



August 27, 2021

Ningbo Jingeao Electronics Inc.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No. 738 Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K202746
Trade/Device Name: Surgical mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 8, 2021
Received: July 26, 2021

Dear Boyle 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,


Liqun Zhao -S

For Clarence W. Murray III, Ph.D.
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

Indications for Use

510(k) Number (if known)

K202746

Device Name

Surgical mask

Indications for Use (Describe)

The surgical mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It is 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.

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510(k) Summary

510(k) number: K202746

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

1.0 Submitter's information

Name: Ningbo Jingeao Electronics Inc.

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Contact: Ms. Yiyun Yu

Date of Preparation: Aug.23, 2021

Designated Submission Correspondent

Mr. Boyle Wang

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2.0 Device information

Trade name: Surgical mask

Common name: Surgical mask

Classification name: Mask, Surgical

Model(s): Ear loop, 175×95mm

3.0 Classification

Production code: FXX

Regulation number: 21CFR 878.4040

Classification: Class II

Panel: Surgical apparel

4.0 Predicate device information

Manufacturer: Wuhan Dymex Healthcare Co., Ltd

Device: Surgical Face Mask

510(k) number: K182515

5.0 Intended Use

The surgical mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It is 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 Device description

The surgical mask is single use, three-layer, flat-pleated style with ear loops and nose piece. The mask is manufactured with three layers, the inner and outer layers are made of nonwoven fabrics, and the middle layer is made of melt blown fabrics. The ear loops are held in place over the users' mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are not made with natural rubber latex. The nose piece in the layers of facemask is to allow the user to fit the facemask around their nose, which is made of galvanized iron wire. The disposable medical face mask will be provided in blue. The masks are sold non-sterile and are intended to be single use, disposable devices.

7.0 Technological Characteristic Comparison Table

Table 1 - General Comparison

Item	Proposed device	Predicated device	Remark
Product Code	FXX	FXX	Identical
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Identical
Class	II	II	Identical
Product name	Surgical mask	Surgical Face Mask	-
510(k) No.	K202746	K182515	-
Models	Ear loop, 175×95mm	Ear loop	-
Indications for Use	The surgical mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It is 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.	Identical
OTC use	Yes	Yes	Identical
Composite	Flat Pleated, 3 layers	Flat Pleated, 3 layers	Identical
	Internal layer	Spun-bond polypropylene	Identical
	Middle layer	Melt blown polypropylene	Identical

Material	External layer	Spun-bond polypropylene	Spun-bond polypropylene	Identical
	Nose piece	Galvanized iron wire	Malleable polyethylene wire	* Gap 1
	Ear loop	Polyester, spandex	spandex	* Gap 2
Color		Blue	Yellow	* Gap 3
Dimension (Length)		17.5cm±0.5cm	17.5cm±0.2cm	* Gap 4
Dimension (Width)		9.5cm±0.5cm	9.5cm±0.2cm	* Gap 5
Sterility		Non-Sterile	Non-Sterile	Identical
Single Use		Yes	Yes	Identical
Sterile		No	No	Identical
ASTM F2100 Level		Level 2	Level 2	Identical
Cytotoxicity		Comply with ISO 10993-5	Comply with ISO 10993-5	Identical
Irritation		Comply with ISO 10993-10	Comply with ISO 10993-10	Identical
Sensitization		Comply with ISO 10993-10	Comply with ISO 10993-10	Identical

* Gap analysis:

Gap 1-3: the two devices have some difference in materials and product color, product materials safety is proved by its biocompatibility, and the difference does not raise additional questions for safety and effectiveness of device.

Gap 4-5: the two devices share same dimensions otherwise the tolerance is different, the little deviation in tolerance does not raise additional questions for safety and effectiveness of device.

8.0 Non-Clinical Test Conclusion

The proposed device was tested and conformed to the related recognized 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.

Table 2 - Performance Testing

Items	Performance	Acceptance Criteria (Level 2, ASTM F2100-19*1)	Result
Bacterial filtration efficiency (BFE) (%)	99.8~99.9%	≥98	Pass
Different pressure (mmH ₂ O/cm ²)	4.0~4.4 mmH ₂ O/cm ²	<6.0 mmH ₂ O/cm ²	Pass
Sub-micron particulate filtration efficiency at 0.1 micron, % (PFE)	99.68~99.83%	≥98	Pass
Resistance to penetration by synthetic blood, Minimum pressure in mmHg for pass result	32 of 32 test articles passed at 120mmHg	29 of 32 test articles passed at 120mmHg	Pass
Flame spread	Class 1, Non Flammable	Class 1	Pass

*1: ASTM F2100-19 Standard Specification for Performance of Materials Used in

Medical Face Masks

Table 3 - Biocompatibility Testing

Item	Result	Conclusion
Cytotoxicity ^{*2}	Under the conditions of the study, the device is noncytotoxic.	Pass
Irritation ^{*3}	Under the conditions of the study, the device is nonirritating.	Pass
Sensitization ^{*3}	Under the conditions of the study, the device is nonsensitizing	Pass

*2: the Cytotoxicity test follows standard of ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

*3: the Irritation and Sensitization test follows standard of ISO 10993-10:2010
Biological Evaluation of Medical Device-Part 10:stimulation and allergic reaction

8.0 Clinical Test Conclusion

No clinical study implemented for the Surgical mask.

10.0 Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K202746, the Surgical mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K182515.