November 16, 2022

Shandong Aida Medical Products Co., Ltd
Wang Bing
Technical Manager
Wangjiazhuang, Wangliu Street Office, Weicheng District
Weifang, Shandong 261053
China

Re: K220302
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: October 17, 2022
Received: October 17, 2022

Dear Wang Bing:

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,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K220302

Device Name
Disposable surgical face mask

Indications for Use *(Describe)*
The Disposable surgical 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. 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.

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B-2. 510(K) Summary

Summary Date: July 23, 2021

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3 Device Information

Trade Name: Disposable surgical face mask

Common/Usual Name: Disposable surgical mask

Model: AD-PR02, AD-PR02-2,AD-PR02-S01,AD-PR02-S02

Regulatory Information

Classification Name: Mask，Surgical

Classification: Class II

Product Code: FXX

Regulation Number: 21 CFR 878.4040

Regulation Description: Surgical Apparel

4 Legally Marketed Predicate device:

Trade Name: Disposable Surgical Face Mask

510(K) Number: K153496

Product Code: FXX

Manufacturer: Xiantao Rayxin Medical Products Co.,Ltd.

5 Device Description:

The proposed device is 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.

The proposed device is manufactured with three layers, the inner and outer layers are made of spun-bond Nonwoven fabric polypropylene, and the middle layer is made of melt blown polypropylene filter. The filter fiber is used for particle adsorption, mechanical sieve retention, inertial deposition, and electrostatic adsorption deposition, so that the air containing harmful substances is filtered through the filter material of the mask and then inhaled or exhaled.

The style of the device, ear loops, is held in place over the users' mouth and nose by two ear loops welded to the facemask. The ear loops are not made with natural rubber latex but made of polyester and spandex.

The nose piece contained in the proposed device is in the layers of facemask to allow

the user to fit the facemask around their nose, which is made of polypropylene and iron.

The proposed device should be stored in a dry, ventilated and pollution-free area; the temperature should be 0-40 ℃, and the humidity should not be higher than 80%; Keep away from fire sources, avoid dust exposure and direct sunlight.

The proposed device is sold non-sterile and is intended to be a single use, disposable device.

6 Intended Use/Indications for Use:

The Disposable surgical 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. This is a single use, disposable device(s), provided non-sterile.

7 Performance Data

Non-Clinical Test Conclusion:

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

<u>Biocompatibility:</u>

The Disposable surgical face mask has been subjected to biocompatibility studies to demonstrate the safety of device. The biocompatibility studies are in accordance with ISO10993:

- 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.

Performance:

- ASTM F2100-2020, Standard Specification for Performance of Materials Used in Medical Face Masks.
- ASTM F2101-2019, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using a nebulizer and a culture suspension of staphylococcus aureus.
- EN 14683:2019+AC:2019 Annex C, Standard Test Method for differential pressure of Medical Face Masks
- ASTM F2299/F2299M-03(Reapproved 2017), Standard test method for determining the initial filtration efficiency of materials used in medical face masks to penetration by particulates using latex sphere aerosol.
- ASTM F1862/F1862M-2017, Standard Test Method for Resistance of Medical Face Masks to penetration by synthetic blood.
- 16 CFR Part 1610-2008, Standard for the Flammability of clothing textiles.

Clinical Test Conclusion：

No clinical study is included in this submission.

8 Substantially Equivalent (SE) Comparison with The Predicate Device:

Comparison with the predicate devices, the device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device as summarized in the following table

Table B-II-1 General Comparison

ITEM	Proposed Device	Predicate Device(K153496)	Remark

Manufacturer	Shandong Aida Medical Products Co.,Ltd	Xiantao Rayxin Medical Products Co.,Ltd.	
Trade name	Disposable surgical face mask	Disposable Surgical Face Mask	
Classification	Class II Device, FXX (21 CFR § 878.4040)	Class II Device, FXX (21 CFR § 878.4040)	SE
Indications for use	The Disposable surgical 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. 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.	SE
Mask Styles and Design features	Ear Loops, Flat Pleated, 3 layers	Ear Loops/Tie-on, Flat Pleated, 3 layers	Different

Materials	Outer Facing Layer	Spun-bond Nonwoven fabric polypropylene	Spun-bond polypropylene	SE
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	SE
	Inner Facing Layer	Spun-bond Nonwoven fabric polypropylene	Spun-bond polypropylene	SE
	Nose clip	Polypropylene and iron	Malleable aluminum wire	Different
	Tie-one		Spun-bond polypropylene	Different
	Ear loops	Polyester and spandex	Polyester	Different
Color		Blue	Blue	SE
Dimension (Width)		17.5 cm +/- 5%	17.5 cm +/- 1 cm	Different
Dimension (Length)		9.5 cm +/- 5%	9.5 cm +/- 1 cm	
OTC use		Yes	Yes	SE
Sterility		No	No	SE
Single Use		Yes	Yes	SE
ASTM F2100-2020		Level 2	Level 2	SE
Biocompatibility		IS010993	IS010993	SE

Table B-II-2 Performance Characteristic Comparison

Test Methodology	Proposed Device	Predicate Device(K153496)	ASTM F2100-2020 Requirements for Level 2 Classification	Remark
Resistance to Penetration by Synthetic Blood	32 out of 32 pass at 120 mmHg	32 out of 32 pass at 120 mmHg	29 out of 32 pass at 120 mmHg	Meet

ASTM F1862				
Particulate Filtration Efficiency ASTMF2299	Pass	98.46%	⩾ 98%	Meet
Bacterial Filtration Efficiency ASTMF2101	99.9%	98.7%	⩾ 98%	Meet
Differential Pressure (Delta P) EN 14683	Max: 4.8 mmH_2O /cm^2 Min: 4.2 mmH_2O /cm^2	4.2 mmH_2O /cm^2	< 6.0 mmH_2O/ cm^2	Meet
Flame spread 16 CFR 1610	Class I	Class I Non-Flammable	Class 1	Meet

Table B-II-3 Biocompatibility Comparison

Item	Subject device	Acceptance Criteria	Remark
Cytotoxicity	Under the conditions of this study, the test article extract did not show potential toxicity to L929 cells	No potential cytotoxicity	SE
Irritation	The test result showed that the response of the test article extract was categorized as negligible under the test condition.	Non-Irritating	SE
Sensitization	Under the conditions of this study, no evidence of skin sensitization in guinea pigs was found.	Non-Sensitizing	SE

All the differences don't affect the safety and effectiveness which is concluded after all the required testing, so no safety and effectiveness issues relating to the system come into conclusion.

9 Conclusion:

Based on the comparison and analysis above, the devices are determined to be Substantially Equivalent (SE) to the predicate devices.

The Shandong Aida Medical Products Disposable surgical face mask 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, Xiantao Rayxin Medical Products Disposable Surgical Face Mask cleared under K153496.