February 25, 2021

Bain Medical Equipment (Guangzhou) Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box. 120-119
Shanghai, 200120
China

Re: K203524
Trade/Device Name: Surgical Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 10, 2020
Received: December 1, 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); 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)*
K203524

Device Name
Surgical Masks

Indications for Use *(Describe)*
The Surgical 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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"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.

1. Date of Preparation: 01/29/2021

2. Sponsor Identification

Bain Medical Equipment (Guangzhou) Co., Ltd.
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3. Designated Submission Correspondent

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

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Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Surgical Masks
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:
The Surgical 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.

Device Description:
The Surgical Masks are single use, three-layer, flat-pleated masks with ear loops and nose clip. The inner and outer layers of the mask 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 mask by ultrasound. The ear loops are made of polyester and spandex. The nose clip is made of polyethylene and galvanized iron wire. Users can adjust the nose clip 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 size of the proposed device is 17.5cm×9.5cm. The proposed device is a Level 2 mask based on ASTM F2100-2019. The Surgical Masks are blue and provided non-sterile.

5. Identification of Predicate Device

510(k) Number: K153496
Product Name: Disposable Surgical Face Mask

6. Summary of Non-Clinical Testing

The following performance data has been provided to demonstrate that the subject device meet the acceptance criteria in the standard.

Table 1 Performance Testing

Name of the Test Methodology / Standard	Purpose	Acceptance Criteria	Results
Resistance to Penetration by Synthetic blood 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)	The test was performed in accordance with ASTM F1862-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) to evaluate the effectiveness of the test sample from possible exposure to blood and other body fluids	No penetration at 120 mmHg	Pass at 120mmHg
Bacterial Filtration Efficiency 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	The test was performed in accordance with 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 to determine the bacterial filtration efficiency (BFE) of the test article.	≥98%	Average 99.9%
Particulate Filtration Efficiency 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	The test was performed in accordance with ASTM F2299-03 (Reapproved 2017) Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres, to determine the Particle Filtration Efficiency.	≥98%	Average 98.8%

Differential Pressure EN 14683:2019 Medical face masks-Requirements and test methods	The test was performed in accordance with EN 14683:2019 Medical face masks-Requirements and test methods, to determine the differential pressure.	<6.0 mm H_2O/cm^2	Average 4.5 mm H_2O/cm^2
Flammability 16 CFR 1610 Standard for the Flammability of Clothing Textiles Corrections	The test was performed in accordance with 16 CFR 1610 STANDARD FOR THE FLAMMABILITY OF CLOTHING TEXTILES to evaluate the flammability of the test sample.	Class I	Class I

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technological characteristics

Table 2 Comparison of Technology Characteristics

ITEM	Proposed Device K203524	Predicate Device K153496	Remark
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Indication for Use	The Surgical 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.	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(s), provided non-sterile.	Same
Mask style	Flat-pleated	Flat-pleated	Same
Design feature	Ear loop	Ear loop/Tie-on	Different 1
Layers	Three	Three	Same
Color	Blue	Blue	Same
Dimension (cm)	17.5cm×9.5cm	17.5cm×9.5cm	Same
Level	Level 2	Level 2	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
Shelf life	2 years	Unknown	Different 2
Fluid resistance ASTM F1862	Pass at 120mmHg	Pass at 120mmHg	Same
Particulate filtration efficiency ASTM F2299	≥98%	≥98%	Same
Bacterial filtration efficiency ASTM F2101	≥98%	≥98%	Same
Differential pressure	<6.0mmH_2O/cm^2 EN 14683	4.0 mmH_2O/cm^2 MIL-M-36954C	Different 3
Flammability 16 CFR Part 1610	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	Spunbond Polypropylene	Spun-bond polypropylene	Different 4
Middle layer	Melt-blown Polypropylene Filter	Melt blown polypropylene filter	
Inner facing layer	Spunbond Polypropylene	Spun-bond polypropylene	
Nose clip	Polyethylene and Galvanized Iron	Malleable aluminum wire	
Ear loop	Polyester and Spandex	Polyester	
Biocompatibility			
Cytotoxicity	Comply with ISO 10993-5; Under the conditions of the study, not cytotoxicity effect.	Under the conditions of the study, not cytotoxicity effect.	Same
Sensitization	Comply with ISO 10993-10; Under the conditions of the study, not an irritant.	Under the conditions of the study, not an irritant.	Same
Irritation	Comply with ISO 10993-10; Under conditions of the study, not a sensitizer.	Under conditions of the study, not a sensitizer.	Same

Different 1 - Design feature

The predicate devices are available in two types, ear loop type and tie-on type. The proposed device is only an ear loop mask and its type is included in the predicate device. Thus, this difference will not affect the safety and effectiveness of the proposed device.

Different 2 - Shelf life

Shelf life will affect the safety and effectiveness of mask. However, the performance testing of the proposed device after two years of aging has been conducted and the test results show that the proposed device after two years of aging meets the requirements of ASTM F2100-2019. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different 3 - Differential pressure

The differential pressure test standards used for the proposed device and predicate device are different. The differential pressure testing for the proposed device was conducted according to Annex C of EN 14683. While the differential pressure testing for the predicate device was conducted according to MIL-M-36954C. The differential pressure test standard specified in ASTM F2100-19 standard is Annex C of EN 14683. In addition, the proposed device has been tested for differential pressure using EN 14683 test method, and the test results meet the requirements of ASTM F2100-19 standard. Thus, this difference will not affect the safety and effectiveness of the proposed devices.

Different 4 - 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 conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe as effective, and performs as well as or better than the legally marketed predicate device K153496.