March 4, 2021

Feng Chun Yuan Medical Equipment (Shenzhen) Co., Ltd
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K210225
Trade/Device Name: Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 27, 2021
Received: January 28, 2021

Dear Prithul Bom:

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 and Part 809); 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 Ryan Ortega, PhD
Acting 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)*
K210225

Device Name
Surgical Face Mask (Ear loops and Tie-on)

Indications for Use *(Describe)*
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, provided non-sterile.

Level 2 Face Mask Models: # FCY-L2-E, FCY-L2-T
Level 3 Face Mask Models: # FCY-L3-E, FCY-L3-T

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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This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: ___K210225_____

1. Date of Preparation: 3/2/2021

2. Sponsor Identification

FENG CHUN YUAN MEDICAL EQUIPMENT (SHENZHEN)CO., LTD
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4. US Agent

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5. Identification of Proposed Devices

Common Name: Surgical Mask
Trade Name: Surgical Face Mask (Ear loops and Tie-on)
Models: Show in Table 1.

Table 1 Surgical Face Mask Model Numbers of proposed devices

Mask Style	**Ear Loops**	**Tie-on**
Level 2	FCY-L2-E	FCY-L2-T
Level 3	FCY-L3-E	FCY-L3-T

Regulatory Information
Classification Name: Mask, Surgical
Classification: II;
Product Code: FXX;
Regulation Number: 21CFR 878.4040
Review Panel: General Hospital

Indication for use:
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, provided non-sterile.

Level 2 Face Mask Models: FCY-L2-E, FCY-L2-T
Level 3 Face Mask Models: FCY-L3-E, FCY-L3-T

Device Description:

The Proposed device has one size 17.5 cm x 9.5 cm and two wear types of Ear Loops and Tie-On. They are available in blue and white colors and three barrier levels (Level 2, Level 3) according to ASTM F2100:2019, The details show in below table:

Specification		17.5cm × 9.5cm	
Models		Ear loops	Tie-on
ASTM F2100 Level	Level 2	Blue	Blue
		White	White
	Level 3	Blue	Blue
		White	White

The proposed Level 2 and Level 3 masks are the same product which can pass ASTM F2100-19 Level

2 & 3 at the same time; they are classified into level 2 or level 3 just because of the marketing strategies. All the materials of proposed tie-on masks are included in ear loops masks. The outer layer, inner layer, middle melt-blown layer and PET coated iron wire nose clip of tie-on masks are exactly the same with ear-loop masks, the tie tapes of tie-on masks are same as the outer layer of white mask body but 3 layers folded and physically ultrasonic welding together.

The proposed mask can form a physical barrier by being worn on the mouth and nose of medical staff to protect both the patient and healthcare personnel from the spread of microorganisms, blood and body fluids, and particulate materials.

The proposed subject device, surgical face mask, operates by acting as a physical barrier. The barrier protects the medical staff, patient, and healthcare personnel from the spread of microorganisms, blood and body fluids, and particulate materials. The barrier goes over the mouth and nose of the user.

6. Identification of Predicate Devices

510(k) Number: K160269
Product Name: Surgical Face Masks (Ear loops and Tie-on)
Models: Show in Table 2

Table 2 Surgical Face Mask Model Numbers of predicate devices

Mask Style	**Ear loops**	**Tie-On**
Level 1	EL 10000	TO 10000
Level 1 with Visor	EL 10010	TO 10010
Level 2	EL 20000	TO 20000
Level 2 with Visor	EL 20010	TO 20010
Level 3	EL 30000	TO 30000
Level 3 with Visor	EL 30010	TO 30010

7. Non-Clinical Test Conclusion

The test results demonstrated that the proposed devices are in compliance with the following standards:

- ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) [FR Recognition #6-406]
- ASTM F2299/F2299M-03(2017) Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres
- ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus [FR

Recognition #6-427]

- 16 CFR 1610 Standard for the Flammability of Clothing Textiles Corrections
- ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks [FR Recognition #6-425]
- EN 14683:2019+AC: 2019 Annex C Medical face masks. Requirements and test methods
- ISO 10993-5:2009 Biological evaluation of medical device- Part 5: Tests for in vitro cytotoxicity [FR Recognition #2-245]
- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritation and skin sensitization.[FR Recognition #2-174]

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Summary of Technological Characteristics

