March 8, 2021

Hunan EEXI Technology & Service Co.,Ltd.
℅ Joyce Yang
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square,
Nanshan District
Shenzhen, Guangdong 518100
China

Re: K202439
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: January 18, 2021
Received: February 8, 2021

Dear Joyce Yang:

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, PhD
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)*
K202439

Device Name
Disposable Medical Face Mask

Indications for Use *(Describe)*
The Disposable Medical 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 mask 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.

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

510(k) Number: K202439

Date of Summary prepared: March 4, 2021

1. Submission Sponsor

Applicant Name	Hunan EEXI Technology & Service Co.,Ltd.
Address	No. 6 North of Pingtou Road, Liuyang Hi-tech Industrial Development Zone, Hunan China.
Contact person	Zhang Xianliang
Phone	+0086-15874115252

2. Submission correspondent

Name	Shenzhen Joyantech Consulting Co., Ltd
Address	1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen
Post Code	518000
Phone No.	+86-755-86069197
Contact Person	Joyce Yang
Email	joyce@cefda.com

3. Device Identification

Type of 510(k) submission:	Traditional
Trade Name:	Disposable Medical Face Mask
Common name:	Surgical face mask
Model:	YX001
Classification name:	Mask, Surgical
Product Code:	FXX
Device Class:	II
Regulation Number:	878.4040

4. Legally Marketed Predicate Device

Trade Name:	Disposable Medical Face Mask
Regulation number:	21 CFR 878.4040
Regulation class:	II
Regulation name:	Surgical Apparel
510(k) Number:	K153496
Product Code:	FXX
Manufacturer:	Xiantao Rayxin Medical Products Co.,Ltd.

5. Device Description

The proposed devices are single use, three-layer, flat masks with ear-loops and nose piece. The Disposable Medical Face Masks are manufactured with three layers, the outer layer is made of PPSB non-woven fabric, which the chemical composition is the mixture of Polypropylene and color master batch. Inner layer is made of Polyethylene, polypropylene and mixture of fiber finishes. And the middle layer is made of melt blown polypropylene filter.

The model of proposed device ,YX001, is held in place over the user’ s mouth and nose bu two elastic ear loops welded to the face mask. The elastic ear loops are not made with natural rubber latex.

The nose piece contained in the proposed device is in the layers of face mask to allow the user to fit the face mask around their nose, which is made of Malleable aluminum wire.

The proposed devices are sold non-sterile and are intended to be single use, disposable devices. The colorants used for mask are Copper phthalocyanine and Titanium dioxide.

6. Intended Use/ Indications for Use

The Disposable Medical 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 mask 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.
potential exposure to blood and body fluids.

7. Technological characteristics comparison

The Disposable Medical Face Mask is compared with the predicate device Disposable Medical Face Mask(K153496). The product characteristics are shown as follow:

Table 1: General Comparison

Comparison item	Subject Device (K202439)	Predicate Device (K153496)	Comments
Product Code	FXX	FXX	Same
Regulation Number	21 CFR § 878.4040	21 CFR § 878.4040	Same
Classification	Class II	Class II	Same
OTC use	Yes	Yes	Same
Intended use & Indications for Use	The Disposable Medical 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 mask 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.	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 mask 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.	Same
Design feature	Ear-loop	Ear-loop, Tie-on	Similar Issue 1
Usage	Single use	Single use	Same
Color	Blue	Blue	Same
Size	(175±10)mm×(95±10)mm	(17.5±1)cm×(9.5±1)cm	Same
Sterile	Non-sterile	Non-sterile	Same
	Outer layer: Spun-bond polypropylene	Outer layer: Spun-bond polypropylene	Same
	Middle layer: Melt blown polypropylene filter	Middle layer: Melt blown polypropylene filter	Same

