February 2, 2021

Improve Medical (HuNan) Co., Ltd.
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
Room 508, Block C, No. 1029 Nanhai Avenue, Nanhan District
Shenzhen, Guangdong 518067
China

Re: K202511
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: January 6, 2021
Received: January 6, 2021

Dear Kevin 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 CAPT Elizabeth Claverie, M.S.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202511

Device Name
Disposable Medical Surgical Mask

Indications for Use *(Describe)*
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.

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

K202511

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2020/12/31

1. Submission sponsor

Name: Improve Medical (HuNan) Co., Ltd.

Address: No. 6, Yizhang East Avenue, Economic Development District, 424200, Yizhang, HuNan, China

Contact person: Wang Jing

Title: RA manager

E-mail: wjing_2008@163.com

2. Submission correspondent

Name: Chonconn Medical Device Consulting Co., Ltd.

Address: Room 508, Block C, No. 1029 Nanhai Avenue, Nanshan District, Shenzhen, Guangdong, P. R. China

Contact person: Kevin Wang

E-mail: kevin@chonconn.com

Tel: +86-755 33941160

3. Subject Device Information

Trade/Device Name	Disposable Medical Surgical Mask
Model	Flat (17.5cm*9.5cm)
Common Name	Surgical Face Mask
Regulatory Class	Class II
Regulation	21CFR 878.4040
Classification name	Mask, Surgical
Product code	FXX
Submission type	Traditional 510(K)

4. Predicate Device

Manufacturer: Xiantao Zhibo Non-woven Products Co., Ltd.

Device: Surgical Face Mask

510(k) No.: K182514.

5. Device Description

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 spun-

bond polypropylene, and the middle layer is made of melt-blown polypropylene filter.
The model of proposed device, ear loops, is 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 contained in the proposed device(s) is in the layers of facemask to allow the user to fit the facemask around their nose, which is made of polyethylene coated steel wire.
The proposed device(s) are sold non-sterile and are intended to be single use, disposable device.

6. Intended use & Indication for use

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.

7. Comparison to the Predicate Device

Features	**Subject Device K202511 Disposable Medical Surgical Mask**	**Predicate Device K182514 Surgical Face Mask**	**Remark**
Applicant	Improve Medical (HuNan) Co., Ltd.	WUHAN DYMEX HEALTHCARE CO., LTD	/
Classification Regulation	21CRF 878.4040	21CRF 878.4040	Same
Classification and Code	Class II, FXX	Class II, FXX	Same
Common name	Surgical Face Mask	Surgical Face Mask	Same
Indication for use	The Surgical Face 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.	The Surgical Face 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
Model	Ear loops, Flat Pleated, 3 layers	Ear loops, Flat Pleated, 3 layers	Same
Material	Outer facing layer: Spun-bond polypropylene	Outer facing layer: Spun-bond polypropylene	Same
	Middle layer: Melt-blown	Middle layer: Melt-blown	Same

	polypropylene filter	polypropylene filter	
	Inner facing layer: Spun-bond polypropylene	Inner facing layer: Spun-bond polypropylene	Same
	Nose wire: Polyethylene coated steel wire	Nose wire: Malleable polyethylene wire	Different (1)
	Ear loops: Polyester	Ear loops: Spandex	Different (2)
Color	Blue	White	Different (3)
Dimension (Width)	17.5cm ± 0.2cm	17.5cm ± 0.2cm	Same
Dimension (Length)	9.5 ± 0.2cm	9.5 ± 0.2cm	Same
OTC use	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Same
Usage	Single use, disposable	Single use, disposable	Same
ASTM F2100 Level	Level 3	Level 2	Similar
Fluid Resistance Performance ASTM F1862	32 out of 32 pass at 160 mmHg	32 out of 32 pass at 120 mmHg	Similar
Particulate Filtration Efficiency ASTM F2299	Pass at 98.6%	pass at 99.88%	Similar
Bacterial Filtration Efficiency ASTM F2101	Pass at 99.9%	pass at 99.6%	Similar
Differential Pressure (Delta P) MIL-M36954C	Pass at 3.5 mmH_2O/cm^2	pass at 3.0mmH2O/cm2	Similar
Flammability 16 CFR 1610	Class 1	Class 1	Similar
Biocompatibility	Under the condition of this study the device is non-cytotoxic, non-sensitizing and non-irritating.	Under the condition of this study the device is non-cytotoxic, non-sensitizing and non-irritating.	Same

Justification of differences:

Justifications for differences between subject device and the predicate device are shown as below:

Different (1), (2), (3): The difference in the materials and colors. Biocompatibility testing accordance with ISO 10993-1 and performance testing accordance with ASTM F2100 have been conducted on the final finished device. Therefore, this difference does not raise any safety or effectiveness issue.

8. Performance Data

The proposed devices were 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.

Item	Proposed device	Acceptance criteria	Result
Fluid Resistance Performance	32 out of 32 pass at 160 mmHg	29 out of 32 pass at 160 mmHg	Pass
Particulate Filtration Efficiency	98.6%	⩾ 98%	Pass
Bacterial Filtration Efficiency	99.9%	⩾ 98%	Pass
Differential Pressure (Delta-P) Test	3.5 mmH_2O/cm^2	< 6.0mmH_2O/cm^2	Pass
Flammability Testing	Class 1	Class 1	Pass

Biocompatibility testing

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA Biocompatibility guidance, 2016 (Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process") and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. Under the condition of this study the device is non-cytotoxic, non-sensitizing and non-irritating.

Clinical data

No clinical study is included in this submission.

9. 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 K182514, Surgical Face Mask