July 12, 2021

Suzhou Bolisi Medical Technology Co., Ltd
% Ryan Li
RA Manager
Shanghai Mind-link Business Consulting Co., Ltd.
Room A08, Floor 14th, No 699, Jiaozhou Road, Jingan District
Shanghai, 200040
China

Re: K210244
Trade/Device Name: Disposable Medical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 7, 2021
Received: June 10, 2021

Dear Ryan 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,

Ryan Ortega, PhD
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210244

Device Name

Disposable Medical Face Mask(145mm*95mm), Blue, Ear Loop type
Disposable Medical Face Mask(175mm*95mm), Blue, Ear Loop type

Indications for Use *(Describe)*

The Disposable Medical 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. The Disposable Medical Face Masks are 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.

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510(K) Summary—K210244

I. SUBMITTER:

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Summary prepared：June 28, 2021

II. DEVICE

Name of Device: Disposable Medical Face Mask
Regulation Number: 21 CFR PART 878.4040
Common Name: Surgical Mask
Classification Name: Surgical Mask
Regulatory Class: II
Product Code: FXX

III. PREDICATE DEVICE

Predicate: K210007

Trade/Device Name: Face Mask

Manufacturer: Jinhua Jingdi Medical Supplies Co.,Ltd

Product Code: FXX

Classification Name: Mask, surgical

Regulation Number: 21 CFR 878.4040

IV. DEVICE DESCRIPTION

Disposable Medical Face Mask is composed of three layers and is flat-pleated. The mask materials consist of an outer layer (spun-bond polypropylene), a middle layer, between the outer layer and inner layers (melt-blown polypropylene), and an inner layer (Spun-bond polypropylene). Each mask contains ear loops to secure the mask over the users' mouth and face and includes a malleable nose piece (galvanized iron wire) to provide a firm fit over the nose.

V. AVAILABLE MODELS

The Disposable Medical Face Masks are available in two models including different sizes.
For the 145mm*95mm model is in blue, barrier level 2 and size 145mm*95mm, ear loop type.
For the 175mm*95mm model is in blue, barrier level 2 and size 175mm*95mm, ear loop type.

VI. INDICATIONS FOR USE

The Disposable Medical 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. The Disposable Medical Face Masks are single use, disposable device, provided non-sterile.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Disposable Surgical Masks are compared with the predicate device (Face Mask (K210007)). The results are shown below in the Technological Characteristics Comparison Table:

DEVICE	Subject Device Disposable Medical Face Mask	Primary Predicate Device Face Mask (K210007)	Comparison
Intended Use	The Disposable Medical 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. The Disposable Medical Face Masks are single use, disposable device, provided non-sterile.	The face mask 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. The face mask is a single-use, disposable device, provided non-sterile.	Same
Classification Product Code	FXX	FXX	Same
Ear Loop Model	Ear Loops	Ear Loops	Same
Materials			
Outer Facing Layer	Spun-bond polypropylene non-woven fabric	Spun-bond polypropylene non-woven fabric	Similar Note 1
Middle Layer	Melt-blown polypropylene	Melt-blown polypropylene	Similar Note 1
Inner Facing Layer	Spun-bond polypropylene non-woven fabric	Spun-bond polypropylene non-woven fabric	Similar Note 1
Nose Piece	Galvanized iron wire	Iron wire covered polypropylene	Different Note 1
Ear Loops	82% Spandex 18% Polyester	75% Polyester 25% Spandex	Similar Note 1
Design Features			
Color	Blue	Blue	Same
Style	Flat - Pleated	Flat - Pleated	Same
Multiple Layers	3 Layers	3 Layers	Same
Single Use	Single use	Single use	Same
Sterility			

Sterile	Non-sterile	Non-sterile	Same
Dimensions			
Length × Width	145×95mm (±5mm) 175×95mm (±5mm)	145×95mm (±5mm) 175×95mm (±5mm)	Same
Technological Characteristics Product Barrier Specifications Per ASTM F2100 – Meets Level 2			
Fluid Resistance ASTM F1862	32 out of 32 Pass at 120mmHg	32 out of 32 pass at 120mmHg	Same
Particulate Filtration Efficiency (PFE) ASTM F2299	Pass at ≥98%	Pass at 99.70%	Similar Note 2
Bacterial Filtration Efficiency (BFE) ASTM F2101	Pass at ≥98%	Pass at 99.95%	Similar Note 2
Differential Pressure (Delta P)MIL-M-36954C	Pass at ＜6.0 mmH_2O/cm^2	Pass at 3.0 mmH_2O/cm^2	Similar Note 2
Flammability 16 CFR PART 1610	Class 1 Non-Flammable	Class 1 Non-Flammable	Same
Biocompatibility			
Cytotoxicity	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	Same
Irritation	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	Same
Sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	Same

Comparison in Detail(s):

Note 1:

Although the material including outer layer, middle layer, inner layer, nose piece and ear loops is a little different from the predicate device, it meets the requirement of essential performance standard ISO 10993. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

Note 2:

Although the Particulate Filtration Efficiency, Bacterial Filtration Efficiency and Differential Pressure of the subject device is a little different from the predicate device. However, they all meet the requirements of essential performance standard ASTM F 2100. Therefore, the differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

VIII. PERFORMANCE DATA

Summary of Non-Clinical Performance Test

Performance Characteristics	Test Method	Pass Criteria For Level 2	Test Results
Bacterial Filtration Efficiency	ASTM F2101 Standard Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus	≥98%	Pass
Differential Pressure (Delta-P)	EN 14683: 2019, Annex C Medical face masks - Requirements and test methods according to ASTM F2100:2019	<6.0 mm $H2O/cm^2$	Pass
Sub-Micron Particulate Filtration Efficiency (PFE) at 0.1 micron	ASTM F2299 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres	≥98%	Pass
Resistance to Penetration by Synthetic Blood	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)	Fluid resistant at 120 mm Hg	Pass
Flammability	16 CFR Part 1610 Standard for the Flammability of Clothing	Class 1	Pass

Biocompatibility Testing

Based on ISO 10993-1:2018, the subject device contacts intact skin and its contact duration is less than or equal to 24h. Therefore, the following tests for the subject device were conducted to demonstrate that the subject device is biocompatible and safe for its intend use:

- In vitro Cytotoxicity Test per ISO 10993-5: 2009 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- Skin Sensitization Tests per ISO 10993-10: 2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization
- Skin Irritation Tests per ISO 10993-10: 2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization

Clinical Test

No clinical study is included in this submission.

IX. CONCLUSION

The conclusion drawn from the nonclinical tests demonstrates that the subject device, the Disposable Medical Face Mask is as safe, as effective, and performs as well as the legally marketed predicate device Face Mask (K210007).