January 24, 2019

Xiantao Zhibo Non-Woven Products Co., Ltd
℅ Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
4th Floor, 1500# Central Avenue
Shanghai, 200122 Cn

Re: K182514
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: October 26, 2018
Received: Oct 29, 2018

Dear Ivy Wang:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K182514

Device Name
Disposable Surgical Face 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 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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(K) Summary

**K182514**

**Date Summary Prepared: 2018-12-23**

## A. Applicant:

Xiantao Zhibo Non-woven Products Co., Ltd
Address: NO.8 in Industrial Park, Hefeng Road, Xiantao City, Hubei, China
Contact Person: Mr. Yao Sanyu
Tel: +86-15327866903
Email: 1208599360@qq.com

Submission Correspondent:
Primary contact: Ms. Ivy Wang
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1309, Dongfang Building, 1500# Central Ave., Shanghai 200122, China
Tel: +86-21-58817802
Email: haiyu.wang@sungoglobal.com
Secondary contact: Mr. Raymond Luo
Room 1309, Dongfang Building, 1500# Central Ave., Shanghai 200122, China
Tel: +86-21-68828050
Email: fda.sungo@gmail.com

## B. Device:

Trade Name: SURGICAL FACE MASK
Common Name: SURGICAL FACE MASK
Model(s): Ear Loop

Regulatory Information
Classification Name: Surgical Face Mask
Classification: Class II.
Product code: FXX
Regulation Number: 878.4040
Review Panel: Surgical Apparel

## C. Predicate device:

K153496
Disposable Surgical Face Mask
Xiantao Rayxin Medical Products Co., Ltd.

## D. 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.

## E. Device Description:

The proposed device(s) are White color, and Flat Pleated type mask, utilizing Ear Loops way for wearing, and they all has Nose Piece design for fitting the facemask around the nose.
The proposed device(s) 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, ear loops, 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 proposed device(s) is in the layers of facemask to allow the user to fit the facemask around their nose, which is made of malleable aluminum wire.
The proposed device(s) are sold non-sterile and are intended to be single use, disposable device.

## F. Technological Characteristics Comparison Table

Table 1 Comparison of technological characteristics between proposed device and predicate devices

| **Device** | **Proposed Device** | **Predicate Device** | **Comparison** |
|---|---|---|---|
| **510 (k)** | K182514 | K153496 | - |
| **Manufacturer** | Xiantao Zhibo Non-woven Products Co., Ltd | Xiantao Rayxin Medical Products Co., ltd. | - |
| **Product Name** | SURGICAL FACE MASK | SURGICAL FACE MASK | Same |
| **Classification** | Class II Device, FXX (21 CFR878.4040) | Class II Device, FXX (21 CFR878.4040) | Same |
| **Intended 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 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. | Similar |
| **Material** | | | |
| Outer facing layer | Spun-bond polypropylene | Spun-bond polypropylene | Similar |
| Middle layer | Melt blown polypropylene filter | Melt blown polypropylene filter | Similar |
| Inner facing layer | Spun-bond polypropylene | Spun-bond polypropylene | Similar |
| Nose piece | Malleable aluminum wire | Malleable aluminum wire | Similar |
| Ear loops | Polyester | Polyester | same |

| | | | |
|---|---|---|---|
| **Design features** | Color: White<br>Ear loops | Color: Blue<br>Ear Loops or Tie-On | Different |
| **Mask Style** | Flat Pleated | Flat Pleated | Similar |
| **Specification and Dimension** | Length: 17.5cm±1cm<br>Width: 9.5cm±1cm | Length: 17.5cm±1cm<br>Width: 9.5cm±1cm | Same |
| **OTC use** | Yes | Yes | Same |
| **Sterility** | Non-Sterile | Non-Sterile | Same |
| **Use** | Single Use, Disposable | Single Use, Disposable | Same |
| **Performance Testing (ASTM F2100-11)** | Level 2 | Level 2 | Same |
| Fluid Resistance Performance ASTM F1862 | 32 out of 32 pass at 120 mmHg | 32 out of 32 pass at 120 mmHg | Same |
| Particulate Filtration Efficiency ASTM F2299 | pass at 99.88% | pass at 98.46% | Similar |
| Bacterial Filtration Efficiency ASTM F2101 | pass at 99.6% | pass at 98.7% | Similar |
| Differential Pressure (Delta P) MIL-M-36954C | pass at 3.0mm$H_2O/cm^2$ | pass at 4.2 mm$H_2O/cm^2$ | Similar |
| Flammability 16 CFR 1610 | Class 1 | Class 1 | same |
| **Biocompatibility** | | | |
| Cytotoxicity | Under the conditions of the study, the subject device extract was determined to be non-cytotoxic. | Under the conditions of the study, the predicate device extract was determined to be non-cytotoxic. | Similar |
| Irritation | Under the conditions of the study, the subject 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. | Similar |
| Sensitization | Under the conditions of the study, the subject 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. | Similar |

## G. Summary of Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications as

the predicate device. The test results demonstrate that the proposed device conforms to the recognized standards ASTM F2100-11, ASTM F1862, ASTM F2101, and ISO 10993 in addition to the requirements stated in the Guidance for Industry and FDA Staff: *Surgical Masks – Premarket Notification [510(k)] Submission* issued on March 5, 2004.

H. **Summary of Clinical Performance Test**

No clinical study is included in this submission.

**I. Conclusion**

The subject device is a safe, as effective, and perform as well or better than the legally marketed predicated K153496, Xianto Rayxin Medical Products Disposable Surgical Mask.