



May 27, 2019

Wuhan Dymex Healthcare Co., Ltd
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
4th Floor, 1500# Central Avenue
Shanghai, 200122 Cn

Re: K182515
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 4, 2019
Received: April 29, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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 David Krause, PhD
Acting Division 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

Indications for Use

510(k) Number (if known)
K182515

Device Name
Surgical Face Mask

Indications for Use (Describe)

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.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

K182515

Date Summary Prepared: 2019-05-22

A. Applicant:

WUHAN DYMEX HEALTHCARE CO., LTD

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Submission Correspondent:

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B. Device:

Trade Name: SURGICAL FACE MASK

Common Name: SURGICAL FACE MASK

Model(s): Ear Loop

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:

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.

E. Device Description:

The Surgical Face Masks are single use, three-layer, flat –folded masks with ear loops and nose piece. The Surgical Face Masks are manufactured with three layers, the inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter. The ear loops are held in place over the users’ mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are not made with natural rubber latex. The nose piece in the layers of facemask is to allow the user to fit the facemask around their nose, which is made of malleable polyethylene wire. The surgical face masks will be provided in yellow. The surgical face masks are sold non-sterile and are intended to be single use, disposable devices.

F. Summary of Technological Characteristic

Table 1 General Comparison

Device		Proposed Device	Predicate Device	Result
Manufacturer		WUHAN DYMEX HEALTHCARE CO., LTD	Xiantao Rayxin Medical Products Co., Ltd.	-
510K number		K182515	K153496	-
Model Name		SURGICAL FACE MASK	SURGICAL FACE MASK	Same
Classification		Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Intend use		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.	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
Model		Ear Loops, Flat Pleated, 3 layers	Ear Loops, Tie-On, Flat Pleated, 3 layers	Same
Material	Outer facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Inner facing	Spun-bond polypropylene	Spun-bond polypropylene	Same

	layer			
	Nose piece	Malleable polyethylene wire	Malleable aluminum wire	Similar
	Ear loops	Spandex	Polyester	Different*
Color		Yellow	Blue	Different*
Dimension (Width)		17.5cm $\pm$ 0.2cm	17.5cm $\pm$ 1cm	Same
Dimension (Length)		9.5cm $\pm$ 0.2cm	9.5cm $\pm$ 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

*The difference in the materials and colors does not raise additional questions for safety and effectiveness. Performance testing including biocompatibility evaluation has been performed on the final finished device which includes all construction materials and color additives.

G. Non-clinical Test performed on the proposed device

The proposed devices were tested and conformed to 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.

Table 2 Performance testing

Item	Proposed device	Acceptance Criteria	Result
Fluid Resistance Performance ASTM F1862	32 out of 32 pass at 120 mmHg	29 out of 32 pass at 120 mmHg	Pass
Particulate Filtration Efficiency ASTM F2299	99.7%	$\geq$ 98%	Pass
Bacterial Filtration Efficiency ASTM F2101	99.9%	$\geq$ 98%	Pass
Differential Pressure (Delta P) MIL-M-36954C	4.0mmH ₂ O/cm ²	< 5.0mmH ₂ O/cm ²	Pass
Flammability 16 CFR 1610	Class 1 Non Flammable	Class 1	Pass

Table 3 Biocompatibility testing

Item	Proposed device	Result
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic.	Pass
Irritation	Under the conditions of the study, the device is non-irritating.	Pass

Sensitization	Under the conditions of the study, the device is non-sensitizing	Pass
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H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusion 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 predicated K153496, Xianto Rayxin Medical Products Disposable Surgical Mask.