July 8, 2021

Xiamen Eagledon Pharmaceutical Co., Ltd
% Ruth Wu
Consultant
Kavalan Consulting Inc.
1100 First Ave. Ste 305
King of Prussia, Pennsylvania 19406

Re: K210267
Trade/Device Name: Disposable Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 29, 2021
Received: February 1, 2021

Dear Ruth Wu:

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 and Part 809); 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,

Ryan Ortega, Ph.D.
Acting 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)*
K210267

Device Name
Disposal Surgical Mask

Indications for Use *(Describe)*
The Disposable Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluid and particulate materials. This face 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 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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510K Summary

The assigned 510(k) Number: K210267

Date of Preparation: June 30, 2021

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92. "

1. Submitter's Information:

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2. Application Correspondent:

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King of Prussia, PA 19406
Tel: +1 610-310-2793
Contact Person: Ruth Wu
Email: ruthwu@kavalangroup.com

3. Subject Device:

The 510(K) number: Traditional
Common Names: Surgical Mask
Trade Name: Disposable Surgical Mask
Regulation Number: 21 CFR 878.4040
Review Panel: Surgical Apparel
Classification Name: Mask, Surgical
Regulatory Class: II
Product Code: FXX

510K Summary

4. Predicate Device:

The 510(K) number: K153496

Manufacturer: Xiantao Rayxin Medical Products Co Ltd

Common Names: Surgical Mask

Trade Name: Surgical Face Mask

Regulation Number: 21 CFR 878.4040

Review Panel: Surgical Apparel

Classification Name: Mask, Surgical

Regulatory Class: II

Product Code: FXX

5. Device Description:

Disposable Surgical Mask is a single-use, disposable surgical mask to cover the nose and mouth to protect the wearer from microorganisms, body fluids and particulates.

Disposable Surgical Mask consists of the following materials: Non-woven cloth in the front and back layers, melt-blown cloth in the middle layer, a nose clip and two ear loops in Spandex. The Disposable Surgical Masks are provided non-sterile:

Model	SKU#	Product Type	Package
YJ002	YJ002-NS2-50	Disposable Surgical Mask (Non-Sterile) Level 2	50 pcs/box, 2000 pcs/carton
YJ002	YJ002-NS2-10	Disposable Surgical Mask (Non-Sterile) Level 2	10 pcs/bag, 1500 pcs/carton

6. Indication for Use:

The Disposable Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluid and particulate materials. This face 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 provided non-sterile.

510K Summary

7. Comparison of Technological Characteristics:

Device		Disposable Surgical Mask	Disposable Surgical Face Mask	Result
Manufacturer		Xiamen Eagledon Pharmaceutical Co., Ltd	Xiantao Rayxin Medical Products Co.,ltd.	-
510K number		K210267	K153496	-
Model Name		Disposable Surgical Mask	Surgical Face Mask	Same
Classification		Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Intended use		The Disposable Surgical Masks are intended to be worn to protect both healthcare personnel and patients from transmission of microorganisms, body fluid and particulates. These surgical masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids.	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(s), provided non-sterile.	Same
Model Type		Ear Loops, Flat Pleated, 3 layers	Ear Loops, Tie-On, Flat Pleated, 3 layers	Same
Material	Outer layer	Polypropylene non-woven cloth	Spun-bond polypropylene	Same
	Middle layer	Polypropylene Melt blown cloth	Melt blown polypropylene filter	Same
	Inner layer	Polypropylene non-woven cloth	Spun-bond polypropylene	Same
	Nose piece	PE material +1 chrome plated iron core 2mm width	Malleable polyethylene wire	Different*
	Ear loops	Polyester Spandex	Polyester	Different*
Color		Blue	Blue	Same

510K Summary

Dimension (Width)	17.5cm±1cm	17.5cm±1cm	Same
Dimension (Length)	9.5cm±1cm	9.5cm±1cm	Same
OTC use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single use, disposable	Single use, disposable	Same
ASTM F2100 Level	Level 2	Level 2	Same
Fluid Resistance Performance	32/32 Passed at 120 mmHg ASTM F1862	13/13 Passed at 120 mmHg ASTM F1862	Same
Particulate Filtration Efficiency	32/32 Passed at ≥98% ASTM F2299-03	13/13 Passed at ⩾98% ASTM F2299	Same
Bacterial Filtration Efficiency	32/32 Passed at ⩾98% ASTM F2101-14	13/13 Passed at ⩾98% ASTM F2101	Same
Differential Pressure	32/32 Passed at <6 mmH2O/cm2 EN 14683: 2019, Annex C	13/13 Passed at <5 mmH2O/cm2 MIL-M36954C	Same
Flammability	32/32 Passed ⩾3 Seconds burn Time-Class 1 16 CFR Part 1610	13/13 Passed ⩾3 Seconds burn Time-Class 1 16 CFR Part 1610	Same
Biocompatibility			
Cytotoxicity	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic	Same
Irritation	Under the conditions of the study, the subject device extract was determined to be non-irritating	Under the conditions of the study, the subject device extract was determined to be non-irritating	Same

Sensitization	Under the conditions of the study, the subject device extract was determined to be non-sensitizing	Under the conditions of the study, the subject device extract was determined to be non-sensitizing	Same

***** The Disposable Surgical Mask and the Surgical Face Mask compared in the above table are substantially similar in Performance and Indications for Use. The differences raised in this table does not raise the concern for safety or effectiveness of the Disposable Surgical Masks submitted by Xiamen Eagledon Pharmaceutical Co Ltd.

8. Summary of Non-Clinical Performance Testing:

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

Samples submitted to the testing lab and passed the following performance tests:

- Color: Blue
- Dimension: 17.5cm x 9.5cm (Ear loops: 17.5 cm)
- Lot numbers: 20210405, 20210504, 20210517

Test item (Performance Level 2)	**Test Method**	**Pass Criteria**	**Results**
Synthetic Blood Penetration Resistance	ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) according to ASTM F2100:2019	Level 2: fluid resistant claim 120mmHg	32/32 passed at 120 mm/Hg/Pass

Flammability of Clothing Textiles	16 CFR Part 1610 Standard for the Flammability of Clothing according to ASTM F2100:2019	Class 1	32/32 Passed ≥3 Seconds burn Time-Class 1 / Pass
Differential Pressure (Delta P)	EN 14683: 2019, Annex C Medical face masks - Requirements and test methods according to ASTM F2100:2019	Level 2:<6.0	32/32 Passed at <6 mmH2O/cm2 / Pass
Bacterial Filtration Efficiency (BFE)	ASTM F2101-14 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus according to ASTM F2100:2019	Level 2: ≥ 98%	32/32 Passed at ⩾ 98% / Pass
Latex Particle Challenge	16 CFR Part 1610 Standard for the Flammability of Clothing according to ASTM F2100:2019	Level 2: ≥ 98%	32/32 Passed at ⩾ 98% / Pass

Biocompatibility testing

According to ISO 10993-1:2009, the nature of body contact for the subject device is Surface Device category, Skin Contact and duration of contact is A-Limited (≤24h). The following tests for the subject device were conducted to demonstrate that the subject device is biocompatible and safe for its intended use:

1) In vitro Cytotoxicity Test per ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity,

2) Skin Sensitization Tests per ISO 10993-10:2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization,

3) Skin Irritation Tests per ISO 10993-10:2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization

9. Summary of Clinical Performance:

No clinical study is included in this submission.

10. Conclusions:

The Conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K210267, Disposable Surgical Mask, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K153496.