Table 3 Comparison of Surgical Face Mask

ITEM	Proposed Device K210225 Surgical Face Mask (Ear loops and Tie-on)		Predicate Device K160269 Surgical Face Masks (Ear loops and Tie-on)			Remark
	Level 2	Level 3	Level 1	Level 2	Level 3	
Product Code	FXX		FXX			Same
Regulation No.	21 CFR 878.4040		21 CFR 878.4040			Same
Class	II		II			Same
Indication for Use	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, provided non-sterile. Level 2 Face Mask Models: # FCY-L2-E, FCY-L2-T Level 3 Face Mask Models: # FCY-L3-E, FCY-L3-T		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, provided non-sterile. Level 1 Face Mask Models: # EL 10000, EL 10010, TO 10000, TO 10010 Level 2 Face Mask Models: # EL 20000, EL 20010, TO 20000, TO 20010 Level 3 Face Mask Models: # EL 30000, EL 30010, TO 30000, TO 30010			Same
Mask style	Flat pleated		Flat pleated			Same
Design feature	Ear loops/ Tie-on		Ear loops/ Tie-on			Same

Dimension (mm)	Ear loops: Body: 175 mm×95 mm, nose clip: 105mm, Earl oops: 200mm Tie-on: Body: 175 mm×95 mm, nose clip: 105mm, Mask tie: 875mm		175 mm×90 mm 180 mm×90 mm			Different Different size Analysis 1
Level	Level 2	Level 3	Level 1	Level 2	Level 3	Same
Fluid resistance	Pass at 120mmHg	Pass at 160mmHg	Pass at 80mmHg	Pass at 120mmHg	Pass at 160mmHg	Same
Particulate efficiency level	Pass at 99.5%	Pass at 99.5%	Pass at 99.6%	Pass at 99.6%	Pass at 99.7%	Similar, Same test and pass, different data, Analysis 2
Bacterial filtration level	Pass at 99.9%	Pass at 99.9%	Pass at >98%	Pass at >98%	Pass at >99%	Similar, Same test and pass, different data, Analysis 3
Differential pressure	Pass at 3.6mmH_2O/cm^2	Pass at 3.6mmH_2O/cm^2	Passed at 2.0 mmH_2O/cm^2	Passed at 1.6 mmH_2O/cm^2	Passed at 2.5 mmH_2O/cm^2	Different, Both reports pass, Using different Recognized Consensus Standards. Analysis 4
Flammability	Class 1		Class 1			Same
Label/Labeling	Complied with 21 CFR part 801		Complied with 21 CFR part 801			Same
Materials						
Outer layer Material	25g/m^2 non-woven fabric (Polypropylene)		Polypropylene			Similar, No weight/unit data available for predicated device

			Analysis 5
Inner layer Material	25g/m^2 non-woven fabric (Polypropylene)	Polypropylene	Similar, No weight/unit data available for predicated device Analysis 6
Middle layer Material	25g/m^2 melt blown (Polypropylene)	1. Polypropylene spunbond 2. Polypropylene meltblown	Different, 1 middle layer of proposed device while 2 middle layers of predicated device, Analysis 7
Nose Clip	PET (Polyethylene terephthalate) coated Iron wire	Polyethylene coated steel wire	Different, Iron wire of proposed device while steel wire of predicated device Analysis 8
Ear Loops	Polyurethane, Poly[imino(1-oxo-1,6-hexanediyl)]	Polyester, Polyurethane, Side tapes: Polyester spunbond (ear loops mask only)	Different, Different fiber composition Analysis 9
Tie Tapes	Non-woven fabric (Polypropylene)	Polypropylene spunbond or Polyester spunbond	Different, 1 kind of composition for proposed device while 2 kinds of composition for choosing for predicated device Analysis 10
Colors	blue and white	blue and white	Same

Biocompatibility			
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Sensitization	No Sensitization	No Sensitization	Same
Irritation	No Irritation	No Irritation	Same
Sterility	Non-Sterile	Non-Sterile	Same

Analysis 1 - Dimension (mm)

The dimension of the proposed devices is different from predicate devices.

Dimensions of proposed device (Ear loops: Body: 175 mm×95 mm, nose clip: 105mm, Earl oops: 200mm；Tie-on: Body: 175 mm×95 mm, nose clip: 105mm, Mask tie: 875mm), while predicated device (175 mm×90 mm, 180 mm×90 mm). The size of proposed device can cover an adult's mouth and nose, the performance testing pass level 2, 3, It can fulfill its function and intended use to protect the wearer. The materials used are biocompatible which are supported by biocompatibility testing, we also have clear user instructions on the labeling and user manual. Therefore, the dimensional difference does not affect the safety and effectiveness between the proposed devices and predicate devices.

