



June 8, 2021

Ammex-Weida (Hubei) Health and Safety Products Co., Ltd  
% Cynthia Xiang  
Consultant  
Shanghai Sungo Management Consulting Company Limited  
14th Floor, 1500# Central Avenue  
Shanghai, Shanghai 200122  
China

Re: K211062

Trade/Device Name: Medical Face Mask  
Regulation Number: 21 CFR 878.4040  
Regulation Name: Surgical Apparel  
Regulatory Class: Class II  
Product Code: FXX  
Dated: April 6, 2021  
Received: April 9, 2021

Dear Cynthia Xiang:

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](mailto: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

## Indications for Use

510(k) Number (if known)  
K211062

Device Name  
Medical Face Mask

### Indications for Use (Describe)

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

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**K211062**

## **510(K) Summary**

### **A. Applicant:**

Name: Ammex-Weida (Hubei) Health and Safety Products Co., Ltd  
Address: Southern Industrial Zone (Xinlirenkou), Xiantao, Hubei, China 433011  
Contact Person: Cai Mingqing  
Tel: +86-27-85577096/85577097/85577099/85577233

Submission Correspondent:

Primary contact: Ms. Cynthia Xiang  
Shanghai SUNGO Management Consulting Co., Ltd.  
Room 1401, Dongfang Building, 1500# Century Ave., Shanghai 200122, China  
Tel: +86-21-58817802  
Email: [shouqiu.xiang@sungoglobal.com](mailto:shouqiu.xiang@sungoglobal.com)  
Secondary contact: Mr. Raymond Luo  
Room 1401, Dongfang Building, 1500# Century Ave., Shanghai 200122, China  
Tel: +86-21-68828050  
Email: [fda.sungo@gmail.com](mailto:fda.sungo@gmail.com)

### **B. Device:**

Trade Name: Medical Face Mask  
Common Name: Disposable Medical Face Mask  
Model: Ear loop; Non-sterile

### Regulatory Information

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

### **C. Predicate device:**

K203426  
Surgical Face Mask(Non-sterile)

### **D. Indications for Use:**

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

### **E. Device Description:**

The proposed device(s) are blue color, and flat pleated type mask, utilizing ear loops way for wearing, and they all has nose clips design for fitting the face mask around the nose.

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, ear loops, is held in place over the users' mouth and nose by two elastic ear loops welded to the face mask. The elastic ear loops are made of Nylon and polyester. The nose piece contained in the proposed device(s) is in the layers of face mask to allow the user to fit the face mask around their nose, which is made of polyethylene coated galvanized wire. The proposed device(s) are sold non-sterile and are intended to be single use, disposable device.

## F. Comparison with predicate device

Table 1 General Comparison

Device	Proposed Device	Predicate Device	Result	
<b>Manufacturer</b>	Ammex-Weida (Hubei) Health and Safety Products Co., Ltd	Nantong Taiweishi Medical Technology Co., Ltd.	-	
<b>510K number</b>	K211062	K203426	-	
<b>Model name</b>	Medical Face Mask	Surgical Face Mask(Non-sterile)	Same	
<b>Classification</b>	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same	
<b>Intended use</b>	The Medical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. They 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 Mask (non-sterile) is 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.	Same	
<b>Model</b>	Ear loop, Flat pleates,3 layers	Ear loop, Tie-on, Flat pleated,3 layers	Similar	
<b>Material</b>	<b>Outer layer</b>	Spun-bond polypropylene	Spun-bond polypropylene	Same
	<b>Middle layer</b>	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	<b>Inner layer</b>	Spun-bond polypropylene	Spun-bond polypropylene	Same
	<b>Nose clip</b>	polyethylene coated galvanized wire.	Polyethylene	Different
	<b>Ear loops</b>	Nylon and polyester	Nylon and Spandex	Different

<b>Color</b>	Blue	Blue	Same
<b>Dimension</b>	175mm+/-10mm	175mm+/-5%	Similar
<b>Dimension (Width)</b>	95mm+/-5mm	95mm+/-5%	Similar
<b>OTC use</b>	Yes	Yes	Same
<b>Sterility</b>	Non-Sterile	Non-Sterile	Same
<b>Use</b>	Single Use, Disposable	Single Use, Disposable	Same
<b>ASTM F2100 level</b>	Level 3	Level 2	Similar
<b>Biocompatibility</b>	ISO10993	ISO10993	Same
<b>Fluid Resistance Performance ASTM F1862</b>	32 out of 32 pass at 160 mmHg;	32 out of 32 pass at 120 mmHg	Similar
<b>Particulate Filtration Efficiency ASTM F2299</b>	98.98%	99.16%	Similar
<b>Bacterial Filtration Efficiency ASTM F2101</b>	99.9%	99.74%	Similar
<b>Differential Pressure (Delta P) EN 14683 Annex C</b>	5.54mmH <sub>2</sub> O/cm <sup>2</sup>	3.7mm H <sub>2</sub> O/cm <sup>2</sup>	Similar
<b>Flammability 16 CFR 1610</b>	Class 1	Class 1	Same

From the comparison we found the material of the current nose clip and the ear loop were different from the predicate device. The biocompatibility tests were conducted to both components to ensure their compliance to the ISO10993-5 and ISO10993-10. There is no new risk generated from the difference of the material.

For the Performance testing, the test results are not identical to each other, but they are similar. The predicate device meet the requirement of Level 2 medical mask according to the ASTM F 2100, the proposed device meet the requirement of Level 3 medical mask according to the ASTM F 2100.

### G. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was similar to the predicate device. The test results demonstrated that the proposed device complies with the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004:

- 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, Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F1862, Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at A Known Velocity);
- EN 14683, Medical Face Masks—Requirements and Test Methods;
- ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using A Biological Aerosol of Staphylococcus Aureus;
- ASTM F2299, 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;

Table 2 - Performance Testing

Item	Proposed device	Predicate device	Acceptance Criteria (level 3)	Result
<b>Fluid Resistance Performance ASTM F1862</b>	32 out of 32 Pass at 160 mmHg	32 out of 32 Pass at 120 mmHg	29 out of 32 Pass at 160 mmHg	PASS
<b>Particulate Filtration Efficiency ASTM F2299</b>	98.98%	99.16%	≥ 98%	PASS
<b>Bacterial Filtration Efficiency ASTM F2101</b>	99.9%	99.74%	≥ 98%	PASS
<b>Differential Pressure (Delta P) EN 14683 Annex C</b>	5.54mmH <sub>2</sub> O/cm <sup>2</sup>	3.7mm H <sub>2</sub> O/cm <sup>2</sup>	< 6.0mmH <sub>2</sub> O/cm <sup>2</sup>	PASS
<b>Flammability 16 CFR 1610</b>	Class 1	Class 1	Class 1	PASS

Table 3 Biocompatibility Comparison

Item	Proposed device	Acceptance Criteria	Result
<b>Cytotoxicity</b>	Under the conditions of the study, the device is non-cytotoxic.	Non-Cytotoxic	PASS
<b>Irritation</b>	Under the conditions of the study, the device is non-irritating.	Non-Irritating	PASS
<b>Sensitization</b>	Under the conditions of the study, the device is non-sensitizing	Non-Sensitizing	PASS

**H. Clinical Test Conclusion**

No clinical study is included in this submission.

**I. Conclusion**

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, K203426 Nantong Taiweishi Medical Technology Co., Ltd. Surgical Face Mask(Non-sterile).