March 15, 2021

Hangzhou Mycode Bio-Medicine Co., Ltd.
Alice Gong
Manager
Floor 4, Building No. 4, No. 2 Xiyuansi Road, Xihu District
Hangzhou, Zhejiang 310030
China

Re: K201698
Trade/Device Name: Medical Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 5, 2021
Received: February 10, 2021

Dear Alice Gong:

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

510(k) Number *(if known)*

K201698

Device Name
Medical Surgical Mask

Indications for Use *(Describe)*

Medical 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(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.

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510(k) Summary
K201698

1.0 Submitter:

Submitter's name:	Hangzhou Mycode Bio-Medicine Co., Ltd.
Submitter's address:	Floor 4, Building No. 4, No. 2 Xiyuansi Road, Xihu District, Hangzhou, China
Phone number:	86-571-87329869
Name of contact person:	Ms. Alice Gong
Summary Preparation Date:	Feb. 5, 2021
Summary Revision:	Rev. 2

2.0 Name of the Device

Proprietary/Trade name:	Medical Surgical Mask
Common Name:	Surgical Mask
510(k) Number:	K201698
Classification Name:	Mask, Surgical
Device Classification:	Class II
Regulation Number:	21 CFR 878.4040
Product Code:	FXX

3.0 Predicate device

Device Name:	SURGICAL FACE MASK
Company name:	Wuhan Dymex Healthcare Co., Ltd
510(K) Number:	K182515

4.0 Device Description

Medical Surgical Masks are disposable medical masks and are made of mask body, nose clips and mask belt by ultrasonic heat sealing. The mask body is divided into three layers: inner, middle and outer layers, the inner and outer layers are Non-woven fabrics and middle layer is polypropylene melt blown cloth, nose piece is made of galvanized iron wire covered plastic materials. The mask belt is made of spandex. The mask style is flat pleated.

5.0 Indications for Use

Medical 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(s), provided non-sterile.

6.0 Summary of the Technological Characteristics of the Device:

Provided below is a comparison of the subject device to the predicate device.

Device Characteristic	**Subject Device**	**Predicate Device**	Comparison (Same, similar, different)
Product name	Medical Surgical Mask	SURGICAL FACE MASK	N/A
510(K) No.	K201698	K182515	N/A
Product Owner	Hangzhou Mycode Bio-Medicine Co., Ltd.	Wuhan Dymex Healthcare Co., Ltd	N/A
Product Code	FXX	FXX	Same

Regulation	21 CFR 878.4040	21 CFR 878.4040	Same
Class	Class II	Class II	Same
Indications for Use	Medical 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(s), provided non-sterile.	The 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
Color	White	Yellow	Different
Single Use	Single Use, Disposable	Single Use, Disposable	Same
Sterile	Non-Sterile	Non-Sterile	Same
Dimensions-Length	17.5cm±5%	17.5cm±0.2cm	Similar
Dimensions-Width	9.5cm±5%	9.5cm±0.2cm	Similar
Ear loops	Yes, Spandex	Yes, Spandex	Simlar
Particulate Filtration Efficiency **(ASTM F2299)**	98.69 %	99.7%	Similar
Fluid resistance **(ASTM F1862)**	32 out 32 pass at 120 mmHg (level 2)	32 out of 32 pass at 120 mmHg	Same
Bacterial Filtration efficiency **(ASTM F2101)**	99.80 %	99.9%	Similar
Flammability **(16 CFR 1610)**	Class 1	Class 1	Same
Delta-Pressure **(EN14683:2019)**	3.4 mmH_2O/cm^2	4.0mmH_2O/cm^2	Similar
Biocompatibility Cytotoxicity (**ISO 10993-5: 2019**) Skin Irritation (**ISO 10993-10: 2010**) Skin sensitization	All items passed	All items passed	Same

7.0 Summary of f Non-Clinical Performance Data:

The following bench testing was conducted to demonstrate that the subject device met the acceptance criteria for the relevant standard for this device.

Summary of Non-clinical Testing			
Name of the standard Characteristic tested	Subject device tested per ASTM F-2100	Passing Standard acceptance criteria	Result
Flammability (16 CFR 1610)	Class 1	Class 1	Pass
Delta Pressure (EN 14683:2019)	3.4 mmH_2O/cm^2	< 5.0 mmH_2O/cm^2	Pass
Fluid Resistance (Provide the number of masks that pass the test) (ASTM F1862)	32 out 32 pass at 120 mmHg level 2	120 mmHg (level 2)	Pass
Bacterial filtration efficacy (ASTM F2101)	99.80 %	≥ 98 %	Pass
Particulate filtration efficacy (ASTM F2299)	98.69 %	≥ 98 %	Pass
Biocompatibility	Primary Skin Irritation in rabbits ISO 10993-10: 2010	Passes Under the conditions of the study, the subject device is not a primary skin irritant.	
	Dermal sensitization in the guinea pig ISO 10993-10: 2010	Passes Under the conditions of the study, the subject device is not a primary skin sensitizer.	
	In vitro cytotoxicity accordance with ISO 10993-5: 2019	Passes Under the conditions of the study, the subject device is not cytotoxic.	

8.0 Clinical Performance Data:

Clinical data was not needed for the subject device.

9.0 Conclusion:

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K201698, the Medical Surgical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K182515