May 14, 2021

Anhui JBH Medical Apparatus Co., Ltd.
% Eva Li
Consultant
Shanghai Sungo Management Consulting Company Limited
Room 1309, Dongfang Building, 1500# Century Ave
Shanghai, Shanghai 200122
China

Re: K210302
Trade/Device Name: Disposable Medical mask（Model: JBHY01, JBHY02）
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 21, 2021
Received: April 21, 2021

Dear Eva Li:

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, Ph.D.
Acting 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)*
K210302

Device Name
Disposable Medical Mask
（Model：JBHY01，JBHY02）

Indications for Use *(Describe)*
The Disposable Medical 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(s), 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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**K210302**

# 510(K) Summary

**A. Applicant**

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Contact Person: Dandan Yang
Tel: 0086-550-8108866
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**Prepared Date: May 14, 2021**

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**B. Device**

Trade Name: Disposable Medical Mask

| Model | Description |
|---|---|
| JBHY01 | Ear Loops, Flat Pleated, 3 layers |
| JBHY02 | Tie-On, Flat Pleated, 3 layers |

Regulatory Information

Classification Name: Surgical Face Mask
Classification: Class II
Product code: FXX
Regulation Number: 878.4040
Review Panel: Surgical Apparel

**C. Predicate device:**

K110455
Kimberly-Clark KC100 Mask
Kimberly-Clark

**D. Intended use of the device:**

The Disposable Medical 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(s), provided non-sterile.

**E. Device Description:**

The Disposable Medical Masks are single use, three-layer, flat –folded masks with ear strings or ties and nose clip.

The two models are exact same except the loop versus tie on design.

The Disposable Medical Masks are manufactured with three layers, the inner and outer layers are made of non-woven Spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter. The three layers fabric are held together by ultrasonic welding.

The earloops/tie-on ties are held in place over the users' mouth and nose by two strings welded to the facemask. The earloops are made of 19cm spandex and the tie-on ties are made of 90cm spandex.

The nose clip in the layers of facemask is to allow the user to fit the facemask around their nose, which is not touch with the users' skin directly.

The Disposable Medical Masks will be provided in blue. The Disposable Medical Masks are sold non-sterile and are intended to be single use, disposable devices.

**F. Comparison with predicate device**

Table 1 General Comparison

| Device | Proposed Device | Predicate Device | Comparison |
|---|---|---|---|
| Manufacturer | Anhui JBH Medical Apparatus Co., Ltd. | Kimberly-Clark | — |
| 510(K) number | K210302 | K110455 | — |
| Model Name | Disposable Medical Mask | Kimberly-Clark KC100 Mask | Similar |
| Classification | Class II Device, FXX (21 CFR878.4040) | Class II Device, FXX (21 CFR878.4040) | Same |
| Intend use | The Disposable Medical 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(s), provided non-sterile. | The Kimberly-Clark KC100 Procedure Mask(s) is 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. The Kimberly-Clark KC100 Procedure Mask(s) is a | Same |

| | | | | |
|---|---|---|---|---|
| | | | single use, disposable devices, provided non-sterile. | |
| Model | | Ear Loops, Tie-On, Flat Pleated, 3 layers | Ear Loops, Tie-On, Flat Pleated, 3 layers | Same |
| Material | Outer facing layer | non-woven Spun-bond polypropylene | Spun-bond polypropylene | Same |
| | Middle layer | Melt blown polypropylene filter | Melt blown polypropylene filter | Same |
| | Inner facing layer | non-woven Spun-bond polypropylene | Spun-bond polypropylene | Same |
| | Ear loops/ties | Spandex | Polyester/lycra knitted | Similar |
| | Nose clip | PVC coated wire | PVC coated wire | Same |
| Color | | Blue | Variety (include blue) | Similar |
| Dimension （length） | | 175mm±3mm | 165±19mm | Similar |
| Dimension （width） | | 95 mm±2mm | 102±19mm | Similar |
| OTC use | | Yes | Yes | Same |
| Sterility | | Non-Sterile | Non-Sterile | Same |
| Use | | Single use, Disposable | Single use, Disposable | Same |
| ASTM F2100 Level | | Level 3 | Level 1 | Similar*1 |
| Biocompatibility | | ISO10993 | ISO10993 | Same*2 |

***1 Similar Discussion：**

The proposed device conducted the test and the pass the Level 3 Acceptance Criteria per ASTM F2100, the predicate device pass the level 1 Acceptance Criteria ASTM F2100. The test and the acceptance is following:

| | ASTM F2100-19 | |
|---|---|---|
| | Level 1 | Level 3 |
| BFE% ASTM F2101 | ≥95 | ≥98 |
| PFE% ASTM 2299 | ≥95 | ≥98 |
| Synthetic Blood ASTM 1862 | Pass at 80 mmHg | Pass at 160 mmHg |
| Differential pressure EN 14683 | ＜5.0 $mmH_20/cm^2$ | ＜6.0 $mmH_20/cm^2$ |
| Flammability 16CFR Part 1610 | Class 1 | Class 1 |

| |
|---|
| Sampling:<br>AQL 4% for BFE, PFE, Delta P; 32 masks for Synthetic Blood (Pass=≥29 passing, Fail=≤2passing<br>Flammability：32 masks were tested, all samples burn time is 3.5 seconds or more ACCEPTABLE（3.5 sec is a pass) |

