October 25, 2021

Jiangmen Ningrui Medical Supplies 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: K212293
Trade/Device Name: Surgical Mask (Model: WK1701-02A, WK1701-03A, WK1701-04A)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX,
Dated: July 19, 2020
Received: July 22, 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,

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)*

K212293

Device Name

Surgical Mask (Model:WK1701-02A, WK1701-03A and WK1701-04A)

Indications for Use *(Describe)*

The Surgical Mask (Model:WK1701-02A, WK1701-03A and WK1701-04A) 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 Mask 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 WK1701-02A is Level 1 barrier as ASTM F2100 requirements.
The Model WK1701-03A is Level 2 barrier as ASTM F2100 requirements.
The Model WK1701-04A is Level 3 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.

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The assigned 510(k) Number: K212293

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:2021/10/25

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: Surgical Mask (Model: WK1701-02A, WK1701-03A, WK1701-04A)

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 Surgical Mask 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 Mask 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 WK1701-02A is Level 1 barrier as ASTM F2100requirements.

The Model WK1701-03A is Level 1 barrier as ASTM F2100requirements.

The Model WK1701-04A is Level 1 barrier as ASTM F2100requirements.

Device Description: The proposed device(s) includes 3 models, which are WK1701-02A, WK1701-03A and WK1701-04A. Three of them all are Blue 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.

All three models of proposed device(s) share same materials and structure, they all are manufactured with three layers, the inner and outer layers are made of polypropylene spunbond fabric, and the middle layer is made of polypropylene meltblown fabric.

The proposed device(s) of Level 1, Level 2 and Level 3 have the same material. The proposed device(s) are manufactured with three layers, the inner and outer layers are made of polypropylene spunbond fabric, and the middle layer is made of polypropylene meltblown 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 polypropylene coated galvanized iron wire.

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 nylon and spandex.

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

The difference between the three models are the claimed Barrier Level.

Model No.	Product Dimension	Product Description		Mask Style		
		Blue Mask	Ear Loops	Level 1	Level 2	Level3
WK1701-02A	17.5× 9.5 cm	X	X	X		
WK1701-03A	17.5× 9.5 cm	X	X		X	
WK1701-04A	17.5× 9.5 cm	X	X			X

5. Identification of Predicate Device(s)

Predicate Device
K202491
Disposable Surgical Face Mask
Jiangsu NewValue Medical Products Co., Ltd.

6. Technological Characteristic Comparison

Table 1 General Comparison

ITEM		Proposed Device			Predicate Device K202491			Comparison
		Level 1	Level 2	Level 3	Level 1	Level 2	Level3	
Intended Use		The Surgical Mask 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 Mask 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, provided non-sterile.			SAME
Basic Design		Ear Loops, Flat Pleated, 3 layers			Ear Loops, Flat-Pleated, 3 layers			SAME
Materials	Outer Facing Layer	polypropylene spunbond fabric			Spun-bond Polypropylene non-woven fabric			Analysis
	Middle Layer	polypropylene meltblown fabric			Melt-blown polypropylene			
	Inner Facing Layer	polypropylene spunbond fabric			Spun-bond Polypropylene non-woven fabric			
	Nose Piece	polypropylene coated galvanized iron wire			Malleable iron wire with plastic covering			
	Ear Loops	nylon , spandex			Spandex Elastic cord			
Color		Blue			Blue			SAME
Dimension (Length, Width)		17.5 cm ±5mm 9.5 cm±3mm			145×95mm (±5mm) 175×95mm (±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 K202491			ASTM F2100 Requirements			Comparison
ASTM F2100 Level	Level 1	Level 2	Level 3	Level 1	Level 2	Level3	Level 1	Level 2	Level 3	SAME
Fluid Resistance Performance ASTM F1862	80 mmHg	120 mmHg	160 mmHg	Pass at 80 mmHg Pass at 120 mmHg Pass at 160 mmHg			80 mmHg	120 mmHg	160 mmHg	SAME
Particulate Filtration	≥99%	≥99%	≥99%	Pass at ＞99.4%			≥ 95%	≥ 98%	≥ 98%	
Efficiency ASTM F2299										
Bacterial Filtration Efficiency ASTM F2101	≥99%	≥99%	≥99%	Pass at ≥99.8%			≥ 95%	≥ 98%	≥ 98%	
Differential Pressure (Delta P) EN 14683:2019+ AC:2019 Annex C	< 3.4 mmH_2O/cm^2	< 3.5 mmH_2O/cm^2	< 3.4 mmH_2O/cm^2	Pass at ＜3.5 mmH_2O/cm^2			< 5.0 mmH_2O/cm^2	< 6.0 mmH_2O/cm^2	< 6.0 mmH_2O/cm^2	
Flammability 16 CFR 1610	Class 1	Class 1	Class 1	Class 1 Non-Flammable			Class 1	Class 1	Class 1	SAME

