January 6, 2021

Jiangsu NewValue Medical Products Co., Ltd.
% Julie Chen
Technical Manager
Shanghai Medical Business Consulting Co., Ltd.
Room 304, No 170 Huajiang Road, Jiading District
Shanghai, 201803
China

Re: K202491
Trade/Device Name: Disposable Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 16, 2020
Received: December 7, 2020

Dear Julie Chen:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202491

Device Name
Disposable Surgical Face Mask

Indications for Use *(Describe)*

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.

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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510(K) Summary — K202491

I. SUBMITTER:

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Summary prepared：01/04/2021

II. DEVICE

Name of Device: Disposable Surgical Face Mask
Regulation Number: 21 CFR PART 878.4040
Common Name: Surgical Mask
Classification Name: Surgical Mask
Regulatory Class: II
Product Code: FXX

III. PREDICATE DEVICE

Primary predicate device: Surgical Face Masks (K160269)

IV. DEVICE DESCRIPTION

Disposable Surgical Face Mask is composed of three layers and is flat-pleated. The mask materials consist of an outer layer (spun-bond polypropylene), a middle layer, between the outer layer and inner layers (melt-blown polypropylene), and an inner layer (spun-bond polypropylene). Each mask contains tie strings (spun-bond polypropylene) or ear loops (Spandex elastic cord) to secure the mask over the users' mouth and face and includes a malleable nose piece (iron wire with plastic covering) to provide a firm fit over the nose.

V. Available Model

REF No.	**Product Size**	**Model Description**		**Mask Style**		
		Blue Mask	**Ear Loop**	**Level 1**	**Level 2**	**Level 3**
EL-M01	145×95mm	**X**	**X**	**X**		
EL-M02	145×95mm	**X**	**X**		**X**	
EL-M03	145×95mm	**X**	**X**			**X**
EL-L01	175×95mm	**X**	**X**	**X**		
EL-L02	175×95mm	**X**	**X**		**X**	
EL-L03	175×95mm	**X**	**X**			**X**

VI. INDICATIONS FOR USE

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.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Disposable Surgical Face Masks are compared with the predicate device (Surgical Face Masks (K160269)). The results are shown below in the Technological Characteristics Comparison Table:

DEVICE	Subject Device Disposable Surgical Face Mask (K202491)			Primary Predicate Device Surgical Face Mask (K160269)			Substantial Equivalence
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	
Intended Use	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. The Disposable Surgical Face Masks are single use, disposable device, 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
Classification Product Code	FXX			FXX			Same
Ear Loop Model and Tie-on Model	Ear Loops			Ear Loops, Tie-on			Similar
Materials							
Outer Facing Layer	Spun-bond Polypropylene non-woven fabric			Polypropylene			Similar
Middle Layer	Melt-blown polypropylene			1. Polypropylene spunbond 2. Polypropylene meltblown			Similar
Inner Facing Layer	Spun-bond Polypropylene non-woven fabric			Polyethylene/Polyester			Similar
Nose Piece	Malleable iron wire with plastic covering			Polyethylene coated steel wire			Similar
Ear Loops	Spandex Elastic cord			Ear loops: Polyester, polyurethane Side tapes:			Similar

		Polyester spunbond (ear loops mask only)	
Design Features			
Color	Blue	Blue, white	Similar
Style	Flat - Pleated	Flat - folded	Same
Multiple Layers	3 Layers	4 Layers	Different
Single Use	Single use	Single use	Same
Sterility			
Sterile	Non-sterile	Non-sterile	Same
Dimensions			
Length × Width	145×95mm (±5mm) 175×95mm (±5mm)	Length: 90 ± 3 mm Width:175 ± 5mm Length: 90 ± 3 mm Width:180 ± 5mm	Similar

Technological Characteristics Product Barrier Specifications Per ASTM F2100 – Meets Level 1 + Leve2, Level 3							
	Level 1	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**	
Fluid Resistance ASTM F1862	Pass at 80 mmHg; Pass at 120 mmHg Pass at 160mmHg;			Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Same
Particulate Filtration Efficiency (PFE) ASTM F2299	Pass at ＞99.8%			Pass at 99.6%	Pass at 99.6%	Pass at 99.7%	Same
Bacterial Filtration Efficiency (BFE) ASTM F2101	Pass at ≥99.8%			Pass at >98%	Pass at >98%	Pass at >99%	Same
Differential Pressure (Delta P) MIL-M-36954C	Pass at ＜4.2mmH_2O/cm^2			Pass at 2.0 mmH_2O /cm^2	Pass at 1.6 mmH_2O/ cm^2	Pass at 2.5 mmH_2O/ cm^2	Same
Flammability 16 CFR PART 1610	Class 1 Non-Flammable			Class 1	Class 1	Class 1	Same
Biocompatibility							
Cytotoxicity	Non-cytotoxic			Non-cytotoxic			Same
Irritation	Non-sensitizing			Non-sensitizing			Same
Sensitization	Non-irritating			Non-irritating			Same

VIII. PERFORMANCE DATA

Non-Clinical Performance Test Conclusion

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

- ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F1862 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 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- ASTM F2101 Standard Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- MIL-M- 36954C Military Specification, Mask, Surgical, Disposable
- 16 CFR Part 1610 Standard for the Flammability of Clothing
- ISO10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity of medical devices
- ISO10993-10 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization

Biocompatibility

Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic, non-sensitizing and non-irritating.

Clinical Test Conclusion

No clinical study is included in this submission.

IX. DISCUSSION AND CONCLUSION

Although the design features of proposed device is slightly different with the predicate device, the data drawn from the non-clinical tests demonstrate that the proposed device, the Disposable Surgical Face Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device Surgical Face

Masks (K160269).