DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Xiantao Rayxin Medical Products Co., Ltd.
% Mr. Ray Wang
Official Correspondent
Beijing Believe Tech. Service Co., Ltd.
1-202, Build 3, Beijing New World, No.5 Chaoyang Rd., Chaoyang District
Beijing, 100024
CHINA

June 15, 2016

Re: K153496
Trade/Device Name: Disposable Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: May 11, 2016
Received: May 16, 2016

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k153496

Device Name
Disposable Surgical Face Mask
Ear Loop and Tie-On

Indications for Use *(Describe)*

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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."

Tab #3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K153496

1. Date of Preparation:2016/06/11

2. Sponsor Identification

Xiantao Rayxin Medical Products Co., ltd.
No. 258 Pengchang Road, Middle Street, Xiantao city, Hubei 433018, China

Establishment Registration Number: Not yet registered

Contact Person: Liang Zhang
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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Disposable Surgical Face Mask
Common Name: Surgical Face Mask
Model(s): Tie-On, Ear Loops

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

Indication for use Statement:
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.

Device Description
The proposed device(s) are ***Blue color***, and ***Flat Pleated*** type mask, utilizing ***Tie-On*** or ***Ear Loops*** way for wearing, and they all has ***Nose Piece*** design for fitting the facemask around the nose.
The blue colorant is *polypropylene (PP) master batch*.

The proposed device(s) 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 model of proposed device, tie-on, is held in place over the uers's mouth and nose by four ties welded to the facemask. The tie is made of spun-bond polypropylene.

The model of proposed device, ear loops, is held in place over the uers's 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 contained in the proposed device(s) is in the layers of facemask to allow the user to fit the facemask around their nose, which is made of malleable aluminum wire.

The proposed device(s) are sold non-sterile and are intended to be single use, disposable device.

5. Identification of Predicate Device(s)

Predicate Device
K133070
Surgical Face Mask

BH Medical Products Co., Ltd.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- 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 F2100-11, Standard Specification For Performance Of Materials Used In Medical Face Masks.
- ASTM F1862-13, Standard Test Method For Resistance Of Medical Face Masks To Penetration By Synthetic Blood (Horizontal Projection Of Fixed Volume At A Known Velocity)
- MIL-M-36945C, Method 1 Military Specifications: Surgical Mask disposable;
- 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;
- ASTM F2299-03, 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;
- Bench Testing for the performance of Dimensions.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM		Proposed Device	Predicate Device	Remark
Intended Use		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.	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.	SE
Ear loop model and tie-on model		Ear Loops, Tie-On, Flat Pleated, 3 layers	Ear Loops, Tie-On, Flat Pleated, 3 layers	SE
Materials	Outer Facing Layer	Spun-bond polypropylene	Spun-bond polypropylene	SE
	Middle Layer	Melt blown polypropylene filter	Melt blown polypropylene filter	
	Inner Facing Layer	Spun-bond polypropylene	Spun-bond polypropylene	
	Tieon	Spun-bond polypropylene	Spun-bond polypropylene	
	Nose Piece	Malleable aluminum wire	Malleable aluminum wire	
	Ear Loops	Polyester	Polyester	
Color		Blue	Blue, Green	SE
Dimension (Width)		17.5 cm +/- 1cm	6.8” +/-0.25” (17.27 cm +/- 0.63cm)	SE
Dimension (Length)		9.5 cm +/- 1cm	4.2” +/-0.25” (10.67 cm +/- 0.63cm) 3.5” +/-0.25” (8.89 cm +/- 0.63cm)	
OTC use		Yes	Yes	SE
Single Use		Yes	Yes	SE
Sterile		No	No	SE
ASTM F2100 Level		Level 2	Level 2	SE

Table 2 Performance Characteristic Comparision

ITEM	Proposed Device	Predicate Device	ASTM F2100 Requirements for Level 2 Classification	Remark
Fluid Resistance Performance ASTM F1862-13	32 out of 32 pass at 120 mmHg	Meet the ASTM F2100 Requirements for Level 2 Classification	29 out of 32 pass at 120 mmHg	SE
Particulate Filtration Efficiency ASTM	98.46%	Meet the ASTM F2100 Requirements for Level 2 Classification	≥ 98%	

F2299				
Bacterial Filtration Efficiency ASTM F2101	98.7%	Meet the ASTM F2100 Requirements for Level 2 Classification	⩾ 98%	
Differential Pressure (Delta P) MIL-M-36954C	4.2 mmH2O/cm^2	Meet the ASTM F2100 Requirements for Level 2 Classification	< 5.0 mmH2O/cm^2	
Flammability 16 CFR 1610	Class 1 Non Flammable	Class 1	Class 1	SE

Table 3 Biocompatibility Comparison

ITEM	Proposed Device	Predicate Device	Remark
Cytotoxicity	Under the conditions of the study, not cytotoxicity effect	Comply with ISO 10993-5	SE
Irritation	Under the conditions of the study, not an irritant	Comply with ISO 10993-10	SE
Sensitization	Under conditions of the study, not a sensitizer.		SE

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.

The Xianto Rayxin Medical Products Disposable Surgical Face Mask is substantially equivalent to the BH Medical Products Surgical Face Mask. Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, BH Medical Products Surgical Face Mask cleared under K133070.