September 26, 2021

Sichuan Prius Biotechnology Co., Ltd.
Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box. 120-119
Shanghai, 200120
China

Re: K210908
Trade/Device Name: Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 9, 2021
Received: August 17, 2021

Dear Diana Hong:

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)*

K210908

Device Name
Surgical Mask (Model numbers identified in the attachment)

Indications for Use *(Describe)*
The surgical mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.

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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Model	Size (cm)	Ear loop	Headband	Tie-on	Sterile	Non-sterile	Non-edging type	Edging type
PRS-WK001	17.5×9.5	√			√			√
PRS-WK002	17.5×9.5	√			√		√	
PRS-WK003	17.5×9.5		√		√			√
PRS-WK004	17.5×9.5		√		√		√	
PRS-WK005	17.5×9.5			√	√		NA	
PRS-WK006	14.5×9.5	√			√			√
PRS-WK007	14.5×9.5	√			√		√	
PRS-WK008	14.5×9.5		√		√			√
PRS-WK009	14.5×9.5		√		√		√	
PRS-WK010	14.5×9.5			√	√		NA	
PRS-WK016	17.5×9.5	√				√		√
PRS-WK017	17.5×9.5	√				√	√	
PRS-WK018	17.5×9.5		√			√		√
PRS-WK019	17.5×9.5		√			√	√	
PRS-WK020	17.5×9.5			√		√	NA	
PRS-WK021	14.5×9.5	√				√		√
PRS-WK022	14.5×9.5	√				√	√	
PRS-WK023	14.5×9.5		√			√		√
PRS-WK024	14.5×9.5		√			√	√	
PRS-WK025	14.5×9.5			√		√	NA	

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K210908

1. Date of Preparation: 09/14/2021

2. Sponsor Identification

Sichuan Prius Biotechnology Co., Ltd.
No. 2, Prius Road, Luo Long Industrial Park Nanxi District, 644104 Yibin City, Sichuan Province, PEOPLE'S REPUBLIC OF CHINA.

Establishment Registration Number: Not registered yet.

Contact Person: Yan Liu
Position: management representative
Tel: +86-831-3839889
Fax: +86-831-3839887
Email: 48363603@qq.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd.
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Product Name: Surgical Mask
Common Name: Surgical Masks

Regulatory Information
Classification Number: 21 CFR 878.4040
Classification Name: Surgical apparel
Product Code: FXX
Regulatory Class: II
Review Panel: General Hospital

5. Identification of Predicate Device

510(k) Number: K202843
Product Name: Surgical Face Masks (Sterile), Surgical Face Masks (Non-sterile)
Sponsor Name: B.J.ZH.F. Panther Medical Equipment Co., Ltd.
Whether subject to a design-related recall: No

6. Device Description:

The proposed device, Surgical Mask, is a single use, three-layer, flat-pleated mask. The inner and outer layers of the mask are made of PP Spunbonded Non-woven Fabric, and the middle layer is made of Melt-blown Nonwoven Fabric. The proposed devices are available in three types, ear-loop, Tie-on and Headband. The ear straps of headband type and ear loop type are made of Spandex and Polyester, and the ear strap of tie-on type is made of PP Spunbonded Non-woven Fabric. The ear strap is held in place over the users' mouth and nose. The nose clip is made of Galvanized Iron Wire. Users can adjust the nose clip according to the shape of the bridge of the nose, and fix the mask on the bridge of the nose to prevent the mask from falling off. The ear loops, tie-on and headband masks are available in different sizes to provide more options for user, as shown in the following table. The proposed devices were available with and without edging and they can be provided in sterile and non-sterile two versions. The proposed devices are blue.

Model	Sterile	Non-sterile	Ear loop	Tie-on	Headband	Size (cm)	Non-edging type	Edging type	Color
PRS-WK001	√		√			17.5×9.5		√	Blue
PRS-WK002	√		√			17.5×9.5	√		Blue
PRS-WK003	√				√	17.5×9.5		√	Blue
PRS-WK004	√				√	17.5×9.5	√		Blue
PRS-WK005	√			√		17.5×9.5	NA		Blue

