January 3, 2023

Anqing Mayfield Medical Limited
Kevin Huang
Official Correspondent
Jingwu Road, Tongcheng Economic and Technological Development Zone
Anqing, Anhui 231400
China

Re: K222809
Trade/Device Name: Medical Disposable Face Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 26, 2022
Received: January 3, 2023

Dear Kevin Huang:

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,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K222809

Device Name
Medical Disposable Face Masks

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

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

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date of Preparation: September 1, 2022

1. **Submitter:**

510(k) Owner's Name: Anqing Mayfield Medical Limited
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2. **Submission Correspondent:**

Contact Person: Kevin Huang
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3. **Identification of the Device**

Device Name: Medical Disposable Face Masks
Common Name: Face Mask, Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Classification: Class Ⅱ
Product Code: FXX

4. **Identification of the Primary Predicate Device**

510(k) Number: K214087
Trade/Device Name: Medical Face Mask
Common Name: Surgical Mask
Manufacturer: Hubei Medlink Healthcare Co., Ltd
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Classification Name: Surgical Face Mask
Classification: Class Ⅱ
Product Code: FXX

5. Indications for Use

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

6. Device Description

The Medical Disposable Face Mask is blue color, single use, three-layer, flat-pleated mask with nose piece and ear loop. The blue colorant is polypropylene (PP) masterbatch.

The Medical Face Mask is manufactured with three layers, the inner and outer layers are made of spunbond polypropylene, and the middle layer is made of melt blown polypropylene filter.

The ear loops are held in place over the users' mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are made of polyester and spandex, not made with natural rubber latex.

The nose piece in the layers of facemask is to allow the user to fit the facemask around their nose, which is made of malleable aluminum with polypropylene (PP) covering. Users can adjust the nose piece 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 medical face masks are available in two size specifications, 17.5×9.5cm, 14.5×9.5cm. The medical face masks are sold non-sterile and are intended to be single use, disposable devices.

7. Substantial Equivalence—Comparison to Predicate Devices

A side by side comparison of the proposed device and the predicate device are provided below.

Comparison between proposed device and predicate device			
Comparison Items	Proposed Device	Predicate Device	Discussion of Differences
Devece Name	Medical Disposable Face Masks	Medical Face Mask	Similar
510k Number	---	K214087	---
Product Code	FXX	FXX	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Regulatory Class	Class Ⅱ	Class Ⅱ	Same
Indications for Use	The Medical Disposable Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The face mask is 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 Medical Disposable Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The face mask is 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
Size specification (Dimension)	17.5×9.5cm 14.5×9.5cm	17.5×9.5cm 16×9.5cm 15.5×9.5cm 14.5×9.5cm 14×9.5cm	Similar. The proposed device's sizes are included within the size range of the predicate device which have been approved by FDA in K214087.
Color	Blue	Blue	Same
Design Feature	Ear Loops, Flat-pleated, 3 layers	Ear Loops, Flat-pleated, 3 layers	Same

Use		Single Use, Disposable	Single Use, Disposable	Same
Materials	Outer layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
	Inner layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
	Middle layer (Filter layer)	Melt-blown Polypropylene	Melt-blown Polypropylene	Same
	Nose piece	Aluminum with Polypropylene (PP) covering	Malleable polyethylene wire	Different. The proposed device has different material of nose piece and ear loop to the predicate device, the biocompatibility test has been conducted on the final finished device and test results show that the proposed device can meet the requirements of ISO 10993. Therefore, the differences in the materials don't raise any additional questions for safety and effectiveness.
	Ear loop	Polyester, Spandex	Spandex	
OTC use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
ASTM F2100 Level		Level 1	Level 1	Same
Fluid Resistance Performance ASTM F1862		32 out of 32 per lot pass at 80 mmHg, 3 non-consecutive lots tested	32 out of 32 per lot pass at 80 mmHg, 3 non-consecutive lots tested	Same
Particulate Filtration Efficiency ASTM F2299		≥ 95%	≥ 95%	Same
Bacterial Filtration Efficiency ASTM F2101		≥ 95%	≥ 95%	Same
Differential Pressure (Delta P) EN14683 Annex C		< 5.0mmH_2O/cm²	< 5.0mmH_2O/cm²	Same
Flammability 16 CFR 1610		Class 1	Class 1	Same
Biocompatibility		ISO 10993-1 Cytotoxicity Skin Irritation Sensitization	ISO 10993-1 Cytotoxicity Irritation Sensitization	Same. All the human contact components are manufactured from materials that meet all the requirements of biocompatibility, the materials in contact were tested as per ISO 10993-1.

The Medical Disposable Face Masks described in this 510(k) have similar technological and performance characteristics to the predicate device.

The proposed device has the same classification information, same indications for use and technological characteristics as compared to the predicate device. Any difference that exists between the Medical Disposable Face Masks and the predicate device have no negative effect on safety or effectiveness, or raise different questions of safety and effectiveness. The

similarities and differences between the proposed and predicate device have been identified and explained in the comparison matrix which has been included in Section 12 of this submission.

Therefore, the proposed Medical Disposable Face Masks are substantially equivalent to the Medical Face Mask(K214087). The proposed device has the same classification information, same indications for use and technological characteristics as compared to the predicate device.

8. Summary of Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was same 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

1) Performance Testing

Performance testing was carried out to verify the safety and the effectiveness of the subject device.

Nonclinical functional performance testing was performed in accordance with:

- ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks
- 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 F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- ASTM F2299/F2299M-03 (R2017) Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- EN 14683:2019+AC:2019 Medical Face Masks - Requirements and Test Methods
- 16 CFR 1610 Standard for the Flammability of Clothing Textiles

Testing datas and results are included in this submission, and demonstrated that the Medical Disposable Face Mask meets all the pre-determined testing and acceptance criteria.

2) Biocompatibility

The contact duration of the proposed device Medical Disposable Face Mask is less than 24 hours. According to ISO 10993-1:2018 Annex A Table A.1 and FDA Biocompatibility guidance, "*Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process*" published on June 16, 2016, the Medical Disposable Face Mask is considered a Surface Device that comes in contact with the Skin for limited exposure (＜24 hours). The following tests were performed: Cytotoxicity, Irritation and Sensitization.

Biocompatibility was completed on the Medical Disposable Face Masks according to the following standards:

- ISO 10993-1:2018 - Biological Evaluation of Medical Devices - Part 1: Evaluation And

Testing Within A Risk Management Process
- 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

Biocompatibility testing reports are included in this submission, and demonstrated that the device componets that are in contact with the patient are biocompatible. All evaluation acceptance criteria were met.

Conclusions Drawn from the Non-Clinical Testing

The results of these tests demonstrate that the device is as safe, as effective, and performs as well as the identified predicate and support a determination of substantial equivalence.

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Conclusion

The Medical Disposable Face Masks is substantially equivalent to predicate device Medical Face Mask(K214087). Based on the indications for use, principle of operation, performance characteristics, and technological characteristics, the proposed Medical Disposable Face Mask is substantially equivalent to and as safe, as effective and performs as the legally marketed predicate device K214087.