November 4, 2021

Haian Medigauze Co., Ltd
Weihua Xu
General Manager
Jiaoxie Industry Park, Haian
Nantong, Jiangsu 226633
China

Re: K212471
Trade/Device Name: Medical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 30, 2021
Received: August 6, 2021

Dear Weihua Xu:

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, Ph.D.
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)*
K212471

Device Name
Medical face mask

Indications for Use *(Describe)*
The medical face mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate materials in infection control practices to reduce the potential exposure to blood and body fluids. It is for single-use and 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

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. SUBMITTER

Haian Medigauze Co., Ltd.
Jiaoxie Industry Park 226633 Haian, Jiangsu, PEOPLE'S REPUBLIC OF CHINA. Phone: +86-13901478762
Fax: +86-513-88240958

Primary Contact Person: Weihua Xu
General Manager
Haian Medigauze Co., Ltd.
Tel: (+86) -13901478762
Fax: (+86) -513-88240958

Date prepared Nov 3, 2021

2. DEVICE

| | |
|---|---|
| Device name: | Medical Face mask |
| Common name: | Mask, Surgical |
| Regulation number: | 21 CFR 878.4040 |
| Regulation Class: | II |
| Product Code: | FXX |

3. PREDICATE DEVICE

K160269, Surgical Face Masks (Ear loops and Tie-on).

This predicate has not been subject to a design-related recall.

4. DEVICE DESCRIPTION

The medical face mask is designed and manufactured by Haian Medigauze Co., Ltd . It is non-sterile and for single use.

The medical face mask is manufactured with three-layers, the inner and outer layers are made of polypropylene, and the middle layer is made of melt blown polypropylene. The elastic ear loop of proposed device is made of spandex and nylon, not made with natural rubber latex. The nose piece contained in the proposed device, which is made from steel wire, allows the user to fitthe face mask around their nose.

The product is level 1 according to ASTM F2100-19. The main parameters of the product are listed as follows:

- Bacterial filtration efficiency (BFE) ≥95%
- Sub-micron particle filtration efficiency ≥95%
- Differential pressure: <5.0 mm $H_2O/cm^2$

- Flammability: class 1
- Resistance to penetration by synthetic blood: 80 mmHg

5. INDICATIONS FOR USE

The medical face mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate materials in infection control practices to reduce the potential exposure to blood and body fluids. It is for single-use and provided non-sterile.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

| | Proposed device | Predicate device | Comparison result |
|---|---|---|---|
| Manufacturer | Haian Medigauze Co., Ltd | SAN-M PACKAGE CO., LTD. | NA |
| 510K Number | K212471 | K160269 | NA |
| Product Common Name | Medical face mask | Surgical Face Masks (Ear loops and Tie-on) | NA |
| Intended Use | The medical face mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate materials in infection control practices to reduce the potential exposure to blood and body fluids. It is for single-use and provided non-sterile. | 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, provided non-sterile. | Same |
| Mask style | Flat pleated | Flat pleated | Same |
| Design feature | Ear loop | Earloop or tie-on | Similar |
| Material of outer facing layer | Polypropylene | Polypropylene | Same |
| Material of middle layer | Melt blown polypropylene | Polypropylene meltblown and polypropylene spunbond | Similar |
| Material of inner facing layer | Polypropylene | Polypropylene | Same |
| Nosepiece | Polypropylene coated steel wire | Polypropylene coated steel wire | Same |
| Attachment | Ear loops: Spandex and nylon | Ear loops: Polyester, polyurethane<br>Side tapes: Polyester spunbond (ear loops mask | Similar |

| | | | |
|---|---|---|---|
| | | only)<br>Tie tapes: Polypropylene spunbond or polyester spunbond | |
| Color | Blue | Blue, White | Similar |
| Dimension (Length × Width) | 17.5 cm × 9.5 cm | 17.5 cm × 9.0 cm<br>18.0 cm × 9.0 cm | Similar |
| OTC use | Yes | Yes | Same |
| Sterility | Non-sterile | Non-sterile | Same |
| Single use | Yes | Yes | Same |
| ASTM F2100 level | Level 1 | Level 1 | Same |
| Biocompatibility | | | |
| Cytotoxicity | Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic. | Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic. | Same |
| Irritation | Under the conditions of the study, the proposed device extract was determined to be non-irritating. | Under the conditions of the study, the proposed device extract was determined to be non-irritating. | Same |
| Sensitization | Under the conditions of the study, the proposed device extract was determined to be non-sensitizing. | Under the conditions of the study, the proposed device extract was determined to be non-sensitizing. | Same |

The subject device is the same as the predicate device in the intended use, material, ASTM F2100 level and biocompatibility, and similar in mask style, design feature and dimension. So the subject device is similar to the predicate device.

7. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the medical face mask was conducted in accordance with the International Standard ISO 10993-1:2018, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" as recognized by FDA. The biocompatible testing included the following tests:

- Cytotoxicity - (ISO 10993-5: 2009)
- Sensitization - (ISO 10993-10:2010)
- Skin Irritation - (ISO 10993-10:2010)

Performance testing

Performance testing was conducted on the medical face mask. All of the tested

parameters met the predefined acceptance criteria.

| Item | Test Methods | Criterion | Result |
|---|---|---|---|
| Flammability | ASTM F2100-19<br>16 CFR Part 1610-2008 | Class 1 | Pass |
| Bacterial Filtration Efficiency | ASTM F2100-2019 9.1 ASTM F2101-2019 | ≥95% | Pass |
| Different Pressure | ASTM F2100-19 9.2 | < 5.0 mm $H_2O/cm^2$ | Pass |
| Sub-Micron Particle Filtration Efficiency | ASTM F2100-2019 9.3<br>ASTM F2299/F2299M-2017 | ≥95% | Pass |
| Resistance to Penetration by Synthetic Blood | ASTM F2100-2019 9.4 ASTM F1862/F1862-2017 | Pass at 80 mmHg | Pass |

8. CLINICAL DATA

No clinical data was included in this submission.

9. CONCLUSION

The indications for use statement for the subject device is similar to that of the predicate. The differences between the medical face mask and its predicate device do not raise new issues of safety and effectiveness. The non-clinical data support the safety of the device and the performance testing report demonstrate that the medical face mask should perform as intended in the specified use conditions.

The conclusions drawn from the nonclinical testing demonstrate that the subject device, the Haian Medigauze Medical Face Mask, is as safe, as effective, and performs as well as or better than the legally marketed as the predicate device (K160269).