September 26, 2022

Jingzhou Haixin Green Cross Medical Products Co., Ltd.
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Century Avenue
Shanghai, 200122
China

Re: K222266
Trade/Device Name: Surgical Mask (GFM 96, GFM 91, GFM 90, GFM 88, GFM 81, GFM 80)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 28, 2022
Received: July 28, 2022

Dear Ivy 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,

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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.

Submission Number *(if known)*

K222266

Device Name

Surgical Mask (GFM 96, GFM 91, GFM 90, GFM 88, GFM 81, GFM 80)

Indications for Use *(Describe)*

The Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The medical surgical mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This 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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JINGZHOU HAIXIN GREEN CROSS MEDICAL PRODUCTS CO.,LTD.
YONGXING NORTH ROAD NO.2 JINGZHOU HUBEI, CHINA

510(K) Summary

(As requirement by 21 CFR 807.92)

Date prepared: 21st, July, 2022

A. Applicant:

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B. Device:

Trade Name: Surgical Mask
Model: GFM 96, GFM 91, GFM 90, GFM 88, GFM 81, GFM 80

Regulatory Information
Classification Name: Surgical Face Mask
Classification: Class II
Product code: FXX
Regulation Number: 21 CFR 878.4040
Review Panel: Surgical Apparel

C. Predicate device: (Primary)

K210147
Proprietary Name:
Unico High Performance Surgical Mask
Unico High Performance Surgical Mask with Face Shield
Common Name: Surgical Mask
Classification Name: Surgical Mask (21 CFR 878.4040)

JINGZHOU HAIXIN GREEN CROSS MEDICAL PRODUCTS CO.,LTD.
YONGXING NORTH ROAD NO.2 JINGZHOU HUBEI, CHINA

Regulatory Class: II
Product Code: FXX

D. Indications for use of the device:

The Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The medical surgical mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This a single use, disposable device(s), provided non-sterile.

E. Device Description:

The proposed surgical masks are blue color, three-layer, flat-pleaded masks with nose piece, ear loops or ties, which are composed of inner layer, middle layer and outer layer, with or without anti-fog foam strips and eye shield. The outer layers contains blue colorant and the inner layer contains white colorant, which are made of polypropylene.

Below are the configuration of each model.

GFM 96 - three-layer, flat-pleated with ear loops
GFM 91 - three-layer, flat-pleated with ear loops and anti-fog foam strip attached to nose clip
GFM 90 - three-layer, flat-pleated with ear loops, anti-fog foam strip attached to nose clip and eye shield
GFM 88 - three-layer, flat-pleated with ties
GFM 81 - three-layer, flat-pleated with ties and anti-fog foam strip attached to nose clip
GFM 80 - three-layer, flat-pleated with ties, anti-fog foam strip attached to nose clip and eye shield

The inner layer and outer layer of the mask are made of spunbond polypropylene, the middle layer is made of melt-blown polypropylene. The ear loops or ties of the subject mask are held in place over the users' mouth and nose by two ear loops or ties welded to the face mask. The ear loop is made with polyester and spandex, while the ties are made of spunbond polypropylene. The nose piece in the layers of face mask is to allow the user to fit the mask around their nose, which is made of PP and metal.

The masks may also contain an eye shield made from a polyethylene terephthalate film (PET) with foam strip. The eye shield is adhered to the top edge of the mask to cover the upper part of the eye to prevent potential exposure to blood and body fluids.

The surgical masks are sold non-sterile and are intended to be single use, disposable devices.

The masks are designed and manufactured in accordance with ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks.

F. Non-clinical Test Conclusion

JINGZHOU HAIXIN GREEN CROSS MEDICAL PRODUCTS CO.,LTD.
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The Surgical Masks were tested in accordance with the tests recommended in the FDA guidance document, Guidance for Industry and FDA Staff Surgical Masks – Premarket Notification [510(k)] Submission issued March of 2004. Based upon the guidance document the following testing has been performed.

Test Methodology	Purpose	Acceptance Criteria for Level 3 Barrier	Result
Bacterial Filtration Efficiency ASTM F2101	Measure bacterial filtration efficiency	≥98%	Passed 3 non-consecutive lots tested, using a sample size of 32/lot Lot 1: ⩾98% Lot 2:⩾98% Lot 3:⩾98%
Differential Pressure (mmH_2O/cm^2) EN 14683:2019 Annex C	Determine breathability of the mask	<6.0 mmH_2O/cm^2	Passed 3 non-consecutive lots tested, using a sample size of 32/lot Lot 1: <6.0 Lot 2: <6.0 Lot 3: <6.0
Sub-micron Particulate Filtration Efficiency ASTM F2299-17	Measure initial particle filtration efficiency	≥98%	Passed 3 non-consecutive lots tested, using a sample size of 32/lot Lot 1: ⩾98% Lot 2: ⩾98% Lot 3: ⩾98%
Resistance to Penetration by Synthetic Blood ASTM F1862-17	Evaluate the resistance to penetration by impact of small volume of synthetic blood	29 out of 32 pass at 160 mmHg	Passed 3 non-consecutive lots tested, using a sample size of 32/lot Lot 1: 32 out of 32 pass at 160 mmHg Lot 2: 32 out of 32 pass at 160 mmHg Lot 3: 32 out of 32 pass at 160 mmHg
Flammability 16 CFR Part 1610-2008	Response of materials to heat and flame	Class I	Passed 3 non-consecutive lots tested, using a sample size of 32/lot Lot 1: Class 1 Lot 2: Class 1 Lot 3: Class 1

Biocompatibility Testing

The biocompatibility evaluation for the Surgical Mask was conducted in accordance with ISO 10993-1:2018 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing within a Risk Management Process, as recognized by FDA. The Medical Surgical Mask is classified as a surface contacting device. Specific biocompatibility tests were selected under the guidance of ISO 10993-1:2018 Annex A.

