January 4, 2022

Wepon Medical Technology Co., Ltd.
Yongxian Sun
Manager Representative
West side of North Baizhang Road, Chengdong Street
Wenling, Zhejiang 317500
China

Re: K212299
Trade/Device Name: Medical Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 21, 2021
Received: December 2, 2022

Dear Yongxian Sun:

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, PhD
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)*
K212299

Device Name
Medical Surgical Mask

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

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

K212299

I Submitter

Device submitter: Wepon Medical Technology Co., Ltd.
West side of North Baizhang Road, Chengdong Street, Wenling City, Zhejiang Province, China

Contact person: Yongxian Sun
Management Representative
Phone: +86 13586268021
E-mail: syx@wepon.cc

II Proposed Device

510(k) Number:	K212299
Trade/Device Name:	Medical Surgical Mask
Regulation Number:	21 CFR 878.4040
Regulation Name:	Surgical Apparel
Regulatory Class:	Class II
Product code:	FXX
Review Panel:	General Hospital

III Predicate Devices

510(k) Number:	K210030
Trade/Device Name:	Medical Surgical Mask
Regulation Number:	21 CFR 878.4040
Regulation Name:	Surgical Apparel
Classification:	Class II
Product Code:	FXX
Manufacturer	Tianjin Aoshang Outdoor Equipment Co., Ltd.

IV Device description

The Medical Surgical Mask is single use, flat-pleated masks that are provided in blue. The Medical Surgical Mask is available in two types, which are Level 2 and Level 3 based on ASTM F2100-19.

The inner and outer layers of the mask are made of polypropylene non-woven fabric, the middle layer is made of polypropylene meltblown fabric, and the nose clip is made of polypropylene and 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 are made of spandex. The ear loops are held in place over the users' mouth and nose by two ear loops welded to the mask.

This is a single use, disposable device(s), provided non-sterile.

V Indication for use

The Medical Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These surgical 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.

VI Non-Clinical Test Conclusion

The Medical Surgical Mask was tested in accordance with the tests recommended in the FDA guidance document, Guidance for Industry and FDA Staff Surgical Masks – Premarket Notification [510(k)] Submission issued March of 2004. Based upon the guidance document the following testing has been performed.

Performance Testing				
Test Methodology	Purpose	Acceptance Criteria for Level 2 Barrier	Acceptance Criteria for Level 3 Barrier	Result
Bacterial Filtration Efficiency ASTM F2101	Measure bacterial filtration efficiency	⩾98%	⩾98%	Passed
Differential Pressure (mm H2O/cm2) EN14683:2019 Annex C	Determine breathability of a mask	<6.0 H_2O/cm^2	<6.0 H_2O/cm^2	Passed
Sub-micron Particulate Filtration Efficiency ASTM F2299/ F2299M-03	Measure initial particle filtration efficiency	⩾98%	⩾98%	Passed
Resistance to Penetration by Synthetic Blood ASTM F1862/F 1862M-2017	Evaluate the resistance to penetration by impact of small volume of synthetic blood	120 mmHg	160 mmHg	Passed
Flame spread 16CFR Part 1610-2008	Response of materials to heat and flame	Class I	Class I	Passed

Biocompatibility Testing

The biocompatibility evaluation for the Medical Surgical Mask was conducted in accordance with ISO 10993-1:2018 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing within a Risk Management Process, as recognized by FDA. The Medical Surgical Mask is classified as a surface contacting device. Specific biocompatibility tests were selected under the guidance of ISO 10993-1:2018 Annex A.

Biocompatibility Evaluation				
Biological Effect		**Standard**	**Results**	
1	Cytotoxicity	ISO 10993-5	Not cytotoxic	Passed
2	Sensitization	ISO 10993-10	Non sensitizing	Passed
3	Irritation	ISO 10993-10	Negligibly irritating	Passed

VII Clinical Test Conclusion

No clinical study is included in this submission.

VIII Summary of Technological characteristics

Table 1 Comparison of Medical Surgical Mask

Item	**Subject device**	**Predicate device (K210030)**	**Discussion**
Product name	Medical Surgical Mask	Medical Surgical Mask	NA
Product Code	FXX	FXX	identical
Intended use	The Medical Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These surgical 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 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 surgical 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.	identical
Mask style	Flat-pleated	Flat-pleated	identical
ASTM F2100 Level	Level 2 and Level 3	Level 2 and Level 3	identical
Design feature	Level 2: Ear loop	Level 2: Ear loop	identical

		Level 3: Ear loop	Level 3: Ear loop and Tie-on	
Color		Blue	Blue	identical
Dimension		17.5cmx9.5cm	17.5cmx9.5cm	identical
Sterility		Non-Sterile	Non-Sterile	identical
Use		Single Use, Disposable	Single Use, Disposable	identical
Particulate filtration efficiency		Level 2 and Level 3: average 99.96%	Level 2 mask: average 99.71% Level 3 mask: average 99.93%	different
Bacterial filtration efficiency		Level 2 and Level 3: average 99.9%	Level 2 mask: average 99.7% Level 3 mask: average 99.9%	different
Differential pressure		Level 2 and Level 3: average 2.8 mmH $_2$O/cm $_2$	Level 2 mask: average 2.8mmH $_2$O/cm $_2$ Level 3 mask: average 4.0 mmH $_2$O/cm $_2$ EN 14683	different
Flammability		Class 1	Class 1	identical
Fluid resistance		Level 2: Pass at 120mmHg Level 3: Pass at 160mmHg	Level 2: Pass at 120mmHg Level 3: Pass at 160mmHg	identical
Label/Labeling		Complied with 21 CFR part 801	Complied with 21 CFR part 801	identical
Patient Contacting Material	Outer facing layer	polypropylene non-woven fabric	Spunbond Polypropylene	Different
	Middle layer	polypropylene meltblown fabric	Meltblown Polypropylene Filter	
	Inner facing layer	polypropylene non-woven fabric	Spunbond Polypropylene	
	Nose clip	polypropylene and iron wire	PE and Iron	
	Ear loops	spandex	Spandex	
Biocompatibility		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.	identical

Different - Particulate filtration efficiency

The test result for particulate filtration efficiency for the proposed device is different from the two predicate devices. However, the test result for the proposed device can meet the requirements of level 2 mask and Level 3 mask. Thus, this difference will not affect the safety and effectiveness between the

proposed device and the two predicate devices.

Different - Bacterial filtration efficiency

The test result for bacterial filtration efficiency for the proposed device is different from the two predicate devices. However, the test result for the proposed device can meet the requirements of level 2 mask and Level 3 mask. Thus, this difference will not affect the safety and effectiveness between the proposed device and the two predicate devices.

Different - Differential pressure

The test result for differential pressure for the proposed device is different from the two predicate devices. However, the test result for the proposed device can meet the requirements of level 2 mask and Level 3 mask based on ASTM F2100-19. Thus, this difference will not affect the safety and effectiveness between the proposed device and the two predicate devices.

Different - Patient Contacting Material

The patient contacting material for the proposed device is different from the two predicate devices. However, biocompatibility test has been performed on the proposed device and the results does not show any adverse effect. Thus, this difference will not affect the safety and effectiveness between the proposed device and the two predicate devices.

IX Conclusion

The proposed device has the same the intended use as the predicate device. It presents similar technological characteristics as the predicate device including the performance parameters and biocompatibility. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.