January 6, 2021

Shandong T&F Nonwoven Co., LTD
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm. 912, Building #15, XiYueHui, No. 5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
China

Re: K202594
Trade/Device Name: Medical Surgical Masks-Non Sterile
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 3, 2020
Received: December 7, 2020

Dear Ray 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/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

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)*
K202594

Device Name
Medical Surgical Masks-Non Sterile

Indications for Use *(Describe)*
The Medical Surgical Masks-Non Sterile is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The Medical Surgical Masks-Non Sterile is 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.

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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The assigned 510(k) Number: K202594

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Preparation:2021/01/06

2. Sponsor Identification

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Medical Surgical Masks-Non Sterile
Common Name: Mask, Surgical

Regulatory Information
Classification Name: Mask, Surgical
Classification: 2
Product Code: FXX
Regulation Number: 878.4040
Review Panel: General Hospital

Indication for use Statement:
The Medical Surgical Masks-Non Sterile is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The Medical Surgical Masks-Non Sterile is 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.

Device Description
The Medical Surgical Masks-Non Sterile is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The Medical Surgical Masks-Non Sterile is 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 proposed device(s) are ***White color***, and ***Flat Pleated*** type mask, utilizing ***Ear Loops'*** way for wearing, and they all have ***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 polypropylene non-woven fabric, and the middle layer is made of polypropylene melt-blown fabric.

The Medical Surgical Masks-Non Sterile is held in place over the user's mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are made with 30% polyamide and 70% polyurethane.

The nose piece contained in the proposed device(s) is in the layers of the facemask to allow the user to fit the facemask around their nose, which is made of polypropylene and iron wire.

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

5. Identification of Predicate Device(s)

Predicate Device

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

6. Non-Clinical Test Conclusion

Applied Standards List:

- ISO 10993-5: 2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ASTM F2100-19, Standard Specification For Performance Of Materials Used In Medical Face Masks.
- ASTM F1862-17, Standard Test Method For Resistance Of Medical Face Masks To Penetration By Synthetic Blood (Horizontal Projection Of Fixed Volume At A Known Velocity)
- MIL-M-36945C, Method 1 Military Specifications: Surgical Mask disposable;
- ASTM F2101-19, Standard Test Method For Evaluating The Bacterial Filtration Efficiency (Bfe) Of Medical Face Mask Materials, Using A Biological Aerosol Of Staphylococcus Aureus;
- ASTM F2299-03, Stand test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres;
- 16 CFR 1610, Standard for the Flammability of clothing textiles;
- Bench Testing for the performance of Dimensions.

Test Result Summary:

Title of the Test	Purpose of the Test	Acceptance criteria and source of references	Results
In Vitro Cytotoxicity	Verify the Biological performance of proposed device	No cytotoxicity effect as the test method of ISO 10993-10	Under the conditions of the study, not cytotoxicity effect
Skin Irritation	Verify the Biological performance of proposed device	No irritation effect as the test method of ISO 10993-5	Under the conditions of the study, not an irritant
Skin Sensitization	Verify the Biological performance of proposed device	No sensitization effect as the test method of ISO 10993-5	Under conditions of the study, not a sensitizer.
Fluid Resistance	Verify the fluid resistance performance of proposed device	120 mmHg as the test method of ASTM F1862	120 mmHg
Particulate Filtration Efficiency	Verify the Particulate filtration efficiency performance of proposed device	≥98% as the test method of ASTM F2299	≥99%
Bacterial Filtration Efficiency	Verify the bacterial filtration efficiency performance of proposed	≥98% as the test method of ASTM F2101	≥99%

	device		
Differential Pressure (Delta P)	Verify the differential pressure performance of proposed device	< 6.0mmH2O/cm^2 as the test method of MIL-M-36945C	<4.8 mmH2O/cm^2
Flammability	Verify the flammability performance of proposed device	Class 1 as the test method of 16 CFR 1610	Class 1
Dimensions	Verify the Physical specifications of proposed device	Length: 17.5 cm ±5mm Width: 9.5 cm±5mm Length of loop: 17 cm±5mm Length of Nosepiece: 10 cm±5mm	Meet the acceptance criteria

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM		Proposed Device K202594	Predicate Device K153496	Remark
Indication For Use		The Medical Surgical Masks-Non Sterile is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The Medical Surgical Masks-Non Sterile is 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.	SAME
Basic Design		Ear Loops, Flat Pleated, 3 layers	Ear Loops, Tie-On, Flat Pleated, 3 layers	SAME
Materials	Outer Facing Layer	polypropylene non-woven fabric	Spun-bond polypropylene	Analysis
	Middle Layer	polypropylene melt-blown fabric	Melt blown polypropylene filter	
	Inner Facing Layer	polypropylene non-woven fabric	Spun-bond polypropylene	
	Nose Piece	PP + iron wire	Malleable aluminum wire	
	Ear Loops	polyamide and polyurethane	Polyester	
Color		White	Blue	Analysis
Dimension (Length)		17.5 cm +/- 5mm	17.5 cm +/- 1cm	Similar
Dimension (Width)		9.5 cm +/- 5mm	9.5 cm +/- 1cm	
OTC use		Yes	Yes	SAME
Single Use		Yes	Yes	SAME
Sterile		No	No	SAME
ASTM F2100 Level		Level 2	Level 2	SAME

Table 2 Performance Characteristic Comparison

ITEM	Proposed Device K202594	Predicate Device K153496	ASTM F2100 Requirements for Level 2 Classification	Remark
Fluid Resistance Performance ASTM F1862	120 mmHg	120 mmHg	120 mmHg	SAME
Particulate Filtration Efficiency ASTM F2299	≥99%	98.46%	≥ 98%	
Bacterial Filtration Efficiency ASTM F2101	≥99%	98.7%	≥ 98%	
Differential Pressure	< 4.8 mmH2O/cm^2	4.2 mmH2O/cm^2	< 6.0 mmH2O/cm^2	

(Delta P) MIL-M-36954C				
Flammability 16 CFR 1610	Class 1	Class 1	Class 1	SAME

Table 3 Biocompatibility Comparison

ITEM	Proposed Device K202594	Predicate Device K153496	Remark
Cytotoxicity	Under the conditions of the study, not cytotoxic	Comply with ISO 10993-5	SAME
Irritation	Under the conditions of the study, not an irritant	Comply with ISO 10993-10	SAME
Sensitization	Under conditions of the study, not a sensitizer.		SAME

Analysis:

The Medical Surgical Masks-Non Sterile is substantially equivalent to the Xiantao Rayxin Medical Products Disposable Surgical Face Mask. Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, Disposable Surgical Face Mask cleared under K153496.

9. Substantially Equivalent (SE) Conclusion

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