March 24, 2021

Guangdong Zhong Ling Industrial Group Co., Ltd.
℅ Jinghua Zhou
Regulation Control Manager
Guangzhou Junyi Information Technology Co., Ltd.
Room 215, Huaming Building, Chebei Road
Guangzhou, Guangdong 511660
China

Re: K202650
Trade/Device Name: Medical disposable face mask non sterile
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 4, 2021
Received: January 4, 2021

Dear Jinghua Zhou:

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 CAPT Elizabeth Claverie, M.S.
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)*
K202650

Device Name
Medical disposable face mask non sterile

Indications for Use *(Describe)*
The device 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

Prepared in accordance with the requirements of 21 CFR Part 807.92

K202650

Date of Summary Preparation: March 5, 2021

1. Submitter's Identifications

Submitter's Name: Guangdong Zhong Ling Industrial Group Co., Ltd.
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2. Correspondent's Identifications

Correspondent's Name: Guangzhou Junyi Information Technology Co., Ltd.
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3. Name of the Device

Device Classification Name: Mask, Surgical
Regulation Description: Surgical apparel
Trade Name: Medical disposable face mask non sterile
Model: ZL-0001
Regulation Medical Specialty: General & Plastic Surgery
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 21 CFR 878.4040
Device Classification: Class II

4. The Predicate Devices

K182515 Surgical Face Mask, Model: Ear Loop
Wuhan Dymex Healthcare Co., Ltd

5. Device Description

The Medical disposable face mask non sterile is single use, three-layer, flat–folded masks with ear loops and nose piece. The Medical disposable face mask non sterile is manufactured with three layers, the inner and outer layers are made of spunbond polypropylene, and the middle layer is made of melt blown polypropylene filter. The outer non-woven cloth is blue and is dyed by colorant of Reactive Blue 2, and the inner non-woven cloth is white and is not dyed by colorant. 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 malleable polyethylene wire. The Medical disposable face mask non sterile will be provided in blue. The Medical disposable face mask non sterile is sold non-sterile and are intended to be single use, disposable devices.

6. Indications for use

The device 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. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1 Comparison to Predicate Device

	Proposed Device	**Predicate device**	**Comparison**
510k Number	K202650	K182515	
Product Code	FXX	FXX	Same
Proprietary Name	Medical disposable face mask non sterile	Surgical Face Mask	
Model	ZL-0001	Ear Loop	
Manufacturer	Guangdong Zhong Ling Industrial Group Co., Ltd.	Wuhan Dymex Healthcare Co., Ltd	
Indications for Use	The device is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and	The Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and	Same

		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.	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		Over-the-counter	Over-the-counter	Same
Structure		Ear Loops, Flat Pleated, 3 layers	Ear Loops, Flat Pleated, 3 layers	Same
Materials	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	Malleable polyethylene wire	Malleable polyethylene wire	Same
	Ear loops	Spandex	Spandex	Same
Color		Blue	Yellow	Different[1]
Dimension		175mm×95mm	17.5cm×9.5cm (± 0.2cm)	Same
OTC use		Yes	Yes	Same
Sterility		Non-sterile	Non-sterile	Same
Use		Single Use, Disposable	Single Use, Disposable	Same
Fluid Resistance Performance ASTM F1862		3 batches, synthetic blood penetration of 32 test articles per each batch is none seen at 120mmHg test pressure	32 out of 32 pass at 120mmHg	Same

Particulate Filtration Efficiency ASTM F2299	3 batches, average PFE of 32 test articles per each batch: >99.986%, >99.986%, >99.982%; standard deviation: 0.0123, 0.0142, 0.0389	99.7%	Same
Bacterial Filtration Efficiency ASTM F2101	3 batches, BFE of 32 test articles per each batch: >99.9%, >99.9%, >99.9%	99.9%	Same
Differential Pressure (Delta P) EN 14683:2019+AC:2019 Annex C, Flow rate 8 L/min	3 batches, Delta P of 32 test articles per each batch: 2.7-3.2 mmH_2O/cm^2, 2.7-2.9 mmH_2O/cm^2, 2.6- 3.0mmH_2O/cm^2	4.0mmH_2O/cm^2	Same
Flammability 16 CFR 1610	Class 1 3 batches, 32 test articles per each batch are ignited, but extinguished	Class 1 Non Flammable	Same
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic	Under the conditions of the study, the device is non-cytotoxic	Same
Irritation	Under the conditions of the study, the device is non-irritating	Under the conditions of the study, the device is non-irritating	Same
Sensitization	Under the conditions of the study, the device is non-sensitizing	Under the conditions of the study, the device is non-sensitizing	Same
Standard	ASTM F2100-19 ISO10993-1	ASTM F2100-19 ISO10993-1	Same

	ISO10993-5 ISO10993-10	ISO10993-5 ISO10993-10	

8. Justification of differences

Note 1: Our device and the predicate device are almost identical in terms of all areas described in the above table (*Table 1*). The difference in the colors 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 and color additives.

9. Summary of Non-Clinical Testing:

The proposed devices were tested and conformed to 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.

Table 2 Performance testing

Item	Proposed device[1]	Acceptance Criteria	Results
Fluid Resistance Performance ASTM F1862	32 out of 32 pass at 120mmHg	29 out of 32 pass at 120mmHg	3 batches, synthetic blood penetration of 32 test articles per each batch is none seen at 120mmHg test pressure
Particulate Filtration Efficiency ASTM F2299	Level 2≥ 98%	Level 2≥ 98%	3 batches, average PFE of 32 test articles per each batch: >99.986%, >99.986%, >99.982%; standard deviation: 0.0123, 0.0142, 0.0389
Bacterial Filtration Efficiency ASTM F2101	Level 2≥ 98%	Level 2≥ 98%	3 batches, BFE of 32 test articles per each batch: >99.9%, >99.9%, >99.9%

Differential Pressure (Delta P) EN 14683:2019+AC:2019 Annex C, Flow rate 8 L/min	Level 2 < 6.0mmH_2O/cm^2	Level 2 < 6.0mmH_2O/cm^2	3 batches, Delta P of 32 test articles per each batch: 2.7-3.2 mmH_2O/cm^2, 2.7-2.9 mmH_2O/cm^2, 2.6- 3.0mmH_2O/cm^2
Flammability 16 CFR 1610	Class 1	Class 1	Class 1 3 batches, 32 test articles per each batch are ignited, but extinguished

Note 1: The samples of three various production batches are complied with the requirements of ASTM F2100-19.

Table 3 Biocompatibility testing

Item	Proposed device	Result
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic	Pass
Irritation	Under the conditions of the study, the device is non-irritating	Pass
Sensitization	Under the conditions of the study, the device is non-sensitizing	Pass

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K182515 Surgical Face Mask.