January 29, 2021

Hunan Heng Chang Pharmaceutical Co., Ltd.
% Shelley Li
Director
Shanghai Landlink Medical Information Technology Co., Ltd.
Room 703, 705, Baohua International Plaza,
West Guangzhong Road 555, Jingan
Shanghai, 200071
China

Re: K202358
Trade/Device Name: Protective Face Mask for Medical Use
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 23, 2020
Received: December 28, 2020

Dear Shelley Li:

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)*
K202358

Device Name
Protective Face Mask for Medical Use

Indications for Use *(Describe)*
The Protective Face Mask for Medical Use is intended to worn by the healthcare personnel during procedure to protect both the patient and the healthcare personnel from the 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/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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510(k) summary: K202358

I. Submitter

Hunan Heng Chang Pharmaceutical Co., Ltd.

Floor 2，3, 102 of Building 16, Standard Plant of Shanhe Pharmaceutical and Health Industrial Park, No. 1048, Zhongqing Road, Kaifu District, Changsha 410000, China

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E-mail: taojingfeng@hcyy.com
Preparation date: Dec.23, 2020

II. Proposed Device

Trade Name of Device:	Protective Face Mask for Medical Use
Common name:	Surgical Mask
Regulation Number:	21 CFR 878.4040
Regulatory Class:	Class II
Product code:	FXX
Review Panel	General Hospital
510(k) Number	K202358

III. Predicate Devices and Reference Device

Predicate device

510(k) Number:	K143287
Trade name:	FLUIDSHIELD Surgical Mask with Expanded Chamber
Common name:	Surgical Mask
Classification:	Class II
Product Code:	FXX
Manufacturer	Halyard Health, Inc.

Reference Device

510(k) Number:	K160271
Trade name:	N95 Particulate and Surgical Mask, Models TN01-11 and TN01-12
Common name:	Surgical Respirator

Classification:	Class II
Product Code:	MSH
Manufacturer	San-M Package Co., Ltd.

IV. Device description

The Protective Face Masks for Medical Use are flat-folded masks are three layers of materials consisting of polypropylene spun-bond (outer layer and inner layer), polypropylene melt-blown (middle layers). The masks contain a conformable nose piece enclosed in a binding tape welding the top edge to conform to the contours of the face. In addition, the masks contain an ultrasonically welded, elastic ear loops not made with natural rubber latex, to secure the masks in place on the wearer. The masks are offered in white.

The Protective Face Masks for Medical Use are single use, disposable device