March 29, 2021

Wuhan Zonsen Medical Products Co., Ltd
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
13th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K202191
Trade/Device Name: Surgical Mask (Model: ZSFM 21, barrier level 2, blue)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 23, 2021
Received: February 26, 2021

Dear Ivy 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,

For Clarence W. Murray III, Ph.D.
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)*
K202191

Device Name
Surgical Mask
Model: ZSFM 21, barrier level 2, blue

Indications for Use *(Describe)*
The Surgical 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.

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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510(K) Summary

K202191

Date of Summary prepared: 2021-02-22

A. Applicant:

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B. Device:

Trade Name: SURGICAL MASK
Common Name: SURGICAL FACE MASK
Model: ZSFM 21, barrier level 2, blue

Regulatory Information
Classification Name: Surgical Face Mask
Classification: Class II
Product code: FXX
Regulation Number: 878.4040
Review Panel: Surgical Apparel

C. Predicate device:

K153496
Disposable Surgical Face Mask
Xiantao Rayxin Medical Products Co., Ltd.

D. Indications for use of the device:

The surgical 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.

E. Device Description:

The Surgical Masks are single use, three-layer, flat-pleated masks with ear loops and nose clip.

Two layers of polypropylene non-woven fabric, with a layer of polypropylene melt-blown filter cloth in the middle; plastic nose clip, ear loop is spandex elastic belt.

The ear loops are held in place over the users' mouth and nose by two elastic ear loops welded to the mask. The elastic ear loops are not made with natural rubber latex.

The nose clip in the layers of mask is to allow the user to fit the mask around their nose, which is made of malleable polyethylene wire.

The surgical masks will be provided in blue. The surgical masks are sold non-sterile and are intended to be single use, disposable devices.

F. Comparison with predicate device

Table 1 General Comparison

Device		**Proposed Device**	**Predicate Device**	**Result**
Manufacturer		Wuhan Zonsen Medical Products Co., Ltd	Xiantao Rayxin Medical Products Co., ltd.	-
510K number		K202191	K153496	-
Model Name		SURGICAL MASK	SURGICAL FACE MASK	Similar
Classification		Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Intend use		The surgical 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.	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.	Same
Design feature		Ear Loops, Flat Pleated, 3 layers	Ear Loops, Tie-On, Flat Pleated, 3 layers	Similar
Material	**Outer facing**	Spun-bond polypropylene	Spun-bond polypropylene	Same

	layer			
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Inner facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose clamp	Malleable polyethylene wire	Malleable aluminum wire	Different
	Ear loops	Spandex	Polyester	Different
Color		Blue	Blue	Same
Dimension (Length)		17.5cm±1cm	17.5cm±1cm	Same
Dimension (Width)		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
Biocompatibility		ISO10993	ISO10993	Same

G. Summary of Technological Characteristics

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was similar to the predicate device. The test results demonstrated that the proposed device complies with ASTM F2100 and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004. Table 2 shows the comparison of performance testing between subject surgical masks and predicate surgical face mask. Table 3 shows the comparison of biocompatibility between subject surgical masks and predicate surgical face mask.

Table 2 - Comparison of Performance Testing

Item	**Proposed device (K202191)**	**Predicate device (K153496)**	**Acceptance Criteria (level 2)**	**Result**
Fluid Resistance Performance ASTM F1862	32 out of 32 pass at 120 mmHg, 3 lots	32 out of 32 pass at 120 mmHg	29 out of 32 pass at 120 mmHg	Similar
Particulate Filtration Efficiency ASTM F2299	Pass at 98.1%	Pass at 98.46%	≥ 98%	Similar
Bacterial Filtration Efficiency ASTM F2101	Pass at 99.9%	Pass at 98.7%	≥ 98%	Similar
Differential Pressure (Delta P) EN 14683 Annex C	Pass at 4.7, 4.9, 4.7 mmH_2O/cm^2	Pass at 4.2mmH_2O/cm^2	< 6.0mmH_2O/cm^2	Similar
Flammability 16	Class 1	Class 1	Class 1	Similar

CFR 1610				

Table 3 Biocompatibility Comparison

Item	**Proposed device (K202191)**	**Predicate device (K153496)**	**Result**
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic.	Under the conditions of the study, the device is non-cytotoxic.	Same
Irritation	Under the conditions of the study, the device is non-irritating.	Under the conditions of the study, the device is non-irritating.	Same
Sensitization	Under the conditions of the study, the device is non-sensitizing	Under the conditions of the study, the device is non-sensitizing	Same

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K153496.