Hunan Yuankang Biological Technology Co., Ltd
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K210487
Trade/Device Name: MIPLNI YK-244 Disposable Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 16, 2021
Received: February 19, 2021

Dear Prithul Bom:

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,

Ryan Ortega, Ph.D.
Acting 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)*
K210487

Device Name
MIPLNI YK-244 Disposable Surgical Mask

Indications for Use *(Describe)*
The Disposable 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Administrative Information

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

Assigned 510(k) Number: **K210487**

Date of Preparation: 2021/3/8

The submitter's information is listed in the Table below:

Submitter Information	
Establishment	Hunan Yuankang Biological Technology Co., Ltd Heping Team, Sanlian Community, Xidu Town Hengyang, Hunan, CN 421000
Registration Number	3016752849
Contact	Kylin Rui Chen Director, Business Operations Heping Team, Sanlian Community, Xidu Town Hengyang, Hunan, CN 421000 Phone: +86 13560755999 / 400-6886-658 Fax: +86-734-6856608 Email: kylin.chen@yuankangbio.com
Submission Correspondent	Kelvin Fei Chu Regulatory Consultant KMax Medtech Consulting 3109 Butte St, Santa Clara, CA 95051 Phone: 612-203-5245 Fax: +86-734-6856608 Email: kelvin.chu@kmaxmedtech.com

Table Submitter information

The subject device's information is listed in the Table below:

Subject Device Information	
Trade Name	MIPLNI YK-244 Disposable Surgical Mask

Subject Device Information	
Common Name	Surgical Face Mask
Product Code	FXX
Classification	Class II
Classification Name	Mask, Surgical
CFR Section #	878.4040
Review Panel	General Hospital

Table Subject device information

The predicate device's information is listed in the Table below:

Predicate Device Information	
Predicate 510(k) #	K153496
Predicate Trade Name	Disposable Surgical Face Mask
Predicate Manufacturer	Xiantao Rayxin Medical Products Co., ltd
Predicate Product Code	FXX

Table Predicate device information

Intended Use / Indications for Use

The Disposable 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.

Device Description

The subject device has been designed following the recommendations provided in ***Surgical Masks - Premarket Notification [510(k)] Submissions Guidance for Industry and FDA Staff*** **(2004)**.

The subject device is a Blue color and Flat Pleated type mask, utilizing the Ear Loops for wearing, and has Nose Piece design for fitting the facemask around the nose.

The subject device is 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 filters.

The subject device 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 subject device is in the layers of facemask to allow the user to fit the facemask around their nose, which is made of metal core plastic (aluminum metal core inside of polypropylene).

The subject device is sold non-sterile and is intended to be single use, disposable device.

Summary of Non-Clinical Performance Testing

Non-clinical performance tests have been conducted to verify that the subject device meets all design requirements following standards and items recommended in ***Surgical Masks - Premarket Notification [510(k)] Submissions Guidance for Industry and FDA Staff*** **(2004)**.

- ASTM F2100-19, Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F1862-13, 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, Stand Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres.
- 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
- EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods Annex C Method for determination of breathability (differential pressure)
- 16 CFR 1610, Standard for The Flammability of Clothing Textiles.
- ISO 10993-5: 2009 Biological Evaluation of Medical Devices – Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation of Medical Devices – Part 10: Tests For Irritation And Skin Sensitization
- Bench Testing for the performance of Dimensions

The summary of non-clinical performance testing is listed below in Table.

Test Item	**Standards**	**Acceptance Criteria**	**Results**
Dimensions	-	Mask Layer: Length: 17.5cm±0.5cm Width: 9.5cm±0.5cm Nose Piece: 3mm x 105 mm x	Pass

Test Item	Standards	Acceptance Criteria	Results
		0.5mm Ear loop: 2.8mm in diameter, 195mm in length.	
ASTM F2100 Level	ASTM F2100-19	Level 3	Pass
Fluid Resistance Performance	ASTM F1862	32 out of 32 pass at 160 mmHg	Pass LOT #YKWK20201108: 32/32 at 160 mmHg LOT #YKWK20201111: 32/32 at 160 mmHg LOT #YKWK20201120: 32/32 at 160 mmHg
Particulate Filtration Efficiency (PFE)	ASTM F2299	≥ 98%	Pass LOT #YKWK20201108: 32/32 99.9% ±0.1% LOT #YKWK20201111: 32/32 99.9% ±0.1% LOT #YKWK20201120: 32/32 99.9% ±0.1%
Bacterial Filtration Efficiency (BFE)	ASTM F2101	≥ 98%	Pass LOT #YKWK20201108: 32/32 99.9% LOT #YKWK20201111: 32/32 99.9% LOT #YKWK20201120: 32/32 99.9%

