January 16, 2022

Xinxiang Kangbeier Medical Technology Co., Ltd.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K213920
Trade/Device Name: Kangbeier Surgical Mask (Model: KBR-1001)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 14, 2021
Received: December 15, 2021

Dear Prithul Bom:

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,

For Clarence W. Murray, III, PhD
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)*
K213920

Device Name
Kangbeier Surgical Mask (Model: KBR-1001)

Indications for Use *(Describe)*
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.

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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# 510(k) SUMMARY
# K213920

This summary of 510(k) is submitted in accordance with the requirements of 21 CFR §807.92:

## I. SUBMITTER

Xinxiang Kangbeier Medical Technology Co., Ltd.
East Mancun Industrial District, Changyuan, Henan 48105 China
Tel: +86-13341254319
Fax: N/A

Contact Person: Shaoju Tian
Date Prepared: December 8, 2021

## II. SUBJECT DEVICE

| | |
|---|---|
| Device Trade Name: | Kangbeier Surgical Mask (Model: KBR-1001) |
| Classification Name: | Surgical Mask |
| Regulation: | 21 CFR §878.4040 |
| Regulatory Class: | Class II |
| Device Panel: | General Hospital |
| Product Classification Code: | FXX |

## III. PREDICATE DEVICE

| | |
|---|---|
| Predicate Manufacturer: | DemeTECH Corporation |
| Predicate Trade Name: | DemeMASK |
| Predicate 510(k): | K201479 |

No reference devices were used in this submission.

## IV. DEVICE DESCRIPTION

The Kangbeier Surgical Mask (Model: KBR-1001) is non-sterile, disposable, single-use surgical mask. It is manufactured with three layers, the inner and outer layers are made of non-woven, spun-bond polypropylene, while the middle filter layer is made of a non-woven, melt-blown polypropylene.

## V. INDICATIONS FOR USE

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.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate device in Table 1 below.

**Table 1 – Comparison of Technological Characteristics**

| Device | **Subject Device -** Kangbeier Surgical Mask (Model: KBR-1001) | **Predicate Device -** DemeMASK (K201479) | **Result** |
|---|---|---|---|
| **Manufacturer** | Xinxiang Kangbeier Medical Technology Co., Ltd. | DemeTECH Corporation | N/A |
| **510K Number** | TBD | K201479 | N/A |
| **Product Common Name** | SURGICAL FACE MASK | SURGICAL FACE MASK | Identical |
| **Trade Name** | Kangbeier Surgical Mask (Model: KBR-1001) | DemeMASK Surgical Mask | N/A |
| **Product Code** | FXX | FXX | Identical |
| **Classification** | Class II (21 CFR 878.4040) | Class II (21 CFR 878.4040) | Identical |
| **Intended Use** | 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.<br>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.<br>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. | Identical |
| **Model** | 3 Ply, Ear Loops, Flat-Pleated Style | 3 Ply, Ear Loops or Tie-On | No tie-on option for subject device |

Table 1 is continued on page 2

| Materials | | | |
|---|---|---|---|
| **Outer Facing Layer** | Spun-Bond Polypropylene | Spun-Bond Polypropylene | Similar |
| **Middle Layer** | Melt-Blown Polypropylene | Melt-Blown Polypropylene Filter | Similar |
| **Inner Facing Layer** | Spun-Bond Polypropylene | Spun-Bond Polypropylene | Similar |
| **Nose Piece** | Galvanized wire coated with polyethylene | Single Galvanized Wire, Coated By PE | Similar |
| **Ear Loops** | Nylon & polyurethane | Not made with natural rubber latex | Similar |
| **Color** | Blue | White | Subject device includes blue colorant |
| **Dimension (Width)** | 9.2 cm ± 0.2 cm | 9.5 cm ± 1.0 cm | More narrow tolerance for subject device |
| **Dimension (Length)** | 17.8 cm ± 0.2 cm | 17.5 cm ± 1.0 cm | More narrow tolerance for subject device |
| **OTC Use** | Yes | Yes | Same |
| **Sterility** | Non-Sterile | Non-Sterile | Same |
| **Use** | Single Use | Single Use | Same |
| **ASTM F2100 Level** | Level 3 | Level 3 | Same |

## VII. NON-CLINICAL DATA

The subject device was tested and conformed to 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. A summary of the benchtop performance testing results is provided below in Table 2 along with the acceptance criteria.

