January 4, 2021

Jiangxi Sanxin Medtec Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120
China

Re: K202719
Trade/Device Name: Disposable Medical Face Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 7, 2020
Received: December 11, 2020

Dear Diana Hong:

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 and Part 809); 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 CAPT Elizabeth F. Claverie
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)*
K202719

Device Name
Disposable Medical Face Masks

Indications for Use *(Describe)*
The non-sterile 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 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.

The sterile disposable medical face masks are intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.

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

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K202719

1. Date of Preparation: 1/1/2021

2. Sponsor Identification

Jiangxi Sanxin Medtec Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Disposable Medical Face Masks
Common Name: Surgical Face Mask

Regulatory Information
Classification Name: Surgical apparel
Class: II;
Product Code: FXX;
Regulation Number: 21CFR 878.4040
Review Panel: General Hospital;

Indication for use
The non-sterile 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 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.

The sterile disposable medical face masks are intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.

Device Description
The proposed device, Disposable medical face masks, is provide in sterile and non-sterile two types.

Both the non-sterile disposable medical face masks and sterile disposable medical face masks are available in five sizes, which are 95mm×175mm, 95mm×155mm, 95mm×140mm, 95mm×145mm and 95mm×160mm. And both the non-sterile disposable medical face masks and sterile disposable medical face masks are available in two ear strap types, Type A, which is ear-loop type, and Type B, which is tie-on type.

5. Identification of Predicate Devices

Predicate Device 1
510K Number: K153496
Manufacturer: Xiantao Rayxin Medical Products Co., Ltd.
Trade Name: Disposable Surgical Face Mask

Predicate Device 2
510K Number: K173062

Manufacturer: V&Q Manufacturing Corporation
Trade Name: Non Woven Face Mask (Models: VQN0185W (earloop) and VQN0185B (ties))

6. Non-Clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-7:2018 Biological Evaluation of Medical Device- Part 7: Ethylene Oxide Sterilization Residuals
- ASTM F88/F88M-15, Standard Test Method For Seal Strength Of Flexible Barrier Materials.(Sterility)
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- ISO 10993-5:2009 Biological evaluation of medical device- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritaion and skin sensitization
- ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- ASTM F2299/F2299M-03 (2017) Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres
- ASTM F2101-2019 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- Annex C, EN 14683:2019 Medical face masks- Requirements and test methods
- 16 CFR 1610 Standard for the Flammability of Clothing Textiles Corrections

7. Clinical Testing

No clinical study is included in this submission.

8. Technological Characteristics Comparison

Table 1 General comparison for non-sterile disposable medical face masks

TEM	Proposed Device	Predicate Device 1 K153496	Remark
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Indication for Use	The non-sterile 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 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	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.	Same
Mask style	Flat pleated	Flat pleated	Same
Design Feature	Ear-loop or tie-on	Ear-loop or tie-on	Same
Mask body dimension (mm)	95mm×175mm 95mm×155mm 95mm×140mm 95mm×145mm 95mm×160mm	175mm×95mm	Different
Ties dimension (mm)	Ear-loop type: 175mm, 160mm, 155mm, 145mm, 140mm Tie-on type: 277.5mm	Unknown	
Nose clip dimension (mm)	105mm	Unknown	
Level	Level 2	Level 2	Same
Fluid resistance	Pass at 120mmHg	Pass at 120mmHg	Same
Particulate efficiency level	Average 98.17%	98.46%	Different
Bacterial filtration level	Average 98.38%	98.7%	Different
Differential	Average 1.78 mmH_2O/cm^2	4.2 mmH_2O/cm^2	Different

pressure			
Flammability	Class 1	Class 1	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Single use	Single use	Single use	Same
ear strap (ear-loop)	Polyester and spandex	Polyester	Different
ear strap (tie-on)	Polypropylene non-woven fabric	Spun-bond polypropylene	
nose clip	Galvanized iron wire coated with polypropylene	Malleable aluminum wire	
mask body	Polypropylene non-woven fabric and Melt-blown polypropylene	Spun-bond polypropylene Melt blown polypropylene filter	
Cytotoxicity	Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic.	Under the conditions of the study, not cytotoxicity effect	Same
Sensitization	Under the conditions of the study, the proposed device extract was determined to be non-sensitizing.	Under the conditions of the study, not a sensitizer	Same
Irritation	Under the conditions of the study, the proposed device extract was determined to be non-irritating.	Under the conditions of the study, not an irritant	Same
Sterility	Non-sterile	Non-sterile	Same

Different - Mask body dimension, Ties dimension and Nose clip dimension

The dimension for the proposed device is different from predicate devices. As the length decreases, the area of the mask decreases gradually. Smaller masks are suitable for patient with smaller face. This difference does not affect intended use and will not raise any safety issues. Therefore, the difference will not affect the safety and effectiveness of the proposed device. Thus, this difference does not affect the substantial equivalence between the proposed device and predicate devices.

Different - Particulate filtration efficiency

The test result for particulate filtration efficiency for the proposed device is different from predicate devices. However, the test result for the proposed device can meet the requirements of level 2 based on ASTM F2100:2019. Therefore, the difference will not affect the safety and effectiveness of the proposed device. Thus, this difference does not affect the substantial equivalence between the proposed device and predicate devices.

