February 22, 2021

Wellpower Sporting Goods Co., Ltd
% Mar Liu
Regulatory Affairs Manager
Shenzhen Reanny Medical Devices Management Consulting Co Ltd
Room 2012#, Gebu commercial building, Hongxing community
Songgang street
Shenzhen, Guangdong 518105
China

Re: K201868
Trade/Device Name: Phyziofit Medical Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 24, 2021
Received: February 1, 2021

Dear Mar Liu:

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,

Ryan Ortega, PhD
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201868

Device Name
Phyziofit Medical Surgical Mask

Indications for Use *(Describe)*

Phyziofit Medical 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

Wellpower Sporting Goods Co., Ltd.
Phyziofit Medical Surgical Mask
K201868

1.0 Submitter:

Submitter's name :	Wellpower Sporting Goods Co., Ltd.
Submitter's address :	No.12, Xinglong New Street, Quantang Industrial Zone, Liaobu Town, Dongguan City, Guangdong Province, 523425 China
Phone number :	+86 13829158242
Fax number :	NA
Name of contact person:	Carol Tseng
Summary Preparation Date:	Feb. 20th 2021

2.0 Consultant Firm

Consultant Firm	Shenzhen Reanny Medical Devices Management Consulting Co., Ltd.
Contact name	Reanny Wang
Company address	Room 1813, Honghaigebu Business Building, Hongxing Community, Songgang Street, Baoan District, Shenzhen
Telephone number	+86-755-27391220/86-15389012257
Contact email	counselor7@reanny.com

3.0 Name of the Device

Proprietary/Trade name:	Phyziofit Medical Surgical Mask
Common Name:	Mask, Surgical
510(k) Number	K201868
Classification Name:	Mask, Surgical
Device Classification:	Class II
Regulation Number:	21 CFR 878.4040
Product Code:	FXX

4.0 Predicate device

Device Name:	Surgical Face Masks (Ear loops and Tie-on)
Company name:	San-M Package Co., Ltd.
510(K) Number:	K160269

5.0 Device Description:

The proposed device(s) are Blue color (colorant: Pigment blue 15:3/CAS No. 147-14-8), and Flat Pleated type mask, utilizing Ear Loops way for wearing, and they all have Nose clips design for fitting the facemask around the nose. The proposed device(s) are manufactured with three layers, the outer layer is made of polypropylene non-woven fabric, the middle layer is made of melt blown non-woven fabric and the inner layer is made of absorbent nonwoven fabric.
The model of proposed device, ear loops, is 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 clips 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 PP plastic material.
The proposed device(s) are sold non-sterile and are intended to be single use, disposable device.

6.0 Indications for Use:

Phyziofit Medical Surgical Masks are intended to be worn to protect both the patient and healthcare personnel form 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.

7.0 Technological Characteristics Comparison:

Comparative Table

Device Characteristic	Predicate Device			Proposed Device	Comparison (Same, Similar, Different)
	Level 1	Level 2	Level 3	Level 1	
Product name	Surgical Face Masks (Ear loops and Tie-on)			Phyziofit Medical Surgical Mask	N/A
510(K) No.	K160269			K201868	N/A
Product Owner	San-M Package Co., Ltd.			Wellpower Sporting Goods Co., Ltd.	N/A
Product Code	FXX			FXX	Same
Regulation	21 CFR 878.4040			21 CFR 878.4040	Same
Class	II			II	Same
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, provided non-sterile. Level I Face Mask Models:# EL 10000, EL l0010, TO 10000, TO 10010 Level 2 Face Mask Models:# EL 20000, EL 20010, TO 20000, TO 20010 Level 3 Face Mask Models:# EL 30000, EL 300 I 0, TO 30000. TO 300 10			Phyziofit Medical 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 is a single use, disposable device(s), provided non-sterile.	Similar
Color	White or Blue			Blue	Similar
Single Use	Single Use, Disposable			Single Use, Disposable	Same
Sterile	Non-Sterile			Non-Sterile	Same
Materials	Outer Material: Polypropylene Inner Material: Polypropylene Filter Media: Polypropylene Spunbond and Polypropylene Meltblown			Outer Layer: polypropylene non-woven fabric Middle layer: melt blown non-woven fabric Inner layer: absorbent nonwoven	Similar

	Nose Clamp: Polyethylene coated steel wire Ear loops: Polyester, polyurethane	fabric Nose Clips: PP plastic material Ear loops: Nylon + spandex	
Design features	Colors: white or blue Flat-pleated	Colors: blue Flat-pleated	Similar
Dimensions-Length	90± 3mm	9.5cm ± 1cm	Similar
Dimensions - Palm Width	175 ± 5mm	17.5cm ± 1cm	Similar
Particulate Filtration Efficiency (ASTM F2299-03 (2017))	Pass at 99.6%	Pass at 98%	Similar
Fluid resistance (ASTM F1862/F1862M-17)	Pass at 80 mmHg	Pass at 80 mmHg	Same
Bacterial Filtration Efficiency (ASTM F2101-19)	Pass at >98%	Pass at >98%	Same
Flammability (16 CFR1610)	Class 1	Class 1	Same
Differential Pressure (EN 14683:2019+AC: 2019 (E))	Pass at 2.0mmH_2O/cm^2	Pass at 3.4 mmH_2O/cm^2	Similar
Biocompatibility Cytotoxicity (ISO10993-5)	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	Similar
Skin Irritation (ISO10993-10)	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	
Skin sensitization (ISO10993-10)	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	

8.0 Summary of Non-Clinical Performance Data

The following bench testing was conducted for design elements and performance characteristics deemed appropriate to demonstrate equivalence to the predicate device, Surgical Face Masks (Ear loops and Tie-on) manufactured by San-M Package Co., Ltd.The subject device Phyziofit Medical Surgical Mask met the acceptance criteria as established by the Standard testing methods utilized as applicable. No new safety or efficacy concerns were raised during testing:

Bench Testing

Test Performed	Test Method	Acceptance Criteria	Average	Results
Differential Pressure	EN 14683:2019+AC: 2019 (E), Annex C	< 5.0mm H_2O/cm^2	3.4 mm H_2O/cm^2 (32/32)	Pass
Fluid resistance	ASTM F1862/F1862M-17	No Penetration at 80 mm Hg	No Penetration at 80 mm Hg (32/32)	Pass
Particulate Filtration Efficiency	ASTM F2299-03 (2017)	≥95%	98% (32/32)	Pass
Flammability	16 CFR Part 1610	Class I	Class I (32/32)	Pass
Bacterial Filtration Efficiency	ASTM F2101-19	≥95%	99.9% (32/32)	Pass
Biocompatibility cytotoxicity Test	ISO 10993-5:2009	Non-Cytotoxic	Under the conditions of the study, the subject device extract was determined to be non cytotoxic	Pass
Biocompatibility Skin irritation	ISO 10993-10: 2010	Non-Irritating	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	Pass
Biocompatibility Skin Sensitization	ISO 10993-10: 2010	Non-Sensitizing.	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	Pass

9.0 Summary of Clinical Performance Data:

Clinical data was not needed to demonstrate that the subject mask is substantially equivalent to the predicate. Therefore, determination of substantial equivalence is not based on an assessment of clinical performance data.

10.0 Conclusion:

The subject product has the same intended use and principle of operation, similar performance specifications as predicate device. The difference between Phyziofit Medical Surgical Mask and predicate device have been analyzed and demonstrates that the difference does not raise any new safety or effectiveness concerns.

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.