**Table 2 – Benchtop Performance Testing**

| Item | Purpose | Acceptance Criteria | Result |
|---|---|---|---|
| Level 3 Fluid Resistance Performance ASTM F1862 | Resistance to Fluid | 29 Out of 32 pass at 160 mmHg | Pass<br>30-31 Out of 32 pass at 160 mmHg<br>LOT #1, 30/32 passed, @ 160 mmHg<br>LOT #2 30/32 passed, @ 160 mmHg<br>LOT #3 31/32 passed, @ 160 mmHg |
| Particulate Filtration Efficiency ASTM F2299 | Particulate Filtration Efficiency | ≥ 98% | Pass<br>98.62-99.34%<br>LOT #1 AVE Filtration Efficiency ≥ 98%<br>LOT #2 AVE Filtration Efficiency ≥ 98%<br>LOT #3 AVE Filtration Efficiency ≥ 98% |
| Bacterial Filtration Efficiency ASTM F2101 | Bacterial Filtration Efficiency | ≥ 98% | Pass<br>99.5 – 99.1%<br>LOT #1 AVE Filtration Efficiency ≥ 98%<br>LOT #2 AVE Filtration Efficiency ≥ 98%<br>LOT #3 AVE Filtration Efficiency ≥ 98% |
| Differential Pressure ASTM F2100 | Differential Pressure | < 6.0 $mmH_20/cm^2$ | Pass<br>3.92 – 4.78 $mmH_20/cm^2$<br>LOT #1 AVE Differential Pressure 5.0<br>LOT #2 AVE Differential Pressure 5.0<br>LOT #3 AVE Differential Pressure 5.0 |
| Class 1 Flammability 16 CFR 1610 | Flammability | < 3.5 second burn time | Pass<br>Class 1, Did Not Ignite (DNI)<br>LOT #1 Did not ignite<br>LOT #2 Did not ignite<br>LOT #3 Did not ignite |

## BIOCOMPATIBILITY TESTING

Biocompatibility testing was performed in accordance with ISO 10993-1:2018. Specifically, the following testing endpoints were evaluated.

**Table 3 - Biocompatibility Testing**

| Standards | Purpose / Method | Acceptance Criteria | Result |
|---|---|---|---|
| Cytotoxicity – ISO 10993-5 | Purpose: Cytotoxic potential<br>Method: Evaluation of test Articles by the MEM Extraction Test | If viability is reduced to <70% of the reagent control extract, a cytotoxic potential exists. | Pass<br>Under the conditions of the study the device is non- cytotoxic |
| Skin Sensitization – ISO 10993-10 | Purpose: Sensitizing potential<br>Method: Magnusson-Kligman Sensitization / Guinea Pig Maximization Test (GPMT) | Magnusson and Kligman grades of less than 1 | Pass<br>Under the conditions of the study the device is non- sensitizing |
| Skin Irritation – ISO 10993-10 | Purpose: Potential for irritation<br><br>Method: Intracutaneous Injection Test | Erythema and Eschar Formation Value (total possible =4)<br>No erythema = 0<br>Very slight erythema (barely perceptible) =1<br>Well defined erythema=2<br>Moderate erythema = 3<br>Severe erythema (beet redness) to eschar Formation (preventing grading of erythema) =4<br>Total possible erythema score = 4<br>Edema Formation Value<br>No edema = 0<br>Very slight edema (barely perceptible) = 1 | Pass<br>Under the conditions of the study the device is non- irritating |

## VIII. CONCLUSIONS

The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device(K201479), manufactured by DemeTECH Corporation.