March 14, 2022

HeNan YADU Industrial Co., Ltd.
℅ Charles Shen
Director
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K212330
Trade/Device Name: YADU Surgical Masks (Model E (ear loops, sterile/non-sterile), Model T (tie on straps, sterile/non-sterile))
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 9, 2022
Received: February 17, 2022

Dear Charles Shen:

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)*
K212330

Device Name
YADU Surgical Masks (Model E (ear loops, sterile/non-sterile), Model T (tie on straps, sterile/non-sterile))

Indications for Use *(Describe)*
YADU Surgical Masks (Model E (ear loops, sterile/non-sterile), Model T (tie on straps, sterile/non-sterile)) are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. It is intended to be used in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device, provided sterile and 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.

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510(k) Summary-K212330:

This summary of 510k safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92

1.0 Submitter Information

HeNan YADU Industrial Co., Ltd.
No.234, West Jianpu Road 453400 Changyuan,
Henan Province, CHINA
Tel: (086) 373-2157057
Submitter's FDA Registration Number:3016452400

Submission Correspondent

Charles Shen
Manton Business and Technology Services
37 Winding Ridge
Oakland, NJ 07436
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: March 13, 2022

2.0 Device Information

Proprietary Name:	YADU Surgical Masks
Common Name:	Surgical Mask, Medical Face Mask
Models:	Model E (ear loop, sterile/non-sterile), Model T (tie on straps, sterile/non-sterile)

3.0 Device Classification

Classification Name:	Surgical Apparel
Classification Regulation:	21 CFR 878.4040
Class:	Class II
Product Code:	FXX

4.0 Predicate Device Information:

Manufacturer:	Hubei Xinxin Non-woven Co., Ltd.
Product Name:	Surgical Mask
510(K)#:	K212120

5.0 Device description:

The YADU Surgical Masks are single use, three-layer, flat-pleated style with ear loops and nose piece. They have three layers structure: inner layer, middle layer, and outer layer. The inner and outer layers are made of spun-bond polypropylene (SPP), and the middle layer is made of melt blown polypropylene filter.

YADU Surgical Masks have two variants: The model with ear loop and the model with tie-on bands. The mask is held in place over the users' mouth and nose by two elastic ear loops or tie-on bands welded to the side of the mask. The ear loops are made from spandex and polyester elastic, while tie-on bands are made from SPP straps.
Neither elastic ear loops nor tie-on bands are made with natural rubber latex.

YADU Surgical Masks also have nose piece that allows the user to fit the mask around his/her nose. The nose piece is made of polyvinyl chloride coated iron wire.

The Surgical Masks provide Level-1 protection per ASTM F2100 definition. They have blue color and are sold in both sterile and non-sterile versions and are intended to be single use, disposable devices.

Sterilization	Model
Non-sterile	Tie-on (Model T)
	Ear loops (Model E)
EO Sterile	Tie-on (Model T)
	Ear loops (Model E)

6.0 Indications for Use:

YADU Surgical Masks 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 to be used in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device, provided sterile and non sterile.

7.1 Comparison to Predicate Devices

YADU Surgical Masks, manufactured by "HeNan YADU Industrial Co., Ltd." are compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

(1) K212120, "Surgical Mask" Model XX009 Ear loop Level 1 and Model XX008 Tie-on Level 1, manufactured by "Hubei Xinxin Non-woven Co., Ltd."

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 1: Comparison of Intended Use, Design, and Material

Description	**Subject Device**	**Predicate Device (K212120)**
Indication for Use	YADU Surgical Masks 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, provided sterile and non sterile.	The 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 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, provided non-sterile.
Layers	Three	Three
Materials	Outer layer is made of 100% spun- bond polypropylene. Middle player is made of 100% meltblown polypropylene filter media. Inner layer is made of 100% spun- bond polypropylene. Ear-loops are made of polyester and spandex. Ties are made from Spunbond Polypropylene The nose piece is iron and plastics	Outer layer is made of 100% spun- bond polypropylene. Middle player is made of 100% meltblown polypropylene filter media. Inner layer is made of 100% spun- bond polypropylene. Ear-loops are made of spandex Ties are made from Spunbond Polypropylene The nose piece is iron and plastics
Dimensions	17.5 x 9.5cm	17.5 x 9.5cm
Mask style	Flat Pleated	Flat Pleated
Design	Ear Loop and Tie-on Bands	Ear Loop (XX009) and Tie-on (XX008)
Color	Blue	Blue
Sterility	Sterile and Non-sterile	Non-sterile
Shelf life	Sterile: 3 years Non-sterile: None stated	Sterile: N/A Non-sterile: 2 years
Single Use	Yes	Yes

ASTM F2100 Level	Level 1	Level 1

The differences between the subject device and predicate device do not raise different questions of safety and effectiveness.

