June 2, 2021

Jiangxi Heying Pharmaceutical Co., Ltd
% Mandy Wu
Consultant
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, 200122 Cn

Re: K210429
Trade/Device Name: Disposable Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 8, 2021
Received: April 26, 2021

Dear Mandy Wu:

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,

Clarence W. Murray, III, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210429

Device Name
Disposable Surgical Face Mask
sterile and non-sterile

Indications for Use *(Describe)*
The Disposable Surgical Face Mask 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. This a single use, disposable device(s), provided sterile and 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.

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510(k) Summary

K210429

510(K) Summary

A. Applicant:

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Date of summary prepared: 2021-05-28

Submission Correspondent:
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B. Device:

Trade Name: Disposable Surgical Face Mask
Common Name: Surgical Face Mask
Model(s): AE17.5×9.5cm

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

C. Predicate device:

K100846
IMC Surgical Face Mask (non-sterile and sterile, yellow)
International Medsurg Connection

D. Indications for use of the device:

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 a single use,

disposable device(s), provided sterile and non-sterile.

E. Device Description:

The Disposable Surgical Face Masks are composed of mask body, nose clip and ear loop. The body of the mask is composed of three layers: the inner and outer layers are made of spun-bond nonwoven fabric, and the middle layer is made of melt blown non-woven fabric. The nose clip is made of polyethylene and iron material, ear loop is made of nylon and spandex material.

The size of the disposable surgical mask is 17.5*9.5cm with tolerance±5%cm, the length of the ear loop is ≧ 10.0cm. The outer layer of disposable surgical mask will be provided in blue, the inner layer of the disposable surgical mask will be provided in white, and it will be provided with sterile and non-sterile and is intended to be single use, disposable devices.

F. Technological Characteristic Comparison Table

Table 1 General Comparison

Device		**Proposed Device**	**Predicate Device**	**Conclusion**
Manufacturer		Jiangxi Heying Pharmaceutical Co., Ltd	International Medsurg Connection	NA
510K number		K210429	K100846	NA
Classification		Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
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 a single use, disposable device(s), provided sterile and non-sterile.	This device is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.	Similar
Material	**Outer**	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middl	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Inner	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose	Polyethylene and iron	NA	Different
	Ear	Nylon and spandex	NA	Different
Color		Blue	Yellow	Different
Dimension		17.5+/-5%cm	17.8cm (7 inches)	Similar
Dimension		9.5+/-5%cm	8.9cm (3.5inches)	Similar
OTC use		Yes	Yes	Same

Sterility	Sterile& Non-Sterile	Sterile& Non-Sterile	Same
Sterilization Method	E.O.	Not available	Different
Use	Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100	Level 3	Level 1,2,3	Similar
Biocompatibility	ISO10993	ISO10993	Same
Fluid Resistance	32 out of 32 per lot pass at 160 mmHg, 3 non-consecutive lots tested for sterile and non-sterile	Low=80 Moderate=120 High=160	Similar
Particulate Filtration Efficiency	≥98%	≥98%	Similar
Bacterial Filtration Efficiency	≥98%	Low≥95% Moderate≥98% High≥98%	Similar
Differential Pressure	< 6.0mmH_2O/cm^2	≤4mm H2O/cm2	Different
Flammability	Class 1	Class 1	Similar

G. Summary of Non-Clinical Test

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was similar to 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, Stand 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;

Table 2 - Performance Testing

Test Methodology	**Purpose:** **The purpose of the performance testing is to demonstrate the functionality of the subject device.**	**Acceptance Criteria:** **ASTM F2100 Level 3**	**Result**
Fluid Resistance ASTM F1862	32 out of 32 per lot pass at 160 mmHg, 3 non-consecutive lots tested for sterile and non-sterile	29 out of 32 pass at 160 mmHg for level 3	PASS
Particulate Filtration Efficiency ASTM F2299	Lot1 before sterile:99.41% Lot1 sterile: 99.50% Lot1 after aging: 99.44% Lot2 before sterile:99.36% Lot2 sterile：99.26% Lot2 after aging:99.18% Lot3 before sterile:99.36% Lot3 sterile：99.29% Lot3 after aging:99.27%	≥ 98%	PASS
Bacterial Filtration Efficiency ASTM F2101	Lot1 before sterile: 99.77% Lot1 sterile：99.79% Lot1 after aging:99.74% Lot2 before sterile:99.80% Lot2 sterile：99.83% Lot2 after aging: 99.77% Lot3 before sterile:99.80% Lot3 sterile：99.78% Lot3 after aging:99.76%	≥ 98%	PASS
Differential Pressure EN 14683	Lot1 before sterile: 4.52 Lot1 sterile：4.52 Lot1 after aging:4.63 Lot2 before sterile: 4.51 Lot2 sterile：4.54 Lot2 after aging:4.57 Lot3 before sterile:4.50 Lot3 sterile：4.50 Lot3 after aging:4.53	< 6.0mmH_2O/cm^2	PASS
Flammability 16 CFR 1610	Lot1 before sterile: class 1 Lot1 sterile: class 1 Lot1 after aging: class 1 Lot2 before sterile: class 1 Lot2 sterile: class 1 Lot2 after aging: class 1 Lot3 before sterile: class 1 Lot3 sterile: class 1 Lot3 after aging: class 1	Class 1	PASS

Table 3 Biocompatibility Comparison

Item	**Purpose:** **The purpose of the testing is to demonstrate the safety of the subject device.**	**Acceptance Criteria**	**Result**
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic.	Non-Cytotoxic	PASS
Irritation	Under the conditions of the study, the device is non-irritating.	Non-Irritating	PASS
Sensitization	Under the conditions of the study, the device is non-sensitizing	Non-Sensitizing	PASS
EtO/ECH Residuals	Max ECH residuals is 9 mg/day. Max EO residuals is 4.4 ug/g	ECH residuals meet the requirement of less than 20ug/g at room temperature for 7 days. EO residuals meet the requirement of less than 10 ug/g at room temperature for 7 days.	PASS

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, K100846 International Medsurg Connection, Single-use Surgical Mask,IMC Surgical Face Mask (non-sterile and sterile, yellow).