Test Item	Standards	Acceptance Criteria	Results
Differential Pressure (Delta P)	EN 14683:2019+AC:2019 Annex C	< 5.0 mmH2O/cm^2	Pass LOT #YKWK20201108: 32/32 < 3.6 mm H_2O / cm^2 (20-22°C and 55-62% RH, Flow Rate: 8 L/min) LOT #YKWK20201111: 32/32 < 4.0 mm H_2O / cm^2 (20-22°C and 55-62% RH, Flow Rate: 8 L/min) LOT #YKWK20201120: 32/32 < 4.0 mm H_2O / cm^2 (20-22°C and 55-62% RH, Flow Rate: 8 L/min)
Flammability	16 CFR 1610	Class 1	Pass LOT #YKWK20201108: 32/32 IBE LOT #YKWK20201111: 32/32 IBE LOT #YKWK20201120: 32/32 IBE
In Vitro Cytotoxicity	ISO 10993-5	Non-cytotoxic	Pass
Skin Irritation	ISO 10993-10	Non-irritating	Pass

Test Item	Standards	Acceptance Criteria	Results
Skin Sensitization	ISO 10993-10	Non-sensitizing	Pass

Table Summary of non-clinical performance testing

Summary of Clinical Performance Test

No clinical study is included in this submission.

Comparison of Technological Characteristics with Predicate Device

A summary of the technological characteristics of the subject device as compared to the predicate device is listed below in Table.

Device	Subject Device	Predicate Device	Comparison
510 (k) #	K210487	K153496	-
Manufacturer	Hunan Yuankang Biological Technology Co., Ltd	Xiantao Rayxin Medical Products Co., ltd.	-
Product Name	Disposable Surgical Face Mask	Disposable Surgical Face Mask	Same
Classification	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Intended use	The Disposable 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 Disposable 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
Material & Design			
Outer facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same

Device	Subject Device	Predicate Device	Comparison
Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
Inner facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
Nose piece	Metal core plastic (aluminum metal core inside of polypropylene)	Malleable aluminum wire	Similar
Ear loops	Spandex	Polyester	Similar
Design features	Color: Blue Ear loops	Color: Blue Ear Loops or Tie-On	Similar
Mask Style	Flat Pleated	Flat Pleated	Same
Specification and Dimension	Length: 17.5cm±0.5cm Width: 9.5cm±0.5cm	Length: 17.5cm±1cm Width: 9.5cm±1cm	Similar
Usage			
OTC use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
Performance Testing			
ASTM F2100 Level	Level 3	Level 2	Better
Fluid Resistance Performance	32 out of 32 pass at 160 mmHg (ASTM F1862) LOT #YKWK20201108: 32/32 at 160 mmHg LOT #YKWK20201111: 32/32 at 160 mmHg LOT #YKWK20201120: 32/32 at 160 mmHg	32 out of 32 pass at 120 mmHg (ASTM F1862)	Better

Device	Subject Device	Predicate Device	Comparison
Particulate Filtration Efficiency (PFE)	≥ 98% (ASTM F2299) LOT #YKWK20201108: 32/32 99.9% ±0.1% LOT #YKWK20201111: 32/32 99.9% ±0.1% LOT #YKWK20201120: 32/32 99.9% ±0.1%	≥ 98% (ASTM F2299)	Same
Bacterial Filtration Efficiency (BFE)	≥ 98% (ASTM F2101) LOT #YKWK20201108: 32/32 99.9% LOT #YKWK20201111: 32/32 99.9% LOT #YKWK20201120: 32/32 99.9%	≥ 98% (ASTM F2101)	Same
Differential Pressure (Delta P)	< 5.0 mmH2O/cm2 (EN 14683:2019+AC:2019 Annex C) LOT #YKWK20201108: 32/32 < 3.6 mm H_2O / cm^2 (20-22°C and 55-62% RH, Flow Rate: 8 L/min) LOT #YKWK20201111: 32/32 < 4.0 mm H_2O / cm^2 (20-22°C and 55-62% RH, Flow Rate: 8 L/min) LOT #YKWK20201120: 32/32 < 4.0 mm H_2O / cm^2 (20-22°C and 55-62% RH, Flow Rate: 8 L/min)	< 5.0 mmH2O/cm2 (MIL-M-36954C)	Same

Device	Subject Device	Predicate Device	Comparison
Flammability	Class 1 (16 CFR 1610) LOT #YKWK20201108: 32/32 IBE LOT #YKWK20201111: 32/32 IBE LOT #YKWK20201120: 32/32 IBE	Class 1 (16 CFR 1610)	Same
Biocompatibility Testing			
In Vitro Cytotoxicity	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic. (ISO 10993-5)	Under the conditions of the study, the predicate device extract was determined to be non-cytotoxic. (ISO 10993-5)	Same
Skin Irritation	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating. (ISO 10993-10)	Under the conditions of the study, the predicate device non-polar and polar extracts were determined to be non-irritating. (ISO 10993-10)	Same
Skin Sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing. (ISO 10993-10)	Under the conditions of the study, the predicate device non-polar and polar extracts were determined to be non-sensitizing. (ISO 10993-10)	Same

Table Comparison of the subject device and the predicate device

Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as the legally marketed predicate device.