November 5, 2021

Zhejiang Senhong Medical&Instrument Co., Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K202676
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: September 20, 2021
Received: October 5, 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, PhD
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)*
K202676

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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510(k) Summary

(K202676)

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's Information

Name: Zhejiang Senhong Medical&Instrument Co., Ltd.
Address: Floor 1-2, Building 2, No 889 North Huancheng Rd, Fu'xi Subdistrict, Deqing County, Huzhou, Zhejiang, 313200, China
Tel: 86-18006712375
Contact: Eric Jian
Date of Preparation: Nov.3,2021

Designated Submission Correspondent

Mr. Boyle Wang
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No. 738 Shangcheng Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device Information

Trade name: Disposable Medical Face Mask
Common name: Surgical Face Mask Classification
name: Surgical Face Mask

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 Device Description

The Disposable Medical Face 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.

6.0 Indication for Use Statement

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.

7.0 Technological Characteristics Comparison to the Predicate Device

Table 1 General Comparison

Item	Subject Device K202676	Predicate Device K182515	Remark
Product Name	Disposable Medical Face Mask	Surgical Face Mask	--
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Intended Use& Indications 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. 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

Design features		Ear Loops, 3 layers	Ear Loops, 3 layers	Same
Mask Styles		Flat pleated	Flat pleated	Same
Material	Outer facing layer	Nonwoven fabrics	Spun-bond polypropylene	Same
	Middle layer	Melt blown fabrics	Melt blown polypropylene filter	Same
	Inner Facing layer	Nonwoven fabrics	Spun-bond polypropylene	Same
	Nose piece	Galvanized iron wire	Malleable polyethylene wire	Different*
	Ear loops	not made with natural rubber latex	not made with natural rubber latex	Same
Color		Blue	Blue	Same
Dimension (Length)		17.5 cm +/- 1cm	17.5 cm +/- 1cm	Same
Dimension (Width)		9.5 cm +/- 1cm	9.5 cm +/- 1cm	Same
OTC use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
Single Use		Yes	Yes	Same
Sterile		No	No	Same
ASTM F2100 Level		Level 2	Level 2	Same

*The difference in the materials does not raise additional questions for safety and effectiveness. Performance testing including biocompatibility evaluation has been performed on the final finished device which includes all construction materials.

8.0 Non-Clinical Test Conclusion

The proposed device was 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.

Table 2 - Performance Testing

Test Methodology	Purpose	Acceptance Criteria	Result
Resistance to penetration by synthetic blood	Determine synthetic blood penetration resistance as specified in Test Method F1862	29 Out of 32 pass at 120 mmHg	Lot 1: 31 out of 32 pass at 120mmHg Lot 2: 31 out of 32 pass at 120mmHg Lot 3: 32 pass at 120mmHg Pass
Particulate Filtration Efficiency ASTM F2299	Determine particulate filtration efficiency as directed in Test Method F2299.	≥ 98%	Lot 1: average 99.23% Lot 2: average 99.29% Lot 3: average 99.29% Pass
Bacterial Filtration Efficiency ASTM F2101	Determine the bacterial filtration efficiency as directed in Test Method ASTM F2101.	≥ 98%	Lot 1: average 99.75% Lot 2: average 99.79% Lot 3: average 99.75% Pass
Differential Pressure (Delta - P)	Determine breathing resistance or differential pressure as directed in EN 14683:2019, Annex C.	< 6.0 mmH_20/cm^2	Lot 1: average 4.07 mm H_20/cm^2 Lot 2: average 4.07 mm H_20/cm^2 Lot 3: average 4.13 mm H_20/cm^2 Pass
Flammability 16 CFR 1610	Determine flammability as specified in 16 CFR Part 1610	Class 1 (Burn time ≥3.5 s, IBE, or DNI)	Lot 1: Class 1 Lot 2: Class 1 Lot 3: Class 1 Pass

Table 3 - Biocompatibility Testing

Test Methodology	Purpose	Acceptance Criteria	Result
Cytotoxicity	Determine the effects on cells following ISO 10993-5	The test article should not have potential toxicity to L-929 in the MTT method.	Pass under the conditions of the study, the device is noncytotoxic.
Irritation	Estimate the potential for contact sensitization following ISO 10993-10	The irritation response category in the rabbit should be negligible.	Pass under the conditions of the study, the device is nonirritating.
Sensitization	Estimate the irritation potential of medical device following ISO 10993- 10	The test article should not cause delayed dermal contact sensitization in the guinea pig.	Pass under the conditions of the study, the device is nonsensitizing.

9.0 Clinical Test Conclusion

No clinical study is included in this submission.

10.0 Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device in K182515.