	Ear loops, Flat Pleated, 3 layers	SAME
Materials	Outer Facing Layer	polypropylene spunbond fabric	Spun-bond polypropylene	Analysis
	Middle Layer	polypropylene meltblown fabric	Melt-blown polypropylene filter	
	Inner Facing Layer	polypropylene spunbond fabric	Spun-bond polypropylene	
	Nose Piece	polypropylene coated steel wire	Polyethylene coated steel wire	
	Ear Loops	nylon , spandex	Polyester	
Color		Blue	Blue	SAME
Dimension (Length, Width)		17.5± 5% cm 9.5 ± 5%cm	17.5cm±0.2cm 9.5±0.2cm	Similar
OTC use		Yes	Yes	SAME
Single Use		Single use, disposable	Single use, disposable	SAME
Sterile		Non-sterile	Non-sterile	SAME

Table 2 Performance Characteristic Comparison

ITEM	Proposed Device K212097	Predicate Device K202511	ASTM F2100 Requirements	Remark
ASTM F2100 Level	Level 3	Level 3	Level 3	SAME
Fluid Resistance Performance ASTM F1862	32 out of 32 pass at 160 mmHg	32 out of 32 pass at 160 mmHg	160 mmHg	SAME
Particulate Filtration Efficiency ASTM F2299	≥99%	Pass at 98.6%	≥ 98%	
Bacterial Filtration Efficiency ASTM F2101	≥99%	Pass at 99.9%	≥ 98%	
Differential Pressure (Delta P) EN 14683:2019+ AC:2019 Annex C	< 4.9 mmH_2O/cm^2	Pass at 3.5 mmH_2O/cm^2	< 6.0 mmH_2O/cm^2	
Flammability 16 CFR 1610	Class 1	Class 1	Class 1	SAME

Table 3 Biocompatibility Comparison

ITEM	Proposed Device K212097	Predicate Device K202511	Remark
Cytotoxicity	Non-cytotoxic	Non-cytotoxic	SAME
Irritation	Non-irritating	Non-irritating	SAME
Sensitization	Non-sensitizing	Non-sensitizing	SAME

Analysis:

The Disposable medical surgical mask is substantially equivalent to the Improve Medical (HuNan) Products Disposable Medical Surgical Mask. Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, Disposable Medical Surgical Mask cleared under K202511.

7. Non-Clinical Test Conclusion

The test results demonstrated that the proposed device complies with the following standards:

- 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 F2100-19, Standard Specification For Performance Of Materials Used In Medical Face Masks.
- ASTM F1862-17, Standard Test Method For Resistance Of Medical Face Masks To Penetration By Synthetic Blood (Horizontal Projection Of Fixed Volume At A Known Velocity)
- EN 14683-2019+AC:2019 Annex C, Medical face masks - Requirements and test methods;
- 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 F2299-03, Stand 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 Method	Purpose	Acceptance Criteria	Results
ASTM F1862	Resistance to penetration by synthetic blood	160 mm Hg	160 mm Hg

ASTM F2299	Sub-micron particulate filtration efficiency at 0.1 micron	≥ 98%	≥ 99%
ASTM F2101	Bacterial Filtration Efficiency	≥ 98%	≥ 99%
EN 14683 Annex C	Differential Pressure	< 6.0 mm H_2O/cm^2	< 4.9 mm H_2O/cm^2
16 CFR 1610	Flammability	Class 1	Class 1
ISO 10993-10	Irritation	No irritation effect	Under the conditions of the study, no irritation effect
	Sensitization	No sensitization effect	Under conditions of the study, no sensitization effect
ISO 10993-5	Cytotoxicity	No cytotoxicity effect	Under the conditions of the study, no cytotoxicity effect

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

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