March 10, 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: K202161
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 16, 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)*
K202161

Device Name
Surgical Face Mask

Indications for Use *(Describe)*
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 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.

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
# K202161

This summary of 510(K) safety and effectiveness information is submitted as required by requirements of SMDA and 21 CFR §807.92.

## 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. Devices Identification

| | |
|---|---|
| **Type of 510(k) submission** | Traditional |
| **Trade Name** | Surgical Face Mask |
| **Model** | YX011, YX121 |
| **Classification name** | Mask, Surgical |
| **Review Panel** | Surgical Apparel |
| **Product Code** | FXX |
| **Device Class** | II |
| **Regulation Number** | 878.4040 |

## 4. Legally Marketed Predicate Devices

| | |
|---|---|
| **Trade Name** | Disposable Surgical Face Mask |
| **Regulation number** | 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 straps and nose piece. The Surgical Face Masks are 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 filter.

The model of proposed device, YX011, is held in place over the user's mouth and nose by two elastic ear loops welded to the face mask. The elastic ear loops are not made with natural rubber latex.

The model of proposed device, YX121, is held in place over the user's mouth and nose by four ties welded to the face mask. The tie is made of spun-bond polypropylene.

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 polyethylene and iron.

The proposed devices are sold non-sterile and are intended to be single use, disposable devices.

## 6. Intended Use/ Indications for Use

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 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.

## 7. Technological characteristics of the subject device compared to the predicate device

### 7.1 Predicate Device Information:

510(K) No.: K153496

Common name: Disposable Surgical Face Mask

Classification name: Mask, Surgical

Production regulation: 21 CFR § 878.4040
Product code: FXX
Panel: Surgical Apparel

## 7.2 Comparison to predicate device:

| Comparison item | Subject Device (K202161) | Predicate Device (K153496) | **Comments** |
|---|---|---|---|
| Applicant | Hunan EEXI Technology & Service Co.,Ltd. | Xiantao Rayxin Medical Products Co.,Ltd. | |
| Product name | Surgical Face Mask | Disposable Surgical Face Mask | Similar |
| 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 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 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. | The Disposable 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 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, provided non-sterile. | Same |
| Design feature | Ear-loop, Tie-on | Ear-loop, Tie-on | Same |
| 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 |
| Material | Outer layer: Spun-bond polypropylene | Outer layer: Spun-bond polypropylene | Same |
| | Middle layer: Melt blown polypropylene filter | Middle layer: Melt blown polypropylene filter | Same |
| | Inner layer: Spun-bond polypropylene | Inner layer:Spun-bond polypropylene | Same |
| | Nose piece: polyethylene and iron | Nose piece:Malleable aluminum wire | Similar |
| | Ear-loops: Elastic fiber | Ear-loops:Polyester | Similar |
| | Tie-on:Spun-bond polypropylene | Tie-on:Spun-bond polypropylene | Same |
| ASTM F 2100 Level | Level 3 | Level 2 | Similar |
| Fluid Resistance Performance ASTM F 1862-13 | Meet the ASTM F2100 Requirements for Level 3 Classification | Meet the ASTM F2100 Requirements for Level 2 Classification | Similar |
| Particulate Filtration Efficiency ASTM F 2299 | Meet the ASTM F2100 Requirements for Level 3 Classification | Meet the ASTM F2100 Requirements for Level 2 Classification | Similar |
| Bacterial Filtration Efficiency ASTM F 2101 | Meet the ASTM F2100 Requirements for Level 3 Classification | Meet the ASTM F2100 Requirements for Level 2 Classification | Similar |
| Differential Pressure (Delta P) EN 14683:2019+ AC：2019 | Meet the ASTM F2100 Requirements for Level 3 Classification | Meet the ASTM F2100 Requirements for Level 2 Classification | Similar |
| 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<br>Non irritating | Comply with ISO 10993-10<br>Non irritating | Same |
| Sensitization | Comply with ISO 10993-10<br>Non sensitizing | Comply with ISO 10993-10<br>Non sensitizing | Same |

## 8. Non-clinical Testing

Surgical Face Mask conforms to the following standards:

- ASTM F 2100-19, Standard Specification for Performance of Materials Use in Medical Face Masks.
- ISO 10993-1:2018, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process.

### Bench testing

The bench testing of Surgical Face Mask include the following tests:

*Fluid Resistance Performance

*Particulate Filtration Efficiency

*Bacterial Filtration Efficiency

*Differential Pressure

*Flammability

### Biocompatibility testing

The biocompatibility evaluations were conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process”, as recognized by FDA. The tests of Surgical Face Mask include the following tests:

* Cytotoxicity
* Sensitization
* Irritation

## 9. Conclusions

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicated device.