January 12, 2021

B.J.ZH.F.Panther Medical Equipment Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box. 120-119
Shanghai, 200120
China

Re: K202843
Trade/Device Name: Surgical Face Masks (Sterile), Surgical Face Masks (Non-sterile)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 21, 2020
Received: August 17, 2020

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 and Part 809); 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 CAPT Elizabeth Claverie, M.S.
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)*
K202843

Device Name
Surgical Face Masks (Non-sterile), Surgical Face Masks (Sterile)

Indications for Use *(Describe)*
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.

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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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: K202843

1. Date of Preparation: 01/12/2021

2. Sponsor Identification

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3. Designated Submission Correspondent

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

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4. Identification of Proposed Device

Trade Name: Surgical Face Masks (Sterile), Surgical Face Masks (Non-sterile)
Common Name: Surgical Face 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 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.

Device Description:

The proposed device, is a three-layer, single-use, flat-pleated mask. The inner and outer layers of the mask are made of spun-bonded nonwoven polypropylene, and the middle layer is made of melt-blown nonwoven polypropylene. The proposed devices are available in two types, ear-loop and Tie-on. The ear loops are made of nylon and spandex, and the ties are made of spun-bonded nonwoven polypropylene. The ear loops/tie-on is held in place over the users' mouth and nose by ear loops/ties welded to the mask. The nose clip is made of Medical polypropylene+Q235. 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. Both the ear loop and tie-on masks are available in different sizes to provide more options for user, which was provided in following table. The proposed device can be provided in sterile and non-sterile two types.

Model	Ear loop	Tie-on	Size (mm)
KWE-14.5×9 (Sterile)	√		145×90
KWE-17.5×9.5 (Sterile)	√		175×95
KWB-14.5×9 (Sterile)		√	145×90
KWB-17.5×9.5 (Sterile)		√	175×95
KWE-14.5×9 (Non-sterile)	√		145×90
KWE-17.5×9.5 (Non-sterile)	√		175×95
KWB-14.5×9 (Non-sterile)		√	145×90
KWB-17.5×9.5 (Non-sterile)		√	175×95

5. Identification of Predicate Device

510(k) Number: K173062
Product Name: NonWoven 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 device. The test results demonstrated that the proposed device complies with the following standards:

- 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 F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection;
- 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;
- 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 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);
- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;
- EN 14683: 2019 Medical face masks- Requirements and test methods
- ISO 10993-7:2008 Biological Evaluation of Medical Device- Part 7: Ethylene Oxide Sterilization Residuals

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technological characteristics

Table 1 Comparison of Surgical Face Masks

ITEM	Proposed Device	Predicate Device	Remark
510(k) Number	K202843	K173062	/
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 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.	Non Woven Face Mask (Models: VQN0185W (earloop) and VQN0185B (ties)) 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
Design feature	Ear loop/Tie-on	Ear loop/Tie-on	Same
Color	Blue	Blue	Same
Dimension	1. 14.5cm×9cm: Nose Clip: 85mm×2.9mm Ear Loop: 180mm×3mm Ties: 910mm×10mm 2. 17.5cm×9.5cm: Nose Clip: 100mm×2.9mm Ear Loop: 180mm×3mm Ties: 910mm×10mm	17.5cm×9.5cm	Different
ASTM F2100 Level	Level 2	Level 2	Same
Sterility	Sterile/Non-sterile	Non-sterile	Different
Use	Single Use, Disposable	Single Use, Disposable	Same
Fluid resistance	Pass at 120mmHg	Pass at 120mmHg	Same
Particulate filtration efficiency	Average 98.98%	Average 99.74% at 0.1μm	Similar
Bacterial filtration efficiency	Average 98.92%	Average 99.4%	Similar
Differential pressure	Average 4.4 mmH_2O/cm^2	Average 2.7mmH_2O/cm^2	Similar
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 facing layer	Spun-bonded nonwoven polypropylene	Spun-bond polypropylene	Different
Middle layer	Melt-blown nonwoven polypropylene	Melt blown polypropylene filter	
Inner facing layer	Spun-bonded nonwoven polypropylene	Spun-bond polypropylene	
nose clip	Medical polypropylene and Q235	Malleable aluminum wire	
Ear loops	Nylon and spandex	Polyester	
Tie-on	Spun-bonded nonwoven polypropylene	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.	Same

Different– Dimension

The dimension for proposed device is different from predicate device. The proposed device provides more dimension options, which can allow users to choose the appropriate dimension of masks according to their needs. In addition, the different size does not affect the indication for use.

Different- Sterility

The proposed device can be provided in sterile and non-sterile. The proposed non-sterile mask is same as the predicate device, while the sterile mask is not covered by the predicate device. However, the sterilization process were validated per ISO 11135 and the result demonstrated that the sterilization process is effective. In addition, the performance test and biocompatibility test were also conducted on the sterilized mask and the test result demonstrated that the device can meet the requirements of level 2 mask and does not raise any adverse effects after sterilization.

Similar –Particulate filtration efficiency

The test result for particulate filtration efficiency for the proposed device is different from predicate device. However, the test result for the proposed device can meet the requirements of level 2 mask.

Similar - Bacterial filtration efficiency

The test result for bacterial filtration efficiency for the proposed device is different from predicate device. However, the test result for the proposed device can meet the requirements of level 2 mask.

Similar - Differential pressure

The test result for different pressure for the proposed device is different from predicate device. However, the test result for the proposed device can meet the requirements of level 2 mask.

Different- Patient Contacting Material

The patient contacting material for the proposed device is different from predicate device. However, biocompatibility test has been performed on the proposed device and the results does not show any adverse effect.

9. Conclusion

The subject device is a safe, as effective, and perform as well as the legally marketed predicate device K173062 Non Woven Face Mask.