Analysis 2 - Particulate efficiency level

The test result of particulate filtration efficiency for the proposed devices is different from predicate devices. However, the test result of the proposed devices can meet the requirements of level 2/ level 3 according to ASTM F2100-19 and ASTM F2299/F2299M-17. Therefore, this difference does not affect the safety and effectiveness of proposed devices.

Analysis 3 - Bacterial filtration level

The test result of bacteria filtration efficiency for the proposed devices is different from predicate devices. However, the test result for the proposed devices can meet the requirements of level 2/ level 3 according to ASTM F2100-19 and ASTM F2101-19. Therefore, this difference does not affect the safety and effectiveness of proposed device.

Analysis 4 - Differential pressure

The test result and reference standard of differential pressure for the proposed devices are different from predicate devices. The test method of

differential pressure for proposed devices is EN14683:2019+AC: 2019 Annex C, while for predicate devices is MIL-M36945C. This difference is due to the fact that the standard EN14683:2019+AC: 2019 is approved by FDA instead of mil-M36945C. Meanwhile, the test result of proposed devices can meet the requirements of level 2/ level 3 according to ASTM F2100-19 and EN14683:2019+AC:2019 Annex C. Therefore, this difference does not affect the safety and effectiveness of proposed devices.

Analysis 5 - Outer Material

The Outer Material of proposed devices is 25g/m^2 non-woven fabric (Polypropylene) and the predicate devices is Polypropylene. Both the two materials refer to the non-woven fabric which is made of polypropylene. The performance test and biocompatibility test were performed, under the conditions of the study, the device was found to be non-cytotoxic, non-sensitizing and non-irritating, so that the material differences will not affect the issue of safety and effectiveness of proposed devices.

Analysis 6 - Inner Material

The Inner Material of proposed devices is 25g/m^2 non-woven fabric (Polypropylene) and the predicate devices is Polypropylene. Both the two materials refer to the non-woven fabric which is made of polypropylene. The performance test and biocompatibility test were performed, under the conditions of the study, the device was found to be non-cytotoxic, non-sensitizing and non-irritating, so that the material differences will not affect the issue of safety and effectiveness of proposed devices.

Analysis 7 - Middle layer material

The middle layer material of proposed device is 25g/m^2 melt blown (Polypropylene), while the predicate devices is Polypropylene spunbond and Polypropylene melt-blown. Both the two materials refer to the melt blown fabric which is made of polypropylene. The performance test and biocompatibility test were performed, under the conditions of the study, the device was found to be non-cytotoxic, non-sensitizing and non-irritating, so that the material differences will not affect the issue of safety and effectiveness of proposed devices.

Analysis 8 - Nose Clip

The materials of Nose Clip for proposed devices are different from predicate devices. The materials of Nose Clip for proposed devices are PET (Polyethylene terephthalate) coated Iron wire while the predicate devices are Polyethylene coated steel wire. The performance test and biocompatibility test were performed, under the conditions of the study, the device was found to be non-cytotoxic, non-sensitizing and non-irritating, so that the material

differences will not affect the issue of safety and effectiveness of proposed devices.

Analysis 9 - Ear Loops

The materials of Ear Loops for proposed devices are partly different from predicate devices. The materials of Ear Loops for proposed devices are Polyurethane and Poly[imino(1-oxo-1,6-hexanediyl)] while the predicate devices is Polyester and Polyurethane. The performance test and biocompatibility test were performed, under the conditions of the study, the device was found to be non-cytotoxic, non-sensitizing and non-irritating, so that the material differences will not affect the issue of safety and effectiveness of proposed devices.

Analysis 10 - Tie Tapes

The material of Tie Tapes for proposed devices is partly different from predicate devices. The material of Tie Tapes for proposed devices is non-woven fabric (Polypropylene) while the predicate devices are Polypropylene spunbond or Polyester spunbond. The performance test and biocompatibility test were performed, under the conditions of the study, the device was found to be non-cytotoxic, non-sensitizing and non-irritating, so that the material differences will not affect the issue of safety and effectiveness of proposed devices.

10. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K210225, the Surgical Face Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K160269.