Comparison item	Subject Device (K202439)	Predicate Device (K153496)	Comments
Material	Inner layer: Spun-bond polypropylene	Inner layer:Spun-bond polypropylene	Same
	Nose piece: PE+ Steel wire	Nose piece:Malleable aluminum wire	Different Issue 2
	Ear-loops: Elastic fiber	Ear-loops:Polyester	Similar Issue 3
ASTM F 2100 Level	Level 2	Level 2	Same
Fluid Resistance Performance ASTM F 1862-13	Meet the ASTM F2100 Requirements for Level 2 Classification	Meet the ASTM F2100 Requirements for Level 2 Classification	Same
Particulate Filtration Efficiency ASTM F 2299	Meet the ASTM F2100 Requirements for Level 2 Classification	Meet the ASTM F2100 Requirements for Level 2 Classification	Same
Bacterial Filtration Efficiency ASTM F 2101	Meet the ASTM F2100 Requirements for Level 2 Classification	Meet the ASTM F2100 Requirements for Level 2 Classification	Same
Differential Pressure (Delta P) MIL-M-36954C	Meet the ASTM F2100 Requirements for Level 2 Classification	Meet the ASTM F2100 Requirements for Level 2 Classification	Same
Flammability 16CFR 1610	Class 1	Class 1	Same
Cytotoxicity	Comply with ISO 10993-5 Non cytotoxic	Comply with ISO 10993-5 Non cytotoxic	Same
Irritation	Comply with ISO 10993-10 Non irritating	Comply with ISO 10993-10 Non irritating	Same
Sensitization	Comply with ISO 10993-10 Non sensitizing	Comply with ISO 10993-10 Non sensitizing	Same

Issue 1: Design differences do not introduce different questions of safety and effectiveness.

Issue 2 : The nose piece of the proposed device is made by PE+Steel wire,which of the predicate device is made by Malleable aluminum wire. The Nose piece is between the inner and outer layers of the mask, which does not contact with the human body directly when used.

Moreover, the whole product has been tested for biocompatibility, and the test results confirm that they have good biocompatibility, these differences do not introduce different questions of safety and effectiveness.

Issue 3: The Ear-loops of the proposed device are made by elastic fiber, which of the predicate device is made by polyester. The major chemical composition of the elastic fiber is segmented polyurethane-urea, which is similar to polyester. In addition, the proposed devices have been tested for biocompatibility, and the test results confirm that they have good biocompatibility, these differences do not introduce different questions of safety and effectiveness.

8. Summary of Non-clinical Testing

Non clinical tests were conducted and conformed to the following standards and the requirements state in the Guidance for Industry and FDA Staff: Surgical Masks - Premarket Notification [510(k)] Submission issued on March 05, 2004.

Standards:

- 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.
- 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.
- 16 CFR 1610 Standard For The Flammability Of Clothing Textiles.
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
- ANSI/AAMI/ISO 11135:2014 Sterilization of health care products - Ethylene oxide - Requirements for Development, validation, and routine control of a sterilization process for Medical devices
- 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.

Table 2: Performance Characteristic Comparison

Items	Purpose	Acceptance criteria	Subject device test result (K202439)	Predicate device(K153496)
Resistance to penetration by synthetic blood(ASTM F1862)	This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration.	Pass at 120 mmHg	Pass at 120 mmHg	Pass at 120 mmHg Pass at 160 mmHg
Sub-micron particulate filtration efficiency (ASTMF2299)	This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized (atomized), dried, and passed through the test article.	> 98%	99.9%	> 98%
Bacterial Filtration Efficiency (ASTM F2101)	The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts up stream of the test article to the bacterial counts downstream.	> 98%	99.9%	> 98%
Differential Pressure (EN 14683:2019)	The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate.	< 6.0 mmH_2O/cm^2	4.7mmH_2O/cm^2	< 6.0 mmH_2O/cm^2

Items	Purpose	Acceptance criteria	Subject device test result (K202439)	Predicate device(K153496)
Flame spread(16 CFR 1610)	This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread.	Class 1	Class 1	Class 1

Table 3: Biocompatibility Comparison

Items	Subject device (K202439)	Predicate device(K153496)
Cytotoxicity	Under the conditions of the study, the test article was found to be non-cytotoxic	Under the conditions of the study, the test article was found to be non-cytotoxic
Irritation	Under the conditions of the study, the test article was found to be non-irritation	Under the conditions of the study, the test article was found to be non-irritation
Sensitization	Under the conditions of the study, the test article was found to be non-sensitizing	Under the conditions of the study, the test article was found to be non-sensitizing

9. Brief discussion of clinical tests

No clinical tests were performed.

10. Conclusions

The conclusion drawn from the nonclinical tests demonstrates that the subject device in this 510(K) submission K202439, the Disposable Medical Face Masks are as safe and effective, and performs as well as or better than the legally marketed predicate device cleared under K153496.