December 16, 2022

Wuhan Zonsen Medical Products Co., Ltd
Cynthia Ye
General Manager
No 8 Jinchao Road, Zhucheng Street, Xinzhou District
Wuhan, Hubei 431000
China

Re: K213601
Trade/Device Name: Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 11, 2022
Received: November 21, 2022

Dear Ms. Ye:

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)*
K213601

Device Name
Surgical Mask

Indications for Use *(Describe)*
The Surgical Masks (model: ZSFM 23, ZSFM 24) are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These 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

510k Number: K213601
Revised date: May 12, 2022

A. Applicant:

Wuhan Zonsen Medical Products Co., Ltd
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B. Device:

Trade Name: Surgical Mask
Common Name: Surgical Mask
Model(s): ZSFM23, ZSFM24

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

C. Predicate device:

K211827
Level 3 Fluid Resistant Procedure/Surgical Mask
Zhejiang Lanhine Medical Products LTD.

D. Indications for use :

The Surgical Masks (model: ZSFM 23, ZSFM 24) are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These 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 proposed device (model: ZSFM 23) is blue color, four-layer, and flat pleated type mask, utilizing tie-on way for wearing, and it has nose clips design for fitting the face mask around the nose.
The proposed device (model: ZSFM 24) is blue color, three-layer, and flat pleated type mask, utilizing ear loops way for wearing, and it has nose clips design for fitting the face mask around the nose.

The proposed device (model: ZSFM 23) is manufactured with four layers, the inner and outer layers are made of polypropylene non-woven fabric, and the two middle layers are made of polypropylene Melt blown non-woven fabric. The proposed device is held in place over the users' mouth and nose by two tie-on bands welded to the face mask. The tie-on bands are made of polypropylene non-woven fabric.The nose clip is fixed between the layers of face mask to allow the user to fit the face mask around their nose, which is made of Malleable polyethylene wire.
The proposed device (model: ZSFM 24) is manufactured with three layers, the inner and outer layers are made of polypropylene non-woven fabric, and the middle layer is made of polypropylene Melt blown non-woven fabric. The proposed device is held in place over the users' mouth and nose by two elastic ear loops welded to the face mask. The elastic ear loops are made of Spandex. The nose clip is fixed between the layers of face mask to allow the user to fit the face 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

Table1

Comparison Component	**Proposed Device**	**Predicate Device**	**Comparison**
Manufacturer	Wuhan Zonsen Medical Products Co., Ltd	Zhejiang Lanhine Medical Products LTD.	/
510K number	K213601	K211827	/
Device name	Surgical Mask	Level 3 Fluid Resistant Procedure/Surgical Mask	/
Classification	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same

Comparison Component		Proposed Device	Predicate Device	Comparison
Indications for use		The Surgical Masks (model: ZSFM 23, ZSFM 24) are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These 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 Level 3 Fluid Resistant Procedure/Surgical Mask (model: 15604F, 15704F) 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 a single use,disposable device(s), provided non-sterile.	Same
Ear loop model and tie-on model		Model: ZSFM 23, Tie-On, Flat Pleated, 4 layers	Ear Loops, Tie-On, Flat Pleated, 3 layers	Similar
		Model: ZSFM 24, Ear Loops, Flat Pleated, 3 layers		Same
Material	**Outer layer**	Polypropylene non-woven fabric	Non-woven Fabric (Polypropylene)	Same
	Middle layer(s)	Polypropylene Melt blown non-woven fabric	Melton brown Fabric (Polypropylene)	Same
	Inner layer	Polypropylene non-woven fabric	Non-woven Fabric (Polypropylene)	Same
	Nose clip	Malleable polyethylene	Polypropylene coating iron	Similar
	Tie-on bands	Polypropylene non-woven fabric	Non-woven Fabric (Polypropylene)	Same
	Ear loops	Spandex	Polyurethane	Same
Color		Blue	Blue	Same
Dimension		17.5 cm +/- 0.5 cm	17.5 cm +/- 0.5 cm	Same
		9.5 cm +/- 0.5 cm	9.5 cm +/- 0.5 cm	Same
OTC use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
Use		Single use; disposable	Single use; disposable	Same
ASTM F2100 Level		Model: ZSFM 23, Level 3	Level 3	Same

Comparison Component	Proposed Device	Predicate Device	Comparison
	Model: ZSFM 24, Level 1		Similar
Biocompatibility	Meet ISO10993-5 and ISO10993-10	ISO10993	Same

