December 21, 2023

Xinxiang Kangbeier Medical Technology Co., Ltd.
Shaoju Tian
East Mancun Industrial District
Changyuan, Henan 453400
China

Re: K221753
Trade/Device Name: Kangbeier Child Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: OXZ
Dated: December 6, 2023
Received: December 6, 2023

Dear Shaoju Tian:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Katherine D. Kavlock -S

for
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)*
K221753

Device Name
Kangbeier Child Surgical Mask

Indications for Use *(Describe)*
The Kangbeier Child Surgical Mask is intended to be worn by the patient (ages 5-10) to cover the nose and mouth to provide a barrier for the respiratory tract for microorganisms and particulate materials. The Kangbeier Child Surgical Mask is a single use, disposable device, provided non-sterile. This Face Mask is recommended for use in a healthcare setting with appropriate adult supervision.

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.

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Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

5.1 Submitter & Foreign Manufacture Identification

Xinxiang Kangbeier Medical Technology Co., Ltd.
East Mancun Industrial District, Changyuan, Henan 453400 , China
Tel： 13341254319
Submitter's FDA Registration Number：N/A

5.2 Contact Person

Name：Shaoju Tian
Company：Blue Land Michigan Inc.
Address：5830 E 2nd St Ste 8 Casper, WY 82609 USA
Tel: 86 13341254319
Email: technology@med-bridges.com

5.3 Date of Summary: December 6, 2023

5.4 Device Name:

Proprietary Name:	Kangbeier Child Surgical Mask
Common Name:	Child Surgical Mask
Classification Name:	Pediatric/Child Facemask
Device Classification:	II
Regulation Number:	21 CFR 878.4040
Panel:	General Hospital
Product Code:	OXZ

5.5 Predicate Device Information:

(1) K160100, "Prestige Ameritech Pediatric/Child's Face Mask", manufactured by "Prestige Ameritech"

5.6 Device Description:

The Kangbeier Child Surgical Mask is composed of three layers of materials and pleated to form the mask. The inner layer is composed of spun-bond nonwoven polypropylene, the middle layer is meltblown polypropylene filter material, and the outer layer is spun-bond nonwoven polypropylenen. The color on the outer layer is consists of Phthalocyanine Blue and PE wax and PP. Masks are held in place on wearer with elastic spun-bond polypropylene earloop and contain a malleable aluminum nosepiece strip.

The Kangbeier Child Surgical Mask is appropriately sized to the smaller faces of

children across a diverse population.

The Kangbeier Child Surgical Mask is a single use, disposable device, provided non-sterile with no shelf-life. Storage conditions will not affect device safety of effectiveness. All of the materials used in this device are typical materials commonly used in the construction of Surgical Masks and are being used in current legally marketed devices..

5.7 Indications for Use:

The Kangbeier Child Surgical Mask is intended to be worn by the patient (ages 5-10) to cover the nose and mouth to provide a barrier for the respiratory tract for microorganisms and particulate materials. The Kangbeier Child Surgical Mask is a single use, disposable device, provided non-sterile. This Face Mask is recommended for use in a healthcare setting with appropriate adult supervision.

5.8 Testing Summary:

To prove the safety and effectiveness of the Kangbeier Child Surgical Mask , we tested the device according to corresponding standards. Those tests include performance tests and biocompatibility tests.

The Kangbeier Child Surgical Mask has been tested under the following standards:

ASTM F2100-20 Standard Specification for Performance of Materials Used in Medical Face Masks
ASTM F1862-17 Standard Test Method for Resistance of Surgical Mask to Penetration by Synthetic Blood
ASTM F2299(2017) Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of surgical masks using a Biological Aerosol of Staphylococcus aureus
16 CFR Part 1610 Standard for the flammability of clothing textiles
EN 14683:2019,Annex C Medical Fask Masks-Requirements and Test Methods
CPSC-CH-E1002-08 Total Lead Content Analysis
CPSC-CH-E1001-09.4 Standart Operating Procedure for Determination of Phthalates
EN71-3:2019 Safety of Toys-Migration of certain 19 elements
ISO 10993-1, 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

5.9 Comparison with Predicate Device

The following table shows similarities and differences between our device and the predicate devices.

Table 5.1: Comparison

Characteristic	Subject Device	K160100 (Predicate)	Comparison
Particulate Filtration Efficiency at 0.1 microns	≥98%	≥98%	Same
Bacterial Filtration	≥98%	96.32%	Similar（Subject Device better than Predicate Device）
Differential Pressure(Delta P, mm H2O/cm2)	<6.0	<6.0	Same
Flammability Class, 16 CFR Part 1610	Class I	Class I	Same
Resistance to penetration by synthetic blood (minimum pressure in mmHg for pass result)	≥ 160 mmHg	≥ 160 mmHg	Same
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	Same
Intended Use	The Kangbeier Child Surgical Mask is a single use, disposable device, provided non-sterile. The Kangbeier Child Surgical Mask is intended to be worn by the patient (ages 5-10) to cover the nose and mouth to provide a barrier for the respiratory tract for microorganisms and particulate materials. This Face Mask is recommended for use in a healthcare setting with appropriate adult supervision.	The Prestige Ameritech Pediatric/Child Face Mask is intended to be worn by the patient/child(recommended ages 4-12) to provide protection for the respiratory tract. The Pediatric/Child's Face Mask is a single use, disposable device, provided non-sterile with no shelf- life. Storage conditions will not affect device safety of effectiveness. This Face Mask is recommended for use in a healthcare setting with appropriate adult supervision.	Similar (The age range of Subject Device is smaller than Predicate Device)

Suitable population	Child(ages5-10)	Child(ages4-12)	Similar (The age range of Subject Device is smaller than Predicate Device)
Intended Use Sites	Healthcare setting	Healthcare setting	Same
Product Code, Device Class, and Regulation	OXZ, Class II Mask, surgical (21 CFR 878.4040)	OXZ, Class II Mask, Surgical (21 CFR 878.4040)	Same

Mask Construction and Technological Features	The Kangbeier Child Surgical Mask is composed of three layers of materials and pleated to form the mask. The inner layer is composed of spun-bond nonwoven polypropylene, the middle layer is meltblown polypropylene filter material, and the outer layer is spun-bond nonwoven polypropylenen. The color on the outer layer is consists of Phthalocyanine Blue and PE wax and polypropylene. Masks are held in place on wearer with elastic spun-bond polypropylene earloop and contain a malleable aluminum nosepiece strip. The Kangbeier Child Surgical Mask is appropriately sized to the smaller faces of children across a diverse population. The Kangbeier Child Surgical Mask is a single use, disposable device, provided non-sterile with no shelf-life. Storage conditions will not affect device safety of effectiveness. All of the materials used in this device are typical materials commonly used in the construction of Surgical Masks and are being used in current legally marketed devices	The Prestige Ameritech Pediatric/Childs Face Mask is manufactured using ultrasonic bonding, composed of three layers of materials and pleated to form the mask. The device is composed of nonwoven and meltblown polypropylene filter material. Decorative patterns are printed with colored inks. Masks are held in place on wearer with knitted polyester/spandex elastic earloop and contain a malleable aluminum nosepiece strip. The Pediatric/Child's Face Mask is appropriately sized to the smaller faces of children across a diverse population. The Pediatric/Child's Face Mask is a single use, disposable device, provided non-sterile with no shelf- life. Storage conditions will not affect device safety or effectiveness. All of the materials used in this device are typical materials commonly used in the construction of Surgical Masks and are being used in current legally marketed devices. This product is not made with natural rubber latex.	Same
Performance Standards	ASTM F2100 ASTM F1862 ASTM F2299 ASTM F2101 16 CFR Part 1610 EN 14683:2019 CPSC-CH-E1002-08 CPSC-CH-E1001-09	ASTM F2100 ASTM F1862 ASTM F2299 ASTM F2101 16 CFR Part 1610 Mil M36954 C CPSC-CH-E1002-08 CPSC-CH-E1001-09	Same

	EN71-3	EN71-3	

The above table shows that the performance is same or very similar between the subject and predicate device. The subject device is as safe and effective, and its performance meets the requirements of its pre-defined acceptance criteria and intended use.

5.10 Substantial Equivalence Conclusion

Based on the comparison of intended use, design and performance, Kangbeier Child Surgical Mask manufactured by “Xinxiang Kangbeier Medical Technology Co., Ltd.” Is substantial equivalent to its predicate devices.