PRS-WK006	√		√			14.5×9.5		√	Blue
PRS-WK007	√		√			14.5×9.5	√		Blue
PRS-WK008	√				√	14.5×9.5		√	Blue
PRS-WK009	√				√	14.5×9.5	√		Blue
PRS-WK010	√			√		14.5×9.5	NA		Blue
PRS-WK016		√	√			17.5×9.5		√	Blue
PRS-WK017		√	√			17.5×9.5	√		Blue
PRS-WK018		√			√	17.5×9.5		√	Blue
PRS-WK019		√			√	17.5×9.5	√		Blue
PRS-WK020		√		√		17.5×9.5	NA		Blue
PRS-WK021		√	√			14.5×9.5		√	Blue
PRS-WK022		√	√			14.5×9.5	√		Blue
PRS-WK023		√			√	14.5×9.5		√	Blue
PRS-WK024		√			√	14.5×9.5	√		Blue
PRS-WK025		√		√		14.5×9.5	NA		Blue

7. Indications for Use:

The surgical mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.

8. Summary of Technological characteristics

Table 1 Comparison of Surgical Mask

ITEM	Proposed Device	Predicate Device K202843	Remark
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Indication for Use	The surgical mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.	The Surgical Face Mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.	Same
Mask style	Flat-pleated, 3 layers	Flat-pleated, 3 layers	Same
Color	Blue	Blue	Same

Dimension	17.5cm×9.5cm 14.5cm×9.5cm	17.5cm×9.5cm 14.5cm×9cm	Same
Level	Level 2	Level 2	Same
Sterility	Sterile/Non-Sterile	Sterile/Non-Sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
Fluid resistance	Sterile: Pass at 120mmHg Non-sterile: Pass at 120mmHg	Pass at 120mmHg	Same
Particulate Filtration Efficiency	Sterile: Average 98.21% Non-sterile: Average 98.20%	Average 98.98%	Different
Bacterial Filtration Efficiency	Sterile: Average 99.64% Non-sterile: Average 99.60%	Average 98.92%	Different
Differential Pressure	Sterile: Average 3.02 mmH_2O/cm^2 Non-sterile: Average 2.87 mmH_2O/cm^2	Average 4.4 mmH_2O/cm^2	Different
Flammability	Class 1	Class 1	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Patient Contacting Material			
Outer layer of mask	PP Spunbonded Non-woven Fabric	Spun-bonded nonwoven polypropylene	Different
Middle layer of mask	Melt-blown Nonwoven Fabric	Melt-blown non-woven polypropylene	
Inner layer of mask	PP Spunbonded Non-woven Fabric	Spun-bonded nonwoven polypropylene	
Nose Clip	Galvanized Iron Wire	Medical polypropylene and Q235	
Ear Strap	PP Spunbonded Non-woven Fabric; Spandex and Polyester	Spun-bonded nonwoven polypropylene; Spandex and nylon	
Biocompatibility			
Cytotoxicity	ISO 10993-5 and ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic, non-sensitizing, and non-irritating.	ISO 10993-5 and ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic, non-sensitizing, and non-irritating.	same
Sensitization			
Irritation			

Differences in technological characteristics do not raise different questions of safety and effectiveness.

9. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications. The

test results demonstrated that the proposed device complies with the following standards:

- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;
- ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- ASTM F2299/F2299M-03 (2017) Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres
- ASTM F2101-2019 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- EN 14683: 2019 Medical face masks- Requirements and test methods
- ISO 10993-5:2009 Biological evaluation of medical device- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritaion and skin sensitization
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ISO 10993-7:2008 Biological Evaluation of Medical Device-Part 7: Ethylene Oxide Sterilization Residuals

Table 2 Biocompatibility Testing

Test Method	Purpose	Acceptance Criteria	Results
Cytotoxicity	The test was performed in accordance with ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity to evaluate the cytotoxicity of the test sample.	The viability should be ⩾ 70% of the blank. And the 50% extract of the test sample should have at least the same or a higher viability than the 100% extract.	The viability of the tested samples included PRS-WK002 and PRS-WK017 was ⩾ 70% of the blank. And the 50% extract of the test sample had a higher viability than the 100% extract. Under the conditions of the study, the proposed device was non-cytotoxic.
Sensitization	The test was performed in accordance with ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization to evaluate the sensitization of the test	Non-sensitizing	The tested samples included PRS-WK002 and PRS-WK017 showed no evidence of causing delayed dermal contact sensitization in the guinea pigs. Under the conditions of the study, the proposed device was non-sensitizing.

	sample.		
Irritation	The test was performed in accordance with ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization to evaluate the irritation of the test sample.	Non-irritating	The irritation response category of the test samples included PRS-WK002 and PRS-WK017 was classified as Negligible for polar extract and Negligible for non-polar extract. Under the conditions of the study, the proposed device was non-irritating.

