December 15, 2021

Heilongjiang Yinjia Medical Equipment Co., Ltd.
% Doris Dong
Manager
Shanghai CV Technology Co., Ltd.
Room 903, No.19 Dongbao Road, Songjiang Area
Shanghai, Shanghai 201613
China

Re: K212944
Trade/Device Name: Disposable Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 2, 2021
Received: September 13, 2021

Dear Doris Dong:

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,

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)*
K212944

Device Name
Disposable Surgical Mask

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

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510(k) Summary

[As required by 21 CFR 807.92]

1. Submission Information:

510(k) Number:	K212944
Date:	December 15, 2021
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Applicant/Manufacturer:	Heilongjiang Yinjia Medical Equipment Co., Ltd. F3-4, Plant 6, No.10, Hanan 12th Road, Nangang District, Harbin City, Heilongjiang, China 150000
Contact person:	Doris Dong [Consultant, from Shanghai CV Technology Co., Ltd.] Add: Room 903, No. 19 Dongbao Road, Songjiang Area, Shanghai, 201613 China E-mail: doris.d@ceve.org.cn Tel: 86 21-31261348 / Fax: 86 21-57712250

2. Device Description:

Proprietary Name:	Disposable Surgical Mask
Model	Size M, Size S
Common Name:	Surgical mask
Classification Name:	Mask, Surgical
Regulation Number:	878.4040
Product Code:	FXX
Device Class:	II
Review Panel:	General Hospital

3. Predicate device

Surgical Face Mask, K182515

WUHAN DYMEX HEALTHCARE CO., LTD

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

4. Device Description

Disposable Surgical Mask, Ear Loop Type, Size M and S is a single use, three-layer, flat-pleated mask with ear loops and a nose piece. The Disposable Surgical Mask is manufactured with three layers, of which 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 face mask. The latex free elastic ear loops are made of polyamide fibers and spandex. The nose piece in the layers of face mask allows the user to fit the face mask around their nose, which is made of core iron wire with halogen-free polyethylene covering. The Disposable Surgical Mask will be provided in blue of outside and white of inside. The Disposable Surgical Mask is provided non-sterile and for single use.

5. Intended Use/Indication for use

The Disposable Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The Disposable 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.

6. Technological Characteristics Comparison with the predicate device:

Table 1 General comparison

Device	Proposed device	Predicate device	Comparison
510(k) Holder	Heilongjiang Yinjia Medical Equipment Co., LTD	WUHAN DYMEX HEALTHCARE CO., LTD	--
510(k) Number	K212944	K182515	--
Name	Disposable Surgical Mask	Surgical Face Mask	--
Model	Size M, Size S	/	--
Classification	Class II Device, FXX (21 CFR 878.4040)	Class II Device, FXX (21 CFR 878.4040)	Same
Intended use/ Indications for Use	The Disposable Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The Disposable 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 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), providednon-sterile.	Same
Mask style	Flat Pleated	Flat Pleated	Same
Design	Ear loop	Ear loop	Same
Layers	Three	Three	Same
Dimension	Size M: 175*95mm Size S: 140*95mm	175*95mm	Similar Note 1
Color	Blue outside; white inside	Yellow	Different Note 2
Sterility	Non-sterile	Non-sterile	Same
Target population	Adults	Adults	Same
Use	Single use, disposable	Single use, disposable	Same
Anatomical site	Nose and mouth	Nose and mouth	Same
Technology	Self-suction filter mask	Self-suction filter mask	Same
Environment of use	OTC	OTC	Same
Material			

Outer facing layer	Spunbond polypropylene	Spunbond polypropylene	Same
Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
Inner facing layer	Spunbond polypropylene	Spunbond polypropylene	Same
Ear loops	Polyamide fibers, Spandex	Spandex	Same Note 2
Nose piece	Core iron wire with polyethylene covering	Malleable polyethylene wire	
Colorants	Polypropylene (PP) master batch	Unknown	
ASTM F2100 Level	Level 2	Level 2	Same
Biocompatibility (limited contact (<24h) surface devices on intact skin)			
Cytotoxicity	Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic.	Under the conditions of the study, the predicate device extract was determined to be non-cytotoxic.	Same
Irritation	Under the conditions of the study, the proposed device non-polar and polar extracts were determined to be non-irritating.	Under the conditions of the study, the predicate device non-polar and polar extracts were determined to be non-irritating.	Same
Sensitization	Under the conditions of the study, the proposed device non-polar and polar extracts were determined to be non-sensitizing.	Under the conditions of the study, the predicate device non-polar and polar extracts were determined to be non-sensitizing.	Same

Differences between New device and Predicate Device:

Note 1:

The proposed device has two sizes while the predicate device only has one size. Because the physical performance tests and Biocompatibility tests results of mask depend on the materials and manufacturing process not the size. Furthermore, there is no difference between the two models except for the size.

Note 2:

Biocompatibility evaluation has been performed on the final finished device which includes all construction materials and color additives.

7. Non-clinical test performed on the proposed device:

The proposed device was tested and conformed to the following standards and requirements stated in guidance for industry passed and FDA Staff Surgical Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004:

Table 2 Performance Testing

Performance Characteristics	Test Method	Proposed device	Acceptance Criteria	Result
Fluid Resistance Performance	ASTM F1862	31 out of 32 pass at 120mmHg	29 out of 32 pass at 120mmHg	Pass
Particulate Filtration Efficiency	ASTM F2299	99.7%	≥ 98%	Pass
Bacterial Filtration Efficiency	ASTM F2101	99.5%	≥ 98%	Pass
Differential Pressure (Delta-P)	MIL-M-36954C	4.24mmH_2O/cm^2	< 6.0mmH_2O/cm^2	Pass
Flammability class	16CFR 1610	Class 1	Class 1	Pass

8. Clinical test conclusion

No clinical study is included in this submission.

9. Conclusion

The conclusion 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 predicated K182515.