***2** The biocompatibility test conducted of the proposed device and the predicate device

| **Item** | **Standard/ Acceptance Criteria** | proposed device | predicate device |
|---|---|---|---|
| **Cytotoxicity** | ISO10993-5:2009/ Non-Cytotoxic | Meet the Criteria | Meet the Criteria |
| **Irritation** | ISO10993-10:2010/ Non-Irritating | Meet the Criteria | Meet the Criteria |
| **Sensitization** | ISO10993-10:2010/ Non-Sensitizing | Meet the Criteria | Meet the Criteria |

**G. Summary of Non-Clinical Performance Testing**

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

- 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
- ASTM F2100, Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F1862, Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at A Known Velocity);
- EN 14683, Medical Face Masks—Requirements and Test Methods;
- ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using A Biological Aerosol of Staphylococcus Aureus;
- ASTM F2299, Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres;
- 16 CFR 1610, Standard for the Flammability of clothing textiles;

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Table 2-performance Testing

| Model | JBH01 | | | |
|---|---|---|---|---|
| Item | Acceptance Criteria (level 3) | Result of Lot20200701 | Result of Lot20200706 | Result of Lot202007014 |
| Synthetic Blood Performance ASTM F1862 | 29 out of 32 pass at 160 mmHg | 32 out of 32 pass at 160mmHg | 32 out of 32 pass at 160mmHg | 32 out of 32 pass at 160mmHg |
| Particulate Filtration Efficiency ASTM F2299 | ≥ 98% | Max:99.48% Min:99.93% | Max:99.85% Min:99.68% | Max:99.93% Min:99.73% |
| Bacterial Filtration Efficiency ASTM F2101-19 EN 14683:2019 Annex B | ≥ 98% | Max: 99.85% Min:99.63% | Max: >99.88% Min:99.77% | Max:99.85% Min:99.66% |
| Differential Pressure(Delta P) ASTM F2100-19 EN 14683:2019 Annex C ( $mmH_2O/cm^2$) | < 6.0 | Max:3.7mmH20/cm2 Min:3.1 $mmH_20/cm^2$ | Max:3.7mmH20/cm2 Min:3.1 $mmH_20/cm^2$ | Max:3.7mmH20/cm2 Min:3.1 $mmH_20/cm^2$ |
| Flammability 16 CFR 1610 (IBE=Test Article ignited, but extinguished) | Class 1 (Burn time≥3.5 seconds) | Class I | Class I | Class I |
| Model | JBH02 | | | |
| Item | Acceptance Criteria (level 3) | Result of Lot20200701 | Result of Lot20200706 | Result of Lot202007014 |
| Synthetic Blood Performance ASTM F1862 | 29 out of 32 pass at 160 mmHg | 32 out of 32 pass at 160mmHg | 32 out of 32 pass at 160mmHg | 32 out of 32 pass at 160mmHg |
| Particulate Filtration Efficiency ASTM F2299 | ≥ 98% | Max: 99.98% Min: 99.79% | Max: 99.89% Min: 99.79% | Max: 99.89% Min: 99.78% |

| | | | | |
|---|---|---|---|---|
| Bacterial Filtration Efficiency ASTM F2101-19 EN 14683:2019 Annex B | ≥ 98% | Max: 99.83% Min: 99.59% | Max: 99.83% Min: 99.59% | Max: 99.83% Min: 99.50% |
| Differential Pressure(Delta P) ASTM F2100-19 EN 14683:2019 Annex C ( $mmH_2O/cm^2$) | < 6.0 | Max: 3.7 $H_2O/cm^2$ Min: 3.2 $H_2O/cm^2$ | Max: 3.8 $H_2O/cm^2$ Min: 3.2 $H_2O/cm^2$ | Max: 3.7 $H_2O/cm^2$ Min: 3.2 $H_2O/cm^2$ |
| Flammability 16 CFR 1610 (IBE=Test Article ignited, but extinguished) | Class 1 (Burn time≥3.5 seconds) | Class I | Class I | Class I |

Table3 Biocompatibility Testing

| Item | Proposed device | Acceptance Criteria | Result |
|---|---|---|---|
| In Vitro Cytotoxicity Test MTT with 10FBS extract ISO10993-5:2009 | Under the conditions of the study, the device is non-cytotoxic. | Non-Cytotoxic | No cytotoxic potential. |
| Skin Sensitization Test Guinea Pig Maximization Test 0.9% Sodium Chloride Injection Extract ISO10993-10:2010 | Under the conditions of the study, the device is non-irritating. | Non-Irritating | No Irritation. |
| Skin Sensitization Test Guinea Pig Maximization Test Sesame Oil Extract ISO10993-10:2010 | | | |
| Skin Irritation Test 0.9% Sodium Chloride Injection Extract ISO 10993-10:2010 | Under the conditions of the study, the device is non-sensitizing | Non-Sensitizing | Not considered a sensitizer. |
| Skin Irritation Test Sesame Oil Extract ISO 10993-10:2010 | | | |

**H. Summary of Clinical Performance Test**

No clinical study is included in this submission.

Anhui JBH Medical Apparatus Co., Ltd.
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**I. Conclusion**

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K210302, the Disposable Medical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Kimberly-Clark KC100 Mask cleared under K110455.