



December 23, 2020

Jiangsu Province Jianerkang Medical Dressing Co., Ltd
Hongfang Tang
Quality System Director
No.1 Jianerkang Road, Zhixi Industry Concentration Area,
Zhixi Town, Jintan
Changzhou, Jiangsu 213251
China

Re: K202061

Trade/Device Name: Medical Face mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 4, 2020
Received: November 12, 2020

Dear Hongfang Tang:

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,

CAPT Elizabeth Claverie, M.S.
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

Indications for Use

510(k) Number (if known)
K202061

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.

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510(k) Summary

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

1. SUBMITTER

Jiangsu Province Jianerkang Medical Dressing Co., Ltd.

No.1 Jianerkang Road, Zhixi Industry Concentration Area, ZhixiTown,213251 Jintan
Changzhou City, PEOPLE'S REPUBLIC OF CHINA.

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Primary Contact	Hongfang Tang
Person:	Quality System Director
	Jiangsu Province Jianerkang Medical Dressing Co., Ltd
	Tel: (+86)-519-8244 4628
	Fax: (+86) -519-8244 4745

Date prepared	December 22th, 2020
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2. DEVICE

Device Name:	Medical Face mask
Common name:	Mask, Surgical
Regulation number	21 CFR 878.4040
Regulation Class:	2
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 Jiangsu Province Jianerkang Medical Dressing 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 allows the user to fit the

face mask around their nose, which is made from steel wire.

It is a self-inhalation filter mask, which works by filtering the air containing microorganisms, body fluids, and particulate matters through the filter material of the mask before being inhaled or exhaled.

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

- Bacterial filtration efficiency (BFE) $\geq 95\%$
- Sub-micron particle filtration efficiency $\geq 95\%$
- Different pressure: $< 5.0 \text{ mm H}_2\text{O}/\text{cm}^2$
- 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	Jiangsu Province Jianerkang Medical Dressing Co., Ltd	SAN-M PACKAGE CO., LTD.	NA
510K Number	K202061	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 Side tapes: Polyester spunbond (ear loopsmask only) Tie tapes: Polypropylene spunbond or polyester spunbond	Similar
Color	Blue	Blue, White	Similar
Dimension (Length × Width)	17.5 cm × 9.5 cm	17.5 cm × 9.0 cm 18.0 cm × 9.0 cm	Similar
OTC use	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Same
Single use	Yes	Yes	Same
ASTM F 2100 level	Level 1	Level 1 Level 2 Level 3	Similar
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	Result value	Level
Flammability	ASTM F2100-19 16 CFR Part 1610-2008	NA	Class 1
Bacterial Filtration Efficiency	ASTM F2100-2019 9.1 ASTM F2101-2019	Average 99.8%	Level 3
Different Pressure, mm H ₂ O/cm ²	ASTM F2100-19 9.2	Average 3.9	Level 3
Sub-Micron Particle Filtration Efficiency	ASTM F2100-2019 9.3 ASTM F2299/F2299M-2017	Average 96.09%	Level 1
Resistance to Penetration by Synthetic Blood (mmHg)	ASTM F2100-2019 9.4 ASTM F1862/F1862-2017	160	Level 3

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.

From the results of non-clinical data including the performance testing described, Jiangsu Province Jianerkang Medical Dressing Co., Ltd concludes that the medical face mask is as safe, as effective, and performs as well as or better than the legally marketed as the predicate device (K160269).