January 20, 2022

Wuhan Raytex Protection CO., LTD
Maggie Yao
General Manager
RM1201,Mingchuang Building,Greenland,Heping Avenue,
Wuchang District
Wuhan, Hubei 430060
China

Re: K203161
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 25, 2021
Received: December 16, 2021

Dear Maggie Yao:

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)*
K203161

Device Name
Surgical face mask

Indications for Use *(Describe)*
When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate material. This device is non-sterile and for single use only.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Summary Prepared Date
19 January 2022

1. Submitter Information

Sponsor Name: WUHAN RAYTEX PROTECTION CO., LTD

Address: RM1201,Mingchuang Building,Greenland,Heping Avenue,Wuchang District,Wuhan,Hubei Province,430060,China.

Contact Person:Maggie Yao (General Manager)

Phone: +86-27 87263395

Fax: +86-27 88398709

E-mail:sales@vicogard.com

2. Subject Device Information

Type of 510(k):	Traditional
Common Name:	Surgical face mask
Trade Name:	Surgical face mask
510(k) number:	K203161
Classification Name:	Mask,Surgical
Review Panel:	General Hospital
Product Code:	FXX
Regulation Number:	21 CFR 878.4040
Regulation Class:	Class II

3. Predicate Device Information

Sponsor:	Jiangsu Province Jianerkang Medical Dressing Co., Ltd
Common Name:	Medical Face Mask
Trade Name:	Medical Face Mask
510(k) number:	K202061
Review Panel:	General Hospital
Product Code:	FXX
Regulation Number:	21 CFR 878.4040

Regulation Class: Class II

4. Device Description

The surgical face masks are non-sterile, single use, 3 layers, flat-pleated style with ear loops and nose piece. The outer layer and inner facing layer of face mask consist of Polypropylene, and the middle layer consists of Melt Blown Polypropylene Filter. Each mask contains ear loops to secure the mask over the user's face and mouth with nose piece to firmly fit over the nose.

5. Intended Use

When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate material. This device is non sterile and for single use only.

6. Summary of Comparison and Technological Characteristics

Table 1 - General Comparison

Elements of Comparison	**Subject Device**	**Predicate Device**	**Verdict**
Product Name	Surgical face mask	Medical face mask	--
510(k) number	K203161	K202061	
General Comparison			
Intended Use	When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and particulate material. This device is non-sterile and for single use only.	The medical face mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate materials in infection control practices to reduce the potential exposure to blood and body fluids. It is for single-use and provided non-sterile.	Same
Model	Flat type	Flat Pleated	Same
Design features	Ear loop	Ear loop	Same
Layers	3	3	Same

Elements of Comparison		**Subject Device**	**Predicate Device**	**Verdict**
Target population		Adults	Adults	Same
Material	Outer facing layer	polypropylene	polypropylene	Same
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene	Same
	Inner facing layer	polypropylene	polypropylene	Same
	Nose piece	Single Galvanize Wire, Coated by PE	Polypropylene coated steel wire	Note 1
	Ear loops	Spandex and nylon	Spandex and nylon	Same
Color		Blue	Blue	Same
Dimension (Width)		9.5cm ± 0.5cm	9.5cm	Same
Dimension (Length)		17.5cm ± 0.5cm	17.5cm	Same
Sterility		Non-Sterile	Non-Sterile	Same
Use		Single Use	Single Use	Same
ASTM F2100 Level		Level 1	Level 1	Same
Synthetic Blood Penetration Resistance ASTM F 1862		Lot 1: 32 Out of 32 pass at 80 mmHg Lot 2: 32 Out of 32 pass at 80 mmHg Lot 3: 32 Out of 32 pass at 80 mmHg	80 mmHg	Same
Particulate Filtration Efficiency ASTM F 2299		Lot 1:Average 96.6％ Lot 2:Average 96.1％ Lot 3:Average 96.2％	Average 96.09%	Same
Bacterial Filtration Efficiency ASTM F2101		Lot 1: Average 99.5% Lot 2: Average 99.4% Lot 3: Average 99.4%	Average 99.8%	Same
Differential Pressure (Delta P) EN 14683:2019+AC：		Lot 1: Average 3.9 mmH_2 0/cm^2 Lot 2: Average 3.8 mmH_2	Average 3.9 mmH_2 0/cm^2	Same

Elements of Comparison	Subject Device	Predicate Device	Verdict
2019	0/cm^2 Lot 3: Average 4.0 mmH_2 0/cm^2		
Flammability 16CFR 1610	Lot 1: Class 1 Lot 2: Class 1 Lot 3: Class 1	Class 1	Same
Cytotoxicity	Comply with ISO 10993-5 Non cytotoxic	Comply with ISO 10993-5 Non cytotoxic	Same
Irritation	Comply with ISO 10993-10 Non irritating	Comply with ISO 10993- 10 Non irritating	Same
Sensitization	Comply with ISO 10993-10 Non sensitizing	Comply with ISO 10993- 10 Non sensitizing	Same

Note 1: The nose piece material of the subject device is Single Galvanize Wire, Coated by PE. The predicate device uses polypropylene coated steel wire. The nose piece does not directly contact the user ' s skin. Biocompatibility testing was conducted on the final device. Performance testing was conducted according to ASTM F2100-19.