G. Summary of Non-Clinical Test

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 the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004:

- 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;
- ASTM F2100-20, Standard Specification for Performance of Materials Used In Medical Face Masks;
- ASTM F1862-17, Standard Test Method for Resistance of Medical Face Masks To Penetration by Synthetic Blood;
- EN 14683: 2019, Requirements and Test Methods of Differential pressure of Medical Face Mask;
- ASTM F2101-19, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using A Biological Aerosol of Staphylococcus Aureus;
- ASTM F2299-17, Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres;
- 16 CFR Part 1610-2008, Standard for the Flammability of clothing textiles;

Table 2 - Performance Testing

Performance	Purpose	Requirement	Test results of Proposed device	
			Surgical Mask (model: ZSFM 23)	**Surgical Mask (model: ZSFM 24)**
Bacterial Filtration Efficiency ASTM F2101-19	Assess the performance of a mask to penetration by a prepared solution with known concentration of an indicator bacterial organism	Level 1: ≥95% Level 3: ≥98%	PASS 3 non-consecutive lots tested, using a sample size of 32/ lot. Lot 1: 99.9%; Lot 2: 99.9%; Lot 3: 99.9%;	PASS 3 non-consecutive lots tested, using a sample size of 32/ lot. Lot 1: 99.9%; Lot 2: 99.9%; Lot 3: 99.9%;
Differential Pressure	Assess the performance of	Level 1:< 5.0mmH_2O/cm^2	PASS 3 non-consecutive lots	PASS 3 non-consecutive lots

EN 14683:2019, Annex C	a mask for resistance to air movement through the materials of the face of the mask	Level 3:< 6.0mmH_2O/cm^2	tested, using a sample size of 32/ lot. Lot 1: 4.86; Lot 2: 4.83; Lot 3: 4.87;	tested, using a sample size of 32/ lot. Lot 1: 4.5; Lot 2: 4.5; Lot 3: 4.5;
Sub-micron particulate filtration efficiency ASTM F2299-17	Assess the performance of a mask to penetration by sub-micron polystyrene latex particles of 0.1 micron	Level 1: ≥95% Level 3: ≥98%	PASS 3 non-consecutive lots tested, using a sample size of 32/ lot. Lot 1: 99.9%; Lot 2: 99.9%; Lot 3: 99.9%;	PASS 3 non-consecutive lots tested, using a sample size of 32/ lot. Lot 1: 98.5%; Lot 2: 98.6%; Lot 3: 98.6%;
Synthetic Blood Penetration ASTM F1862-17	Assess the performance of a mask to resistance to a synthetic blood preparation targeted toward the mask at a set pressure	Level 1: 80 mm Hg Level 3: 160 mm Hg	PASS 3 non-consecutive lots tested, using a sample size of 32/ lot. Lot 1: 32 out of 32 pass at 160 mm Hg; Lot 2: 32 out of 32 pass at 160 mm Hg; Lot 3: 32 out of 32 pass at 160 mm Hg;	PASS 3 non-consecutive lots tested, using a sample size of 32/ lot. Lot 1: 32 out of 32 pass at 80 mm Hg; Lot 2: 32 out of 32 pass at 80 mm Hg; Lot 3: 32out of 32 pass at 80 mm Hg;
Flammability Test 16 CFR Part 1610-2008	Assess the resistance of a mask to ignition	Class 1	PASS 3 non-consecutive lots tested, using a sample size of 32/ lot. Class 1	PASS 3 non-consecutive lots tested, using a sample size of 32/ lot. Class 1
Conclusion	/	/	**Meet the requirement for Level 3 barrier**	**Meet the requirement for Level 1 barrier**

Table 3 -Biological Specifications:

Performance	**Requirement**	**Results (ZSFM23 & ZSFM24)**
Cytotoxicity EN ISO10993-5	Non-Cytotoxic	**PASS** Under the conditions of the study, the device is non-cytotoxic.
Irritation EN ISO 10993-10	Non-Irritating	**PASS** Under the conditions of the study, the device is non-irritating.

Sensitization EN ISO 10993-10	Non-Sensitizing	**PASS** Under the conditions of the study, the device is non-sensitizing.

H. Clinical Performance

No clinical study is included in this submission.

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in this 510(K) submission, the Surgical Mask (model: ZSFM23, ZSFM24), is as safe, as effective, and performs as well as the legally marketed predicate device cleared under K211827.