Table 3 Performance Testing

Test Method	Purpose	Acceptance Criteria	Results
Resistance to Penetration by Synthetic blood	The test was performed in accordance with ASTM F1862/F1862M: 2017 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) to evaluate the effectiveness of the test sample from possible exposure to blood and other body fluids.	No penetration at 120 mmHg	Sterile Ear loop Non-edging (PRS-WK002): Lot 200401: Pass at 120mmHg Lot 200407: Pass at 120mmHg Lot 200413: Pass at 120mmHg Non-sterile Ear loop Non-edging (PRS-WK017): Lot 200401: Pass at 120mmHg Lot 200405: Pass at 120mmHg Lot 200407: Pass at 120mmHg
Particulate Filtration Efficiency	The test was performed in accordance with ASTM F2299/F2299M-03 (2017) Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres to determine the particle filtration efficiency (PFE) of the test article.	≥98%	Sterile Ear loop Non-edging (PRS-WK002): Lot 200401: 98.19% Lot 200407: 98.20% Lot 200413: 98.24% Non-sterile Ear loop Non-edging (PRS-WK017): Lot 200401: 98.22% Lot 200405: 98.16% Lot 200407: 98.22%
Bacterial	The test was performed in	≥98%	Sterile: Average 99.64%

Filtration Efficiency	accordance with ASTM F2101: 2019 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus to determine the bacterial filtration efficiency (BFE) of the test article.		Non-sterile: Average 99.60% Sterile Ear loop Non-edging (PRS-WK002): Lot 210405: 99.74% Lot 210407: 99.72% Lot 210409: 99.70% Non-sterile Ear loop Non-edging (PRS-WK017): Lot 210405: 99.56% Lot 210407: 99.54% Lot 210409: 99.53%
Differential Pressure	The test was performed in accordance with EN 14683:2019+AC: 2019 Annex C Medical face masks - Requirements and test methods.	<6.0 mmH_2O/cm^2	Sterile Ear loop Non-edging (PRS-WK002): Lot 200401: 3.03 mmH_2O/cm^2 Lot 200407: 3.01 mmH_2O/cm^2 Lot 200413: 3.01 mmH_2O/cm^2 Non-sterile Ear loop Non-edging (PRS-WK017): Lot 200401: 2.88 mmH_2O/cm^2 Lot 200405: 2.88 mmH_2O/cm^2 Lot 200407: 2.85 mmH_2O/cm^2
Flammability	The test was performed in accordance with 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles.	Class 1	Sterile Ear loop Edging (PRS-WK001): Lot 210522: Class 1 Lot 210706: Class 1 Lot 210812: Class 1 Sterile Ear loop Non-edging (PRS-WK002): Lot 200401: Class 1 Lot 200407: Class 1 Lot 200413: Class 1 Sterile Headband Edging (PRS-WK003): Lot 210522: Class 1 Lot 210706: Class 1 Lot 210812: Class 1

			Sterile Headband Non-edging (PRS-WK004): Lot 210522: Class 1 Lot 210706: Class 1 Lot 210812: Class 1 Sterile Tie-on (PRS-WK005): Lot 210522: Class 1 Lot 210706: Class 1 Lot 210812: Class 1 Non-sterile Ear loop Edging (PRS-WK016): Lot 210817: Class 1 Lot 210819: Class 1 Lot 210823: Class 1 Non-sterile Ear loop Non-edging (PRS-WK017): Lot 200401: Class 1 Lot 200405: Class 1 Lot 200407: Class 1 Non-sterile Headband Edging (PRS-WK018): Lot 210817: Class 1 Lot 210819: Class 1 Lot 210823: Class 1 Non-sterile Headband Non-edging (PRS-WK019): Lot 210817: Class 1 Lot 210819: Class 1 Lot 210823: Class 1 Non-sterile Tie-on (PRS-WK020): Lot 210817: Class 1 Lot 210819: Class 1 Lot 210823: Class 1

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Conclusion

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K202843.