April 23, 2021

Tianjin Aoshang Outdoor Equipment Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box. 120-119
Shanghai, 200120
China

Re: K210030
Trade/Device Name: Medical Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 4, 2021
Received: January 5, 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K**210030**

Device Name
Medical surgical mask

Indications for Use *(Describe)*

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, 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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Tab #6 510(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: K210030

1. Date of Preparation: 03/09/2021

2. Sponsor Identification

Tianjin Aoshang Outdoor Equipment Co., Ltd.
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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

Trade Name: Medical surgical mask
Common Name: Surgical mask

Regulatory Information
Classification Name: Mask, Surgical
Classification: II;
Product Code: FXX;
Regulation Number: 21CFR 878.4040
Review Panel: General Hospital

Indication for use:
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, provided non-sterile.

Device Description:
The Medical Surgical Masks are single use, flat-pleated masks that are provided in blue. The Medical Surgical Masks are available in two types, which are Level 2 and Level 3 based on ASTM F2100-19. The outer and inner layers of the mask are made of spunbond polypropylene. The middle filter layer of Level 2 mask is made of one layer of meltblown polypropylene filter, and the middle filter layer of Level 3 mask is made of two layers of meltblown polypropylene filter. The nose clip is made of polyethylene (PE) and iron. 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 Level 2 masks are ear-loop masks. The Level 3 masks are available in two types, ear-loop and Tie-on. The ear loops for Level 2 and Level 3 masks are made of spandex. The ties are made of spunbond polypropylene. The ear loops/ties are held in place over the users' mouth and nose by two ear loops/ties welded to the mask.

5. Identification of Predicate Devices

Predicate Device 1
510(k) Number: K201479
Product Name: DemeMASK Surgical Mask

Predicate Device 2
510(k) Number: K153496

Product Name: Disposable Surgical Face Mask

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 devices. 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
- ASTM F2100: 2019 Standard Specification for Performance of Materials Used in Medical Face Masks
- EN 14683: 2019, Annex C, 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

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technological characteristics

Table 1 Comparison of Medical Surgical Masks

ITEM	Proposed Device K210030	Predicate Device 1 K201479	Predicate Device 2 K153496	Remark
Product Code	FXX	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	II	Same
Indication for Use	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.	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 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
Mask style	Flat-pleated	Flat-pleated	Flat-pleated	Same
ASTM F2100 Level	Level 2 and Level 3	Level 3	Level 2	Similar
Design feature	Level 2: Ear loop Level 3: Ear loop and Tie-on	Ear loop and Tie-on	Ear loop and Tie-on	Similar
Color	Blue	Blue	Blue	Same
Dimension	17.5cm×9.5cm	17.5cm×9.5cm	17.5cm×9.5cm	Same
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Single Use, Disposable	Same
Particulate filtration efficiency	Level 2 mask: average 99.71% Level 3 mask: average 99.93%	≥99%	98.46%	Different
Bacterial filtration efficiency	Level 2 mask: average 99.7% Level 3 mask: average 99.9%	≥99%	98.7%	Different
Differential	Level 2 mask: average	3.6mmH_2O/cm^2	4.2mmH_2O/cm^2	Different

pressure	2.8mmH_2O/cm^2 Level 3 mask: average 4.0 mmH_2O/cm^2 EN 14683	MIL-M-36954C	MIL-M-36954C	
Flammability	Class 1	Class 1	Class 1	Same
Fluid resistance	Level 2: Pass at 120mmHg Level 3: Pass at 160mmHg	Pass at 160mmHg	Pass at 120mmHg	Similar
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Patient Contacting Material				
Outer facing layer	Spunbond Polypropylene	Spunbond Polypropylene	Spunbond Polypropylene	Different
Middle layer	Meltblown Polypropylene Filter	Meltblown Polypropylene Filter	Meltblown Polypropylene Filter	
Inner facing layer	Spunbond Polypropylene	Spunbond Polypropylene	Spunbond Polypropylene	
Nose clip	PE and Iron	Galvanized wire coated with polyethylene	Malleable aluminum wire	
Ear loop	Spandex	Spandex and Nylon – Not made from natural rubber latex	Polyester	
Ties	Spunbond Polypropylene	Spandex and Nylon – Not made from natural rubber latex	Spun-bond polypropylene	
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.	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

Similar - ASTM F2100 Level

The proposed devices are available in two types, which are Level 2 and Level 3 based on ASTM F2100-19. The proposed Level 2 mask can be covered by the predicate device K201479 and proposed Level 3 mask can be covered by the predicate device K153496. Thus, this difference will not affect the safety and effectiveness between the proposed device and the two predicate devices.

Similar - Design feature

The proposed Level 2 masks are ear-loop masks. The proposed Level 3 masks are available in two types, ear-loop and Tie-on. The design features of the two levels of masks for the proposed device can be covered by the design features of the two predicate devices. Thus, this difference will not affect the safety and effectiveness between the proposed device and the two predicate devices.

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.

Similar - Fluid resistance

The proposed devices are available in two types, which are Level 2 and Level 3 based on ASTM F2100-19. 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 - 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.

9. Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device in 510(K) submission K210030, the Medical surgical mask is as safe, as effective, and performs as well as or better than the legally marketed predicate devices cleared under K201479 and K153496.