September 8, 2021

Zhejiang Lanhine Medical Products LTD
℅ Ivy Wang
Consultant
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K211832
Trade/Device Name: Fluid Resistant Procedure Mask/Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX,
Dated: June 14, 2021
Received: June 14, 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)*
K211832

Device Name
Fluid Resistant Procedure/Surgical Mask

Indications for Use *(Describe)*
The Fluid Resistant Procedure/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 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.

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510(K) Summary

K211832

Document prepared date: 9/8/2021

A. Applicant:

Name: Zhejiang Lanhine Medical Products LTD.
Address: 1989 Cidong Road, Cidongbinhai District, 315300 Cixi City，Zhejiang Province, China
Contact Person: Jerry Gu
Tel: +86-015255006789
Mail: mark@kanghuimedical.com

Submission Correspondent:
Primary contact: Ivy Wang
Shanghai SUNGO Management Consulting Co., Ltd.
14th floor 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-58817802
Email: haiyu.wang@sungoglobal.com
Secondary contact: Mr. Raymond Luo
14th floor 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-68828050
Email: fda.sungo@gmail.com

B. Device:

Trade Name: Fluid Resistant Procedure/Surgical Mask
Common Name: Surgical Face Mask
Model(s): 15603F, 15703F

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

C. Predicate device:

510K	Device name	ASTM F2100 level	Manufacturer
K153496	Disposable Surgical Face Masks	Level2	Xiantao Rayxin Medical Products Co., Ltd.

D. Indications for use of the device:

The Fluid Resistant Procedure/Surgical Masks (model: 15603F, 15703F) 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.

E. Device Description:

The proposed device (model: 15603F) is blue color, 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: 15703F) is blue color, 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 devices are manufactured with three layers, the inner and outer layers are made of Non-woven Fabric(polypropylene), and the middle layer is made of Melton brown Fabric (Polypropylene). The 15603F model of proposed device, ear loops, 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 polyurethane. The nose piece contained in the proposed device(s) is in the layers of face mask to allow the user to fit the face mask around their nose, which is made of Polypropylene coating iron. The 15703F model of proposed device, tie-on, 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 non-woven Fabric (Polypropylene). The nose piece contained in the proposed device(s) is in the layers of face mask to allow the user to fit the face mask around their nose, which is made of Polypropylene coating iron.
The proposed devices are sold non-sterile and are intended to be single use, disposable device.

F. Comparison with predicate device/

Table 1 General Comparison

Device	Proposed Device	Predicate Device	Comparison
Manufacturer	Zhejiang Lanhine Medical Products LTD.	Xiantao Rayxin Medical Products Co., Ltd.	-
510K number	K211832	K153496	-
Classification	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Indications for use	The Fluid Resistant Procedure/Surgical Mask (model: 15603F, 15703F) are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material.	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	Similar

		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.	control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	
Styles		Ear Loops, Tie-On, Flat Pleated, 3 layers	Ear Loops, Flat Pleated, 3 layers	Different
Material	**Outer layer**	Non-woven Fabric (Polypropylene)	Spun-bond polypropylene	Same
	Middle layer	Melton brown Fabric (Polypropylene)	Melt blown polypropylene filter	Same
	Inner layer	Non-woven Fabric (Polypropylene)	Spun-bond polypropylene	Same
	Nose clip	Polypropylene coating iron	Malleable aluminum wire	Different
	Tie-on bands	Non-woven Fabric (Polypropylene)	/	--
	Ear loops	Polyurethane	Polyester	Different
Color		Blue	Blue	Same
Dimension(Length)		17.5 cm +/- 0.5 cm	17.5 cm +/- 0.1 cm	Different
Dimension (Width)		9.5 cm +/- 0.5 cm	9.5 cm +/- 0.1 cm	Different
OTC use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
Use		Single Use,	Single Use, Disposable	Same
ASTM F2100 level		Level 2	Level 2	Same
Biocompatibility		ISO10993	ISO10993	Same

Difference analysis: The proposed device has different styles, different nose clip & ear loops material as well as dimension to the predicate device, but the performance and biocompatibility of the device has been tested.

G. Non-Clinical Test Conclusion

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, Standard Specification for Performance of Materials Used In Medical Face Masks
- ASTM F1862, Standard Test Method for Resistance of Medical Face Masks To Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume At A Known Velocity);
- EN 14683, Medical Face Masks—Requirements and Test Methods;
- ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using A Biological Aerosol of Staphylococcus Aureus;
- ASTM F2299, Stand test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres;
- 16 CFR 1610, Standard for the Flammability of clothing textiles;

Table 2 - Performance Testing

Item	**Purpose**	**Proposed device (model: 15603F)**	**Proposed device (model: 15703F)**	**Acceptance Criteria**	**Result**
Fluid Resistance Performance ASTM F1862	The purpose of the performance testing is to demonstrate the functionality of the subject	3 non-consecutive lots tested, using a sample size of 32/lot. 32 out of 32 pass at 120 mmHg	3 non-consecutive lots tested, using a sample size of 32/lot. 32 out of 32 pass at 120 mmHg	29 out of 32 pass at 120 mmHg for level 2	PASS
Particulate Filtration Efficiency ASTM F2299		3 non-consecutive lots tested, using a sample size of 32/lot. Lot1: 99.15% Lot2: 99.22% Lot3: 99.22%	3 non-consecutive lots tested, using a sample size of 32/lot. Lot1: 99.03% Lot2: 99.10% Lot3: 99.30%	≥ 98%	PASS
Bacterial Filtration Efficiency ASTM F2101		3 non-consecutive lots tested, using a sample size of 32/lot. Lot1: 99.40% Lot2: 99.50%	3 non-consecutive lots tested, using a sample size of 32/lot. Lot1: 99.20% Lot2: 99.30%	≥ 98%	PASS

	device.	Lot3: 99.60%	Lot3: 99.30%		
Differential Pressure (Delta P) EN 14683 Annex C		3 non-consecutive lots tested, using a sample size of 32/lot. Lot1: 3.55 mmH_2O/cm^2 Lot2: 3.59 mmH_2O/cm^2 Lot3: 3.60 mmH_2O/cm^2	3 non-consecutive lots tested, using a sample size of 32/lot. Lot1: 3.59 mmH_2O/cm^2 Lot2: 3.58 mmH_2O/cm^2 Lot3: 3.56 mmH_2O/cm^2	< 6.0m mH_2O/cm^2	PASS
Flammability 16 CFR 1610		3 non-consecutive lots tested, using a sample size of 32/lot. Class 1	3 non-consecutive lots tested, using a sample size of 32/lot. Class 1	Class 1	PASS

Table 3 Biocompatibility Comparison

Item	**Proposed device**	**Predicate device**	**Acceptance Criteria**	**Result**
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic.	Under the conditions of the study, the device is non-cytotoxic.	Non-Cytotoxic	PASS
Irritation	Under the conditions of the study, the device is non-irritating.	Under the conditions of the study, the device is non-irritating.	Non-Irritating	PASS
Sensitization	Under the conditions of the study, the device is non-sensitizing	Under the conditions of the study, the device is non-sensitizing	Non-Sensitizing	PASS

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

Based on the nonclinical tests performed, the subject devices (Model:15603F & 15703F) are as safe, as effective, and performs as well as the legally marketed predicate device, K153496, BYD Precision Manufacturer Co. Ltd, Single-use Surgical Masks.