January 21, 2021

Jiangxi Feilikang Medical Technology Co., Ltd.
℅ Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box. 120-119
Shanghai, 200120
China

Re: K202904
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 23, 2020
Received: September 29, 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)*

K202904

Device Name
Surgical Face Mask

Indications for Use *(Describe)*

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.

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

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K202904

1. Date of Preparation: 01/15/2021

2. Sponsor Identification

Jiangxi Feilikang Medical Technology Co., Ltd.
Building 8, Anyuan Electronic Information Industry Park, Pingxiang City, Jiangxi Province, China.

Establishment Registration Number: 3017247636.

Contact Person: Shijun Zhang
Position: Chairman
Tel: +86-799-2181 777
Email: Keller@midbluegroup.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

Mid-Link Consulting Co., Ltd.
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: +1-360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device
Trade Name: Surgical Face Mask
Common Name: Surgical Face Mask
Size: 17.5cm×9.5cm

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

Indication for use:

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 polypropylene non-woven fabric, and the middle layer is made of polypropylene melt-blown fabric. The ear loops, which are made of nylon and spandex, are held in place over the users' mouth and nose by two elastic ear loops welded to the mask. The nose clip is to allow the user to fit the facemask around their nose, which is made of polypropylene and iron wire.

5. Identification of Predicate Devices

Predicate Device
510(k) Number: K173062
Product Name: Non-Woven Face Mask

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications. 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 Mask

ITEM	Proposed Device K202904	Predicate Device K173062	Remark
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Indication for Use	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 (ear loop) 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	Ear loop/Tie-on	Different
Color	Blue	Blue	Same
Dimension	Mask Body:17.5cm×9.5cm Nose Clip: 10.5cm Ear Loop: 17cm	Mask Body:17.5cm×9.5cm Nose Clip: Unknown Ear Loop: Unknown	Similar
ASTM F2100 Level	Level 2	Level 2	Same
Sterilization	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 98.74% at 0.1μm	Average 99.74% at 0.1μm	Different
Bacterial filtration efficiency	Average 99.65%	Average 99.4%	Different
Differential pressure	Average 4.6mmH_2O/cm^2	Average 2.7mmH_2O/cm^2	Different
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	Polypropylene Non-Woven Fabric	Spun-bond polypropylene	Different
Middle layer	Polypropylene Melt-Blown Fabric	Melt blown polypropylene filter	

Inner facing layer	Polypropylene Non-Woven Fabric	Spun-bond polypropylene	
nose clip	Polypropylene and Iron Wire	Malleable aluminum wire	
Ear loop	Nylon and Spandex	Polyester	
Biocompatibility			
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Sensitization	No Sensitization	No Sensitization	Same
Irritation	No Irritation	No Irritation	Same

Different - Design feature

The design feature for the proposed device is ear loop type, which can be covered with that for the predicate device, namely ear loop type and tie-on type. In addition, both ear loop type and tie-on type are designed to secure the mask to the user's mouth and nose, which will not affect the indication for use and will not cause safety problems. Thus, difference in design feature will not affect the safety and effectiveness of the proposed device.

Similar - Dimension

The dimension of the proposed device is the same as that of the predicate device, and the proposed device details the dimensions of the nose clip and ear loop. Therefore, this difference does not affect the safety and effectiveness of the proposed device.

Different - Sterilization

The final product status of the proposed device is different from predicate device, one is sterilized and the other is non-sterilized. Sterilization will affect the safety and effective of the mask. The performance testing of the proposed device has been conducted on the final product and the test results show that the proposed sterile mask meets the requirements of ASTM F2100-2019. And biocompatibility testing of the proposed device has also been conducted on the final product and the test results showed that there are no negative impacts from the materials that are used in the proposed sterile mask. Therefore, although there differences between the proposed device and predicate device, the differences do not raise the issue of safety and effectiveness of the proposed device.

Different - Particulate filtration efficiency

The test result for particulate 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. Thus, this difference does not affect the safety and effectiveness of the proposed device.

Different - Bacterial filtration efficiency

The test result for bacteria 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. Thus, this difference does not affect the safety and effectiveness of the proposed device.

Different - 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. Thus, this difference does not affect the safety and effectiveness of the proposed device.

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. Thus, this difference in materials will not affect the safety and effectiveness of the proposed device.

9. Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device in 510(k) submission K202904, the Surgical Face Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K173062.