June 11, 2021

Chongqing Chaoke Industry Development Co., Ltd.
℅ Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K202714
Trade/Device Name: Medical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX,
Dated: April 30, 2021
Received: May 14, 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,

Ryan Ortega, PhD
Acting Assistant Director
DHT4B: Division of Infection Control 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)*
K202714

Device Name
Medical Face Mask

Indications for Use *(Describe)*
The Medical 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 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

(K202714)

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

1.0 submitter's Information

Name: CHONGQING CHAOKE INDUSTRY DEVELOPMENT CO.,LTD.
Address: C31, Yangtze River Industry Park, Tea Garden New Zone, Nan'an District, Chongqing, China 400067
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Contact: Liu Xincheng
Date of Preparation: Apr.30,2020

Designated Submission Correspondent

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2.0 Device Information

Trade name: Medical Face Mask
Common name: Surgical Face Mask
Classification name: Surgical Face Mask
Model: CK-MFM-002

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 Device Description

The Medical Face Masks are single use, three-layer, flat-pleated style with ear loops and nose piece. The Medical Face Masks are manufactured with 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 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+ Polyethylene(PE). The medical face masks will be provided in blue. The medical face masks are sold non-sterile and are intended to be single use, disposable devices.

6.0 Indication for Use Statement

The Medical 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 is a single use, disposable device(s), provided non-sterile.

7.0 Comparison to the Predicate Device

Table 1 General Comparison

Item	Subject Device K202714	Predicate Device K182515	Remark
Product Name	Medical Face Mask	Surgical Face Mask	--
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Intended Use& Indications for use	The Medical 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	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	Same

		and body fluids. This is a single use, disposable device(s),provided non-sterile.	practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	
Design features		Ear Loops, 3 layers	Ear Loops, 3 layers	Same
Mask Styles		Flat pleated	Flat pleated	Same
Material	Outer facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
	Inner Facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose piece	Galvanized iron wire+ Polyethylene(PE)	Malleable polyethylene wire	Different*
	Ear loops	not made with natural rubber latex	not made with natural rubber latex	Same
Color		Blue	Blue	Same
Dimension (Length)		175 mm +/- 8mm	17.5 cm +/- 1cm	Same
Dimension (Width)		95 mm +/- 4mm	9.5 cm +/- 1cm	Same
OTC use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
Single Use		Yes	Yes	Same
Sterile		No	No	Same
ASTM F2100 Level		Level 2	Level 2	Same

*The difference in the materials does not raise additional questions for safety and effectiveness. Performance testing including biocompatibility evaluation has been performed on the final finished device which includes all construction materials.

8.0 Non-Clinical Test Conclusion

The proposed device was tested and conformed to the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Medical face masks – Premarket Notification [510(k)] Submission issued on March 5, 2004.

Table 2 - Performance Testing

Item	Subject Device K202714	Acceptance Criteria	Result

Fluid Resistance Performance ASTM F1862	32 Out of 32 pass at 120 mmHg(16.0 kPa)	29 Out of 32 pass at 120 mmHg (16.0 kPa)	Pass
Particulate Filtration Efficiency ASTM F2299	99.7%	≥ 98%	Pass
Bacterial Filtration Efficiency ASTM F2101	98.7%	≥ 98%	Pass
Differential Pressure (Delta P) MILM-36954C	1.98 mmH_20/cm^2	< 6.0 mmH_20/cm^2	Pass
Flammability 16 CFR 1610	Class 1	Class 1	Pass

Table 3 - Biocompatibility Testing

Item	**Subject Device K202714**	**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 is included in this submission.

10.0 Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device in K182515.