Different - Bacterial filtration efficiency

The test result for bacterial filtration efficiency for the proposed device is different from predicate devices. However, the test result for the proposed device can meet the requirements of level 2 based on ASTM F2100:2019. Therefore, the difference will not affect the safety and effectiveness of the proposed

device. Thus, this difference does not affect the substantial equivalence between the proposed device and predicate devices.

Different - Differential Pressure

The test result for differential pressure for the proposed device is different from predicate devices. However, the test result for the proposed device can meet the requirements of level 2 based on ASTM F2100:2019. Therefore, the difference will not affect the safety and effectiveness of the proposed device. Thus, this difference does not affect the substantial equivalence between the proposed device and predicate devices.

Different - Patient Contacting Material

The patient contacting material for the proposed device is different from predicate devices. However, biocompatibility test has been conducted on the proposed device and the test result does not show any adverse effect. Therefore, the difference will not affect the safety and effectiveness of the proposed device. Thus, this difference does not affect the substantial equivalence between the proposed device and predicate devices

Table 2 General comparison for sterile disposable medical face masks

ITEM	Proposed Device	Predicate Device 2 K173062	Remark
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Indication for Use	The sterile disposable medical face masks are intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.	Non Woven Face Mask (Models: VQN0185W (earloop) and VQN0185B (ties)) is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.	Same
Mask style	Flat pleated	Flat pleated	Same
Design Feature	Ear-loop or tie-on	Ear-loop or tie-on	Same
Dimension (mm)	95mm×175mm 95mm×155mm 95mm×140mm 95mm×145mm	175mm×95mm	Different

	95mm×160mm		
Ties dimension (mm)	Ear-loop type: 175mm, 160mm, 155mm, 145mm, 140mm Tie-on type: 277.5mm	Unknown	
Nose clip dimension (mm)	105mm	Unknown	
Level	Level 2	Level 2	Same
Fluid resistance	Pass at 120mmHg	Pass at 120mmHg	Same
Particulate efficiency level	Average 98.14%	Average 99.74%	Different
Bacterial filtration level	Average 98.64%	Average 99.4%	Different
Differential pressure	Average 1.78 mmH_2O/cm^2	Average 2.7mmH_2O/cm^2	Different
Flammability	Class 1	Class 1	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Single use	Single use	Single use	Same
ear strap (ear-loop)	Polyester and spandex	Urethane elastic fiber or spun-bond polypropylene	Different
ear strap (tie-on)	Polypropylene non-woven fabric		
nose clip	Galvanized iron wire coated with polypropylene	White aluminum strip covered by polypropylene covering	
mask body	Polypropylene non-woven fabric and Melt-blown polypropylene	Spun-bond polypropylene	
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
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
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	Same

		non-irritating.	
Sterility	sterile	non-sterile	Different

Different - Mask body dimension, Ties dimension and Nose clip dimension

The dimension for the proposed device is different from predicate devices. As the length decreases, the area of the mask decreases gradually. Smaller masks are suitable for patient with smaller face. This difference does not affect intended use and will not raise any safety issues. Therefore, the difference will not affect the safety and effectiveness of the proposed device. Thus, this difference does not affect the substantial equivalence between the proposed device and predicate devices.

Different - Particulate filtration efficiency

The test result for particulate filtration efficiency for the proposed device is different from predicate devices. However, the test result for the proposed device can meet the requirements of level 2 based on ASTM F2100:2019. Therefore, the difference will not affect the safety and effectiveness of the proposed device. Thus, this difference does not affect the substantial equivalence between the proposed device and predicate devices.

Different - Bacterial filtration efficiency

The test result for bacterial filtration efficiency for the proposed device is different from predicate devices. However, the test result for the proposed device can meet the requirements of level 2 based on ASTM F2100:2019. Therefore, the difference will not affect the safety and effectiveness of the proposed device. Thus, this difference does not affect the substantial equivalence between the proposed device and predicate devices.

Different - Differential Pressure

The test result for differential pressure for the proposed device is different from predicate devices. However, the test result for the proposed device can meet the requirements of level 2 based on ASTM F2100:2019. Therefore, the difference will not affect the safety and effectiveness of the proposed device. Thus, this difference does not affect the substantial equivalence between the proposed device and predicate devices.

Different - Patient Contacting Material

The patient contacting material for the proposed device is different from predicate devices. However, biocompatibility test has been conducted on the proposed device and the test result does not show any adverse effect. Therefore, the difference will not affect the safety and effectiveness of the proposed device. Thus, this difference does not affect the substantial equivalence between the proposed device and predicate devices.

Different - Product status

The final product status of the proposed device is different from predicate device, one is sterilized and

the other is non-sterilized. Sterilization will affect the safety and effective of the mask. The performance testing of the proposed device has been conducted on the final product and the test results show that the proposed sterile mask meets the requirements of ASTM F2100-2019. And biocompatibility testing of the proposed device has also been conducted on the final product and the test results showed that there are no negative impacts from the materials that are used in the proposed sterile mask. Therefore, although the final product status is different between the proposed device and predicate device, the final product status does not affect the safety and effectiveness of the proposed device. Therefore, this difference does not affect the substantial equivalence between the proposed device and predicate device.

9. Conclusions

Based on the comparison and analysis above, the proposed devices are as safe, as effective, and performs as well as the legally marketed predicate devices.