August 25, 2021

Qinhuangdao Taizhi Medical Technology Co., Ltd.
℅ Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K211451
Trade/Device Name: Disposable Surgical Mask (non sterile)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 21, 2021
Received: July 29, 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,

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

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)*
K211451

Device Name
Disposable surgical mask (non sterile)

Indications for Use *(Describe)*
Disposable surgical mask (non sterile) 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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: Qinhuangdao Taizhi Medical Technology Co., Ltd.
Address: No.5, Small and Medium Enterprises Incubator Base, East Circular Economy Park, Haigang District, Qinhuangdao City, Hebei Province，China
Phone Number: +86-13383659307
Contact: Ms. Fan Xifan
Date of Preparation: 16/04/2021

Designated Submission Correspondent

Mr. Boyle Wang
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Room 608, No. 738 Shangcheng Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device information

Trade name: Disposable surgical mask (non sterile)
Common name: Surgical face mask
Classification name: Mask, Surgical
Model(s): ear strap, 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 Indication for Use Statement

Disposable surgical mask (non sterile) 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 Disposable surgical mask (non sterile) is single use, three-layer, flat-pleated style with ear straps 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 straps are held in place over the users' mouth and nose by two elastic ear straps welded to the facemask. The elastic ear straps are not made with natural rubber latex. The nose piece on the layers of facemask is to allow the user to fit the facemask around their nose, which is made of PE (polyethylene) with dual-Galvanized wire. The Disposable surgical mask (non sterile) will be provided in blue. The masks are sold non-sterile and are intended to be single use, disposable devices.

7.0 Comparison of Technological Characteristic

Table 1 - General Comparison

Item	Proposed device	Predicated device	Remark
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Product name	Disposable surgical mask (non sterile)	Surgical Face Mask	-
510(k) No.	K211451	K182515	-
Models	ear strap, 175×95mm	ear strap	-
Intended Use / Indications for Use	The Disposable surgical mask (non sterile) 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.	Same
OTC use	Yes	Yes	Same
Composite	Flat Pleated, 3 layers	Flat Pleated, 3 layers	Same

Material	Internal layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene	Melt blown polypropylene	Same
	External layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose piece	PE (polyethylene) with dual-Galvanized wire	Malleable polyethylene wire	Different * (Gap 1)
	ear strap	Nylon, spandex	spandex	Different * (Gap 2)
Color		Blue	Yellow	Different * (Gap 3)
Dimension (Length)		17.5cm±0.5cm	17.5cm±0.2cm	Different* (Gap 4)
Dimension (Width)		9.5cm±0.5cm	9.5cm±0.2cm	Different * (Gap 5)
Sterility		Non-Sterile	Non-Sterile	Same
Single Use		Yes	Yes	Same
Sterile		No	No	Same
ASTM F2100 Level		Level 2	Level 2	Same
Biocompati-bility	Cytotoxicity	Under the conditions of the study, the device is noncytotoxic.	Under the conditions of the study, the device is noncytotoxic.	Same
	Irritation	Under the conditions of the study, the device is nonirritating.	Under the conditions of the study, the device is nonirritating.	Same
	Sensitization	Under the conditions of the study, the device is nonsensitizing	Under the conditions of the study, the device is nonsensitizing	Same

* 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 face masks
- Premarket Notification [510(k)] Submission issued on March 5, 2004.

Table 2 - Performance Testing

Items	Performance	Acceptance Criteria	Result

		(Level 2, ASTM F2100-19)	
Bacterial filtration efficiency (BFE) (%)	99.9%	≥98	Pass
Different pressure (mmH_2O/cm^2)	2.8-3.6 mmH_2O/cm^2	<6.0 mmH_2O/cm^2	Pass
Sub-micron particulate filtration efficiency at 0.1 micron, % (PFE)	99.48~99.95%	≥98	Pass
Resistance to penetration by synthetic blood, Minimum pressure in mmHg for pass result	Test 1-3: 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

Table 3 - Biocompatibility Testing

Item	Proposed Device	Result
Cytotoxicity	Under the conditions of the study, the device is noncytotoxic.	Pass
Irritation	Under the conditions of the study, the device is nonirritating.	Pass
Sensitization	Under the conditions of the study, the device is nonsensitizing	Pass

9.0 Clinical Test Conclusion

No clinical study implemented for the Disposable surgical mask (non sterile).

10.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicated device in K182515.