8.1 Non-Clinical Study Summary

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- Sterilization Validation: ISO-11135-1: 2014
- ASTM F2100: 2018 Standard Specification for Performance of Materials Used in Medical Face Masks
- 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 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)
- ASTM F2299− 03 (Reapproved 2017) Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- EN 14683-2019 Medical Face Masks – Requirements and Test Methods
- In Vitro Cytotoxicity Test: ISO 10993-5: 2009
- Skin Irritation Test: ISO 10993-10: 2010
- Skin Sensitization Test: ISO 10993-10: 2010

ASTM F2100 Testing for Level 1

Table 2 - Sterile masks, ear loops, 3 years real time aged

Name of the test	Purpose	Acceptance Criteria	Results		
			Lot 1	Lot 2	Lot 3
ASTM F2101-19 Bacterial Filtration Efficiency (BFE)	To evaluate the bacterial efficiency of the mask	≥ 95%	95.1-97.4%	95.1-98.4%	95.1-98.4%
ASTM F2299− 03 (Reapproved 2017) Penetration by Particulates	To evaluate particle filtration efficiency of the mask	≥ 95%	95.1-97.9%	95.1-99.6%	95.1-97.4%

EN 14683-2019 Differential Pressure	To evaluate differential pressure of the device	< 5.0 mm H_2O/cm^2	3.7-4.2	3.7-4.1	3.7-4.1
ASTM F1862-17 Resistance to penetration by Synthetic Blood	To evaluate resistance to penetration by Synthetic Blood	No penetration under 80 mm Hg	32/32 pass	32/32 pass	32/32 pass

Table 3 - Sterile masks, tie on straps, 3 years real time aged*

Name of the test	Purpose	Acceptance Criteria	Results		
			Lot 1	Lot 2	Lot 3
16 CFR part 1610	Flammability	Class 1	32/32 IBE	32/32 IBE	32/32 IBE

Table 4 – Non-sterile masks, ear loops, unaged

Name of the test	Purpose	Acceptance Criteria	Results		
			Lot 1	Lot 2	Lot 3
ASTM F2101-19 Bacterial Filtration Efficiency (BFE)	To evaluate the bacterial efficiency of the mask	≥ 95%	99.8-99.9%	99.2-99.9%	99.8-99.9%
ASTM F2299− 03 (Reapproved 2017) Penetration by Particulates	To evaluate particle filtration efficiency of the mask	≥ 95%	99.5 – 99.9 %	99.5 – 99.9 %	99.5 – 99.9 %
EN 14683-2019 Differential Pressure	To evaluate differential pressure of the device	< 5.0 mm H_2O/cm^2	3.1 – 3.6 N=32	3.1 – 3.5 N=32	3.0 – 3. N=32
ASTM F1862-17 Resistance to penetration by Synthetic Blood	To evaluate resistance to penetration by Synthetic Blood	No penetration under 80 mm Hg	32/32 pass	32/32 pass	32/32 pass

Table 5 – Non-sterile mask, tie on straps, unaged*

Name of the test	Purpose	Acceptance Criteria	Results		
			Lot 1	Lot 2	Lot 3
16 CFR part 1610	Flammability	Class 1	32/32 IBE	32/32 IBE	32/32 IBE

* Testing on masks with ear loops is representative of masks with tie on straps for all tests but flammability. Therefore, flammability was conducted on masks with tie on straps.

Table 6 – Biocompatibility

Identification of test	Purpose	Acceptance criteria	Results Sterile Mask	Results Non-Sterile Mask
ISO 10993-5	Assess the cytotoxicity of the mask	No Cytotoxicity	No Cytotoxicity	No Cytotoxicity
ISO 10993-10	Assess sensitization of the mask	No Sensitization	No Sensitization	No Sensitization
ISO 10993-10	Assess irritation of the mask	No Irritation	No Irritation	No Irritation

9.0 Clinical Study Summary

Clinical data is not needed for YADU Surgical Masks

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.