January 22, 2021

Jiangsu Medpure Biological Technology Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
China

Re: K202640
Trade/Device Name: Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 11, 2020
Received: September 11, 2020

Dear Ray 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 and Part 809); 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 CAPT Elizabeth Claverie, M.S.
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)*
K202640

Device Name
Surgical Mask

Indications for Use *(Describe)*
The Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. This face mask is 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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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: K202640

1. Date of Preparation: 2021/01/14

2. Sponsor Identification

Jiangsu Medpure Biological Technology Co., Ltd.
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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Surgical Mask
Common Name: Surgical Face Mask

Regulatory Information
Classification Name: Surgical Face Mask
Classification: II
Product Code: FXX
Regulation Number: 21CFR 878.4040
Review Panel: Surgical Apparel

Indication for use Statement:
The Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. This face mask is 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 Surgical Mask is Blue color, and Flat Pleated type mask, utilizing Ear Loops' way for wearing, and they all have Nose Piece design for fitting the facemask around the nose. The mask is manufactured with three layers, the inner and outer layers are made of PP spun-bond non-woven, and the middle layer is made of Melt-blown non-woven fabric. The Mask is held in place over the user's mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are made with Polyester fiber and Polyurethane. The nose piece contained in the proposed device(s) is in the layers of the facemask to allow the user to fit the facemask around their nose, which is made of Polyethylene and Metal Wire. The mask is sold non-sterile and are intended to be single-use, disposable devices and the colorant used for mask is TiO2 + Phthalocyanine Blue BGS + Pigment Violet23.

5. Identification of Predicate Device(s)

Predicate Device
K153496
Disposable Surgical Face Mask
Xiantao Rayxin 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 same/similar 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 F2100-19, 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 (Horizontal Projection Of Fixed Volume At A Known Velocity)
- MIL-M-36945C, Method 1 Military Specifications: Surgical Mask disposable;
- 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 F2299-03, Stand test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latexspheres;
- 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. Summary of Technological Characteristics

Table 1 General Comparison

ITEM		Proposed Device K202640	Predicate Device K153496	Remark
Intended Use		The Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. This face mask is 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
Basic Design		Ear Loops, Flat Pleated, 3 layers	Ear Loops, Tie-On, Flat Pleated, 3 layers	SAME
Materials	Outer Facing Layer	Spun-bond non-woven fabric	Spun-bond polypropylene	Similar
	Middle Layer	Melt blown non-woven fabric	Melt blown polypropylene filter	
	Inner Facing Layer	Spun-bond non-woven fabric	Spun-bond polypropylene	
	Nose Piece	Polyethylene and Metal Wire	Malleable aluminum wire	
	Ear Loops	Polyester fiber and Polyurethane	Polyester	
Color		Blue	Blue	SAME
Dimension (Length)		17.5 cm +/- 5%	17.5 cm +/- 1cm	Similar

Dimension (Width)	9.5 cm +/- 5%	9.5 cm +/- 1cm	
OTC use	Yes	Yes	SAME
Single Use	Yes	Yes	SAME
Sterile	No	No	SAME
ASTM F2100 Level	Level 2	Level 2	SAME

Table 2 Performance Characteristic Comparison

ITEM	Proposed Device K202640	Predicate Device K153496	ASTM F2100 Requirements for Level 2 Classification	Remark
Fluid Resistance Performance ASTM	120 mmHg	120 mmHg	120 mmHg	SAME
Particulate Filtration Efficiency ASTM	≥99.73%	98.46%	≥ 98%	
Bacterial Filtration Efficiency ASTM	≥99.07%	98.7%	≥ 98%	
Differential Pressure (Delta P)	≤4.7 mmH2O/cm^2	4.2 mmH2O/cm^2	< 6.0 mmH2O/cm^2	
Flammability 16 CFR 1610	Class 1	Class 1	Class 1	SAME

Table 3 Biocompatibility Comparison

ITEM	Proposed Device K202640	Predicate Device K153496	Remark
Cytotoxicity	Comply with ISO 10993-5 Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic	Comply with ISO 10993-5 Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic	SAME
Irritation	Comply with ISO 10993-10 Under the conditions of the study, the proposed device extract was determined to be non-irritating.	Comply with ISO 10993-10 Under the conditions of the study, the proposed device extract was determined to be non-irritating	SAME
Sensitization	Comply with ISO 10993-10 Under the conditions of the study, the proposed device extract was determined to be non-sensitizing.	Comply with ISO 10993-10 Under the conditions of the study, the proposed device extract was determined to be non-sensitizing	SAME

9. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K202640, the Surgical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under k153496.