December 3, 2021

Weihai Hongyu Nonwoven Fabric Products 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: K212807
Trade/Device Name: Surgical Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 31, 2021
Received: September 3, 2021

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,

For Clarence W. Murray III, PhD
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)*

K212807

Device Name

Surgical Masks

Indications for Use *(Describe)*

The Surgical Masks is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The Surgical Masks 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 Model YH-EZ-004(White Color, Blue Color) is Level 2 barrier as ASTM F2100 requirements.

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

1. Date of Preparation:2021/8/31

2. Sponsor Identification

WEIHAI HONGYU NONWOVEN FABRIC PRODUCTS CO., LTD.
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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name:Surgical Masks
Common Name: Mask, Surgical

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

Indication For Use Statement:
The Surgical Masks is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The Surgical Masks 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 Model YH-EZ-004(White Color, Blue Color) is Level 2 barrier as ASTM F2100 requirements.

Device Description:
The proposed device(s) includes 1 model, which is YH-EZ-004. This model has two colors,Blue color and White color.This model is ***Flat Pleated*** type mask, utilizing ***Ear Loops'*** way for wearing, and it has ***Nose Piece*** design for fitting the facemask around the nose.

All two colors of the model YH-EZ-004 of proposed device(s) share same materials and structure, they all are manufactured with three layers, the inner and outer layers are made of spunbonded non-woven fabric, and the middle layer is made of melt-blown non-woven fabric.

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 polyethylene.

The proposed device(s) 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 terylene and spandex.

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

5. Identification of Predicate Device(s)

510(K) number:K202594
Device name:Medical Surgical Masks-Non Sterile
Manufacturer:SHANDONG T&F NONWOVEN CO., LTD.

6. Technological Characteristics Comparison

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device K202594	Remark
	ASTM F2100 Level 2	ASTM F2100 Level 2	
Intended Use	The Surgical Masks is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The Surgical Masks is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a	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	SAME

		single-use, disposable device(s), provided non-sterile. The Model YH-EZ-004(White Color, Blue Color) is Level 2 barrier as ASTM F2100 requirements.	fluids. This is a single-use, disposable device(s), provided non-sterile.	
Basic Design		Ear Loops, Flat Pleated, 3 layers	Ear Loops, Flat-Pleated, 3 layers	SAME
Materials	Outer Facing Layer	spunbonded non-woven fabric	polypropylene non-woven fabric	Analysis
	Middle Layer	melt-blown non-woven fabric	polypropylene melt-blown fabric	
	Inner Facing Layer	spunbonded non-woven fabric	polypropylene non-woven fabric	
	Nose Piece	polyethylene	PP + iron wire	
	Ear Loops	terylene, spandex	polyamide and polyurethane	
Color		Blue,White	White	Analysis
Dimension (Length, Width)		17.5 cm ±5%cm 9.5 cm±5%cm	17.5 cm +/- 5mm 9.5 cm +/- 5mm	Similar
OTC use		Yes	Yes	SAME
Single Use		Yes	Yes	SAME
Sterile		Non-sterile	Non-sterile	SAME

Table 2 Performance Characteristic Comparison

ITEM	Proposed Device		Predicate Device K202594	ASTM F2100 Requirements	Remark
ASTM F2100 Level	YH-EZ-004 White Level 2	YH-EZ-004 Blue Level 2	Level 2	Level 2	SAME
Fluid Resistance Performance ASTM F1862	120 mmHg	120 mmHg	120 mmHg	120 mmHg	SAME
Particulate Filtration Efficiency ASTM F2299	≥99.77%	≥99.30%	⩾99%	≥ 98%	
Bacterial Filtration Efficiency ASTM F2101	≥99.04%	≥98.54%	⩾99%	≥ 98%	
Differential Pressure (Delta P) EN 14683:2019+ AC:2019 Annex C	< 5.0 mmH_2O /cm^2	< 5.4mmH_2O /cm^2	< 4.8 mmH2O/cm^2	< 6.0 mmH_2O /cm^2	
Flammability 16 CFR 1610	Class 1	Class 1	Class 1	Class 1	SAME

Table 3 Biocompatibility Comparison

ITEM	Proposed Device	Predicate Device K202594	Remark
Cytotoxicity	Non-cytotoxic	Non-cytotoxic	SAME
Irritation	Non-irritating	Non-irritating	SAME
Sensitization	Non-sensitizing	Non-sensitizing	SAME

Analysis:

The proposed device is different with the predicate device in materials used and color, which may raise the risk about biocompatibility, for this risk we have conducted the testing according to the ISO10993-1, cytotoxicity, irritation and sensitization. The test results shown that no biocompatibility risk would be raised.

So, we consider that the proposed device has same biocompatibility performance with the predicate device.

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, Medical Surgical Masks-Non Sterile cleared under K202594.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- 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)
- EN 14683-2019+AC:2019 Annex C，Medical face masks - Requirements and test methods;
- 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 Method	Purpose	Acceptance Criteria	Results(Blue Color)	Results(White Color)
ASTM F1862	Resistance to penetration by synthetic blood	120 mm Hg	120 mm Hg	120 mm Hg
ASTM F2299	Sub-micron particulate filtration efficiency at 0.1 micron	≥ 98%	≥ 99.30%	≥ 99.77%
ASTM F2101	Bacterial Filtration Efficiency	≥ 98%	≥ 98.54%	≥ 99.04%
EN 14683 Annex C	Differential Pressure	< 6.0 mm H_2O/cm^2	< 5.4mm H_2O/cm^2	< 5.0mm H_2O/cm^2
16 CFR 1610	Flammability	Class 1	Class 1	Class 1
ISO 10993-10	Irritation	No irritation effect	Under the conditions of the study, no irritation effect	Under the conditions of the study, no irritation effect
	Sensitization	No sensitization effect	Under conditions of the study, no sensitization effect	Under conditions of the study, no sensitization effect
ISO 10993-5	Cytotoxicity	No cytotoxicity effect	Under the conditions of the study, no cytotoxicity effect	Under the conditions of the study, no cytotoxicity effect

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device K202594.