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Biocompatibility Evaluation				
Biological Effect		**Standard**	**Result**	
1	Cytotoxicity	ISO 10993-5	Non-cytotoxic	Passed
2	Sensitization	ISO 10993-10	Non-sensitizing	Passed
3	Irritation	ISO 10993-10	Negligibly irritating	Passed

G. Summary of Technological Characteristics

Table 1 Comparison of Proposed and Predicate Devices

Device	Proposed Device	Predicate Device	Result
510K #	-	K210147	-
Manufacturer	JINGZHOU HAIXIN GREEN CROSS MEDICAL PRODUCTS CO.,LTD.	Unicoglobal, Inc.	-
Product Name and Models	Surgical Mask GFM 96, GFM 91, GFM 90, GFM 88, GFM 81, GFM 80	Unico High Performance Surgical Mask with Face Shield Unico High Performance Surgical Mask	Similar
Design Feature	GFM 96 - three-layer, flat-pleated with ear loops GFM 91 - three-layer, flat-pleated with ear loops and anti-fog foam strip attached to nose clip GFM 90 - three-layer, flat-pleated with ear loops, anti-fog foam strip attached to nose clip and eye shield GFM 88 - three-layer, flat-pleated with ties GFM 81 - three-layer, flat-pleated with ties and anti-fog foam strip attached to nose clip GFM 80 - three-layer, flat-pleated with ties, anti-fog foam strip attached to nose clip and eye shield	Ear loops or tie-on, flat pleated, 4 layers with eye shied and anti-glare strip	Different
Level	Level 3	Level 3	Same
Product Code	FXX	FXX	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Indications for use	The Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The medical surgical mask is intended for use in infection	The Unico High Performance Surgical Mask and the Unico High Performance Surgical Mask with Face Shield are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and	Same

	control practices to reduce the potential exposure to blood and body fluids. This a single use, disposable device(s), provided non-sterile.	particulate material. These face masks are intended for use in infection control practices to reduce potential exposure to blood and body fluids. The face masks are single use, disposable device, provided non-sterile.	
Color	Blue	Blue and Green	Similar
Dimension	Length: 17.5±0.5cm Width: 9.5±0.5cm	Length: 6.9" ± 0.2" Width: 3.74" ± 0.2"	Same
Sterility	Non-sterile	Non-sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
Material			
Outer layer	Spunbond polypropylene	Polypropylene Spunbond	Same
Middle layer	Melt-blown polypropylene	Polypropylene Spunbond and Polypropylene Meltblown	Different
Inner layer	Spunbond polypropylene	Polypropylene Spunbond	Same
Nose clip	Polypropylene wrapped metal With or without additional foam strip	PVC Coated Zinc Wire	Different
Ear loops	polyester and spandex	Cotton 50% Spandex 50% cord	Different
Tie Strings	Spunbond polypropylene	Polypropylene Spunbond	Same
Eye Shield	Polyethylene terephthalate	Protective film: Polyethylene 100% Film: Polyethylene terephthalate 100%	Different
Technological Characteristics Product Barrier Specifications Per ASTM F2100 – Meets Level 3			
Particulate Filtration Efficiency (PFE)	Passed at ≥98% ASTM F2299	Passed at ≥98% ASTM F2299	Same
Fluid Resistance	Passed at 160mm Hg ASTM F1862	Passed at 160mm Hg ASTM F1862	Same
Bacterial Filtration Efficiency (BFE)	Passed at ≥98% ASTM F2101	Passed at ≥98% ASTM F2101	Same
Differential Pressure	Passed at <6 mmH_2O/cm^2 MIL-M36954C	Passed at <6 mmH_2O/cm^2 MIL-M36954C	Same
Flammability	Class I	Class I	Same
Biocompatibility			
Result	Non-cytotoxic, Nonsensitizing, Non-irritating	Non-cytotoxic, Nonsensitizing, Non-irritating	Same

Difference Analysis:

The proposed device has different product models to the predicate device. The proposed device has six models. The model with the most complex configuration, which has anti-fog foam strip attached to nose clip and eye shield, is similar to the predicate device in regards of design. Other models of the proposed device has no foam strip attached to nose clip or eye shield, which will not raise any concern in safety and effectiveness.

The proposed device has different layer number and materials of middle layer, nose clip and shield. But non-clinical performance tests and the biocompatibility tests have been performed on the proposed device according to ASTM F2100, ISO 10993-5 and ISO 10993-10 respectively and the results do not show any adverse effect.

The subject device and the predicate device have the same indications for use and dimension, and has similar design and technological characteristics. Therefore, the above-mentioned differences will not affect the safety and effectiveness between the proposed device and the predicate device.

H. Summary of Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specification. The test results demonstrated that the proposed device complies with the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Mask - Premarket Notification [510(K)] Submission issued on March 5, 2004:

- ISO 10993-05:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation And Skin Sensitization
- ASTM F2100, Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F1862, Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- EN 14683, Medical Face Masks - Requirements and Test Methods
- ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus Aureus
- ASTM F2299, Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- 16 CFR 1610, Standard for the Flammability of Clothing Textiles

I. Clinical Test Conclusion

No clinical study is included in this submission.

J. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Medical Surgical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K210147.