November 26, 2021

Henan Huibo Medical Co.,Ltd.
Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K202842
Trade/Device Name: Medical surgical mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: October 15, 2021
Received: October 20, 2021

Dear Boyle 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)*
K202842

Device Name
Medical surgical mask

Indications for Use *(Describe)*
The medical surgical mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It 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.

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510(k) Summary

510k number: K202842
Date: Oct.14, 2021
This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

1.0 Submitter's information

Name: Henan Huibo Medical Co.,Ltd.
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Contact: Ms. Hui Lu
Date of Preparation: Sep.17, 2020

Designated Submission Correspondent

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2.0 Device information

Trade name: Medical Surgical mask
Common name: Surgical mask
Classification name: Mask, Surgical
Model(s): Ear loop, 17.5×9.5cm

3.0 Classification

Production code: FXX
Regulation number: 21CFR 878.4040
Classification: Class II
Panel: Surgical apparel

4.0 Predicate device information

Manufacturer: Wuhan Dymex Healthcare Co., Ltd
Device: Surgical Face Mask
510(k) number: K182515

5.0 Indication for Use Statement

The medical surgical mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It 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.

6.0 Device description

The medical surgical mask is single use, three-layer, flat-pleated style with ear loops and nose piece. The mask is manufactured with three layers, the inner and outer layers are made of nonwoven fabrics, and the middle layer is made of melt blown fabrics. 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 galvanized iron wire. The disposable medical face mask will be provided in blue. The masks are sold non-sterile and are intended to be single use, disposable devices.

7.0 Non-Clinical Test Conclusion

The proposed device was tested and conformed to the related recognized 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.

Table 1 - Performance Testing Summary

Item	Test method	Pass Criteria	Results
Bacterial filtration efficiency (BFE) (%)	ASTM F2101-19Standard Test Method for Evaluating the Bacterial Filtration	≥98%	32/32 Passed at ≥98%
Different pressure (Delta-P)	EN 14683: 2019, Annex C Medical face masks - Requirements and test methods according to ASTM F2100:2019	<6.0 mmH_2O/cm^2	32/32 Passed <6 $mmH2O/cm^2$ / Pass
Sub-micron particulate filtration efficiency at 0.1 micron, % (PFE)	ASTM F2299-03 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres according to ASTM F2100:2019	≥98%	32/32 Passed at ≥98% / Pass
Resistance to penetration by	ASTM F1862M-17 Standard Test Method for Resistance of Medical	29 of 32 test articles passed at	32 of 32 test articles passed

synthetic blood, Minimum pressure in mmHg for pass result	Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) according to ASTM F2100:2019	120mmHg/ 160mmHg	at 120mmHg, 160mmHg
Flame spread	16 CFR Part 1610 Standard for the Flammability of Clothing according to ASTM F2100:2019	Class 1	32/32 Passed ≥3 seconds burn Time-Class 1 / Pass
Shelf life	Method of accelerated aging under 55℃ for 80 days	2 years	Pass

- Biocompatibility Testing According to ISO 10993-1:2009, the nature of body contact for the subject device is Surface Device category, Skin Contact and duration of contact is A-Limited (≤24h). The following tests for the subject device were conducted to demonstrate that the subject device is biocompatible and safe for its intended use:
  1) In vitro Cytotoxicity Test per ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity,
  2) Skin Sensitization Tests per ISO 10993-10:2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization,
  3) Skin Irritation Tests per ISO 10993-10:2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization.

8.0 Clinical Test Conclusion

No clinical study implemented for the Medical surgical mask.

9.0 Technological Characteristic Comparison Table

Table 2 - General Comparison

Item	Proposed device	Predicated device	Remark
Product Code	FXX	FXX	same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	same
Class	II	II	same
Product name	Medical surgical mask	Surgical Face Mask	-
510(k) No.	K202842	K182515	-
Models	Ear loop, 17.5×9.5cm	Ear loop	same
Intended Use	The medical surgical mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It is intended for use in infection control practices	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	same

		to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non sterile.	infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	
OTC use		Yes	Yes	same
Composite		Flat Pleated, 3 layers	Flat Pleated, 3 layers	same
Material	Internal layer	Spun-bond polypropylene	Spun-bond polypropylene	same
	Middle layer	Melt blown polypropylene	Melt blown polypropylene	same
	External layer	Spun-bond polypropylene	Spun-bond polypropylene	same
	Nose piece	monofilament	Malleable polyethylene wire	* Different 1
	Ear loop	spandex	spandex	same
Color		Blue	Yellow	* Different 2
Dimension (Length)		17.5cm±5%cm	17.5cm±0.2cm	* similar 3
Dimension (Width)		9.5cm±5%cm	9.5cm±0.2cm	* similar 4
Sterility		Non-Sterile	Non-Sterile	same
Single Use		Yes	Yes	same
Sterile		No	No	same
ASTM F2100 Level		Level 2 / Level 3	Level 2	* different 5
Shelf life		2 years	No identified	* different 6

* Gap analysis:

Different 1-2: the two devices have some difference in material and product color, product materials safety is proved by its bio-compatibility, and the difference does not raise additional questions for safety and effectiveness of device.

Different 3-4: the two devices share same dimensions otherwise the tolerance is different, the little deviation in tolerance does not raise additional questions for safety and effectiveness of device.

Different 5: the proposed device comply to level 2 and level 3 at the same time, has better performance than the predicated device, the performance of proposed device is supported by its performance test, the difference does not raise additional questions for safety and effectiveness of device.

Different 6: the proposed device define its 2 years shelf life and verified, the equivalence device did not its shelf life, compared with the equivalence, defined shelf life of the proposed device can have lower potential risks of over shelf life use.

10.0 Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device

in 510(K) submission K202842, the Medical surgical mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K182515.