January 4, 2022

Jiangxi Bestgrand Health Technology Co., Ltd.
% Ivy Wang
Consultant
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K212375
Trade/Device Name: Disposable Medical Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 6, 2021
Received: December 6, 2021

Dear Ivy Wang:

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, PhD
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)*
K212375

Device Name
Disposable Medical Surgical Mask

Indications for Use *(Describe)*
The Disposable Medical Surgical 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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
K212375

Document prepared date: 2022/1/4

A. Applicant:

Jiangxi Bestgrand Health Technology Co.,Ltd.

Address: BeGrand Industrial Park, Pingxiang Development Zone, Pingxiang City, Jiangxi Province, China

Contact Person: Jian Neng Chen
Tel: +86 18179908058
Mail: Kenny.chen@chinaloda.com

Submission Correspondent:

Primary contact: Ms. Ivy Wang

Shanghai SUNGO Management Consulting Co., Ltd.

14th Floor, Dongfang Building, 1500# Century Ave., Shanghai 200122,

China Tel: +86-21-58817802

Email: haiyu.wang@sungoglobal.com
Secondary contact: Mr. Raymond Luo

14th Floor, Dongfang Building, 1500# Century Ave., Shanghai 200122,

China Tel: +86-21-68828050

Email: fda.sungo@gmail.com

B. Device:

Trade Name: Disposable Medical Surgical Mask
Common Name: Surgical Face Mask
Model: Plane-type with loops

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 Medical Surgical 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 is a single use, disposable device(s), provided sterile.

E. Device Description:

The Disposable Medical Surgical Mask is 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 polypropylene, and the middle layer is made of melt blown polypropylene filter, the nose clip is made of plastic materials and iron wire, ear loop is made of spandex.

The size of the Disposable Medical Surgical Mask is 17.5*9.5cm with tolerance +/- 0.2cm, the length of the ear loop is 17cm with tolerance +/-5 cm, and the length of the nose clip should no less than 8.0cm.

The outer layer of Disposable Medical Surgical Mask will be provided in blue, the inner layer of the Disposable Medical Surgical Mask will be provided in white, and it will be provided with sterile and is intended to be single use, disposable devices.

F. Comparison with predicate device

Table 1 General Comparison

Device	**Proposed Device**	**Predicate Device**	**Conclusion**
Manufacturer	Jiangxi Bestgrand Health Technology Co.,Ltd.	International Medsurg Connection	NA
510K number	K212375	K100846	NA
Classification	Class II Device, FXX (21 CFR878.4040)	Class II Device, FXX (21 CFR878.4040)	Same
Indications for use	The Disposable 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 a single use, disposable device(s), provided	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

		sterile.		
Design feature		Ear Loops, Flat Pleated, 3 layers	Ear Loops, Tie-On, Flat Pleated, 3 layers	Similar
Material	**Outer layer**	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Inner layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose clips	PE material + iron with Zn plating	NA	Different
	Ear loops	Spandex and polyester	NA	Different
Color		Blue	Yellow	Different
Dimension (Length)		17.5+/-0.2 cm	17.8cm (7 inches)	Different
Dimension (Width)		9.5+/-0.2 cm	8.9cm (3.5inches)	Different
OTC use		Yes	Yes	Same
Sterility		Sterile	Sterile& Non-Sterile	Similar
Use		Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100		Level 2	Level 1,2	Similar
Biocompatibility		ISO10993: Non-Cytotoxic, Non-Irritating, and Non-Sensitizing.	ISO10993: Non-Cytotoxic, Non-Irritating, and Non-Sensitizing.	Same

Difference analysis: The proposed device has different nose clip & ear loops material, color, and dimension to the predicate device, but the performance and biocompatibility of the device has been tested, the result has shown the different does not affect the safety of the proposed device.

G. Summary of Technological Characteristic

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, 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;

To demonstrate the Disposable Medical Surgical Mask sterility is maintained during the duration of the stated shelf-life, the final product and its primary packaging has tested for seal strength using following standard:

- ASTM F88/F88M-15: Standard test method for seal strength of flexible barrier materials
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Table 2 - Performance Testing

Item	Proposed device	Acceptance Criteria (level 2)	Result
Fluid Resistance Performance ASTM F1862	32 out of 32 pass at 120 mmHg	29 out of 32 pass at 120 mmHg	PASS
Particulate Filtration Efficiency ASTM F2299	99.9%	≥ 98%	PASS
Bacterial Filtration Efficiency ASTM F2101	99.9%	≥ 98%	PASS
Differential Pressure (Delta P) EN 14683 Annex C	3.26 mmH_2O/cm^2	< 6.0mmH_2O/cm^2	PASS
Flammability 16 CFR 1610	Class 1	Class 1	PASS

Table 3 Biocompatibility Comparison

Item	Proposed 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

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

Based on the comparison above, the proposed devices are determined to be similar to the predicate devices. Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, IMC Surgical Face Mask (non-sterile and sterile, yellow) cleared under K100846.