ITEM	Proposed Device			Predicate Device K202491			Comparison
	Level 1	Level 2	Level 3	Level 1	Level 2	Level3	
Cytotoxicity	Non-cytotoxic			Non-cytotoxic			SAME
Irritation	Non-irritating			Non-irritating			SAME
Sensitization	Non-sensitizing			Non-sensitizing			SAME

Table 3 Biocompatibility Comparison

Note: The proposed device(s) of Level 1, Level 2 and Level 3 have the same material.

Analysis:
The proposed device is different with the predicate device in materials used.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed devices met all design specifications of the standard and test method described below for the 3 nonconsecutive lots with 32 samples per lot. 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
ASTM F2101-19	Verify the Bacterial Filtration Efficiency (BFE) performance of the subject device.	Level 1: ≥95%; Level 2: ≥98%; Level 3: ≥98%;	WK1701-02A (Level 1) 99.9%
			WK1701-03A (Level 2) 99.8 - 99.9%
			WK1701-04A (Level 3) 99.8 - 99.9%
EN 14683-2019+AC:2019 Annex C	Verify the Differential Pressure (Delta P) performance of the subject device.	Level 1: < 5.0 H2O/cm2; Level 2: < 6.0 H2O/cm2; Level 3: < 6.0 H2O/cm2;	WK1701-02A (Level 1) Average 2.7 – 3.4 H2O/cm2
			WK1701-03A (Level 2) Average 2.7 – 3.5 H2O/cm2
			WK1701-04A (Level 3)

			Average 2.8 – 3.3 H2O/cm2
ASTM F2299-03	Verify the Sub-micron particulate filtration efficiency (PFE) performance of the subject device.	Level 1: ≥95%; Level 2: ≥98%; Level 3: ≥98%;	WK1701-02A (Level 1) 99.45 – 99.97%
			WK1701-03A (Level 2) 99.41 – 99.98%
			WK1701-04A (Level 3) 99.58 – 99.77%
ASTM F1862-17	Verify the Resistance to Penetration by Synthetic Blood performance of the subject device.	Level 1: 80 mmHg; Level 2: 120 mmHg; Level 3: 160 mmHg;	WK1701-02A (Level 1) None Senn under 80 mmHg
			WK1701-03A (Level 2) None Senn under 120 mmHg
			WK1701-04A (Level 3) None Senn under 160 mmHg
16 CFR 1610	Verify the Flame spread performance of the subject device.	Class 1	Class 1 (Ignited, but extinguished)
ISO 10993-5: 2009	Verify the Cytotoxicity potential of the subject device	Non-cytotoxic	Under the conditions of this study, the test article have no potential toxicity to L-929 cells.
ISO 10993-10: 2010	Verify the Irritation and Sensitization potential of the subject device	Non-irritating and Non-sensitizing	The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test result showed that the response of the test article extract was categorized as negligible under the test condition.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Disposable Surgical Face Mask cleared under K202491.