Otherwise, all of the specifications and materials of the subject device, Surgical face mask, are the same as the predicate device K202061.

Table 2 - Performance Testing

We have tested three lots of product. The data below is one of these performance tests.

Surgical face mask has been evaluated the safety and performance by lab bench testing according to the following standards:

- ASTM F2299 Standard Test Method for Determining the Initial Efficiency of Materials Used in Surgical face masks to Penetration by Particulates Using Latex Spheres.
- ASTM F1862 Standard test method for resistance of Surgical face masks to penetration by synthetic blood (Horizontal projection of fixed volume at a known velocity)
- ASTM F 2101-19 Standard Test Method For Evaluating The Bacterial Filtration Efficiency (BFE) Of Surgical face mask Materials, Using A Biological Aerosol Of Staphylococcus Aureus.

- 16 CFR Part 1610 STANDARD FOR THE FLAMMABILITY OF CLOTHING TEXTILES
- Determine breathing resistance or differential pressure as directed in EN 14683:2019,Annex C

ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks

Item	Test Method	Acceptance Criteria	Result
Fluid Resistance Performance (mmHg)	ASTM F1862	(A) There are no burn times; or(B) There is only one burn time and it is equal to or greater than 3.5 seconds; or(C) The average burn time of two or more specimens is equal to or greater than 3.5 seconds.	Lot 1: 32 Out of 32 pass at 80 mmHg Lot 2: 32 Out of 32 pass at 80 mmHg Lot 3: 32 Out of 32 pass at 80 mmHg
Particulate Filtration Efficiency Performance (%)	ASTM F2299	≥ 95%	Lot 1:Average 96.6 % Lot 2:Average 96.1% Lot 3:Average 96.2%
Bacterial Filtration Efficiency Performance (%)	ASTM F2101	≥ 95%	Lot 1: Average 99.5% Lot 2: Average 99.4% Lot 3: Average 99.4%
Flammability class	16 CFR 1610	Class 1	Lot 1: Class 1 Lot 2: Class 1 Lot 3: Class 1
Differential Pressure (Delta-P) (mm H2O/cm2)	ASTM F2100-19 EN 14683 :2019+AC (2019)(E), Annex C	< 5.0 mmH_20/cm^2	Lot 1: Average 3.9 mmH_20/cm^2 Lot 2: Average 3.8 mmH_20/cm^2 Lot 3: Average 4.0 mmH_20/cm^2

Table 3 - Biocompatibility Testing

- During use, the Non Woven Face Mask will directly contact with user's skin, so we have it tested to demonstrate conformance to the following standards.

  ISO 10993-5, Biological Evaluation Of Medical Devices -- Part 5: Tests For InVitro Cytotoxicity

  ISO 10993-10, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

Test item	Test method	Acceptance Criteria	Result
In Vitro Cytotoxicity	ISO 10993-5: 2009 MTT method.	The 50% extract of the test aticle should have at least the same or a higher viability than the 100% extract. Otherwise the test should be repeated. The lower the Viab. % value, the higher the cytotoxic potential of the test article is. If viability is reduced to <70% of the blank, it has a cytotoxic potential. The Viab.% of the 100% extract of the test article is the final result.	Under the conditions of the test, the test article was found to be non-cytotoxic
Skin Sensitization	ISO 10993-10:2010 Guinea Pig Maximization	Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals. If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization. If the	Under the conditions of the test, the test article was found to be non-sensitizing

		response is equivocal, rechallenge is recommended to confirm the results from the first challenge. The outcome of the test is presented as the frequency of positive challenge results in test and control animals.	
Skin Irritation	ISO 10993-10:2010 Skin Irritation Test	Use only (24±2) h, (48±2) h and (72±2) h observations for calculation. After the 72 h grading, all erythema grades plus oedema grades (24±2)h, (48±2) h and (72±2) h were totalled separately for each test article and blank for each animal. The primary irritation score for an animal was calculated by dividing the sum of all the scores by 6 (two test/observation sites, three time points). To obtain the primary irritation index for the test article, add all the primary irritation scores of the individual animals and divide by the number of animals. When blank or negative control was used, calculate the primary irritation score for the controls and subtract that score from the score using the test material to obtain the primary irritation score.	Under the conditions of the test, the test article was found to be non-irritating

7. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K203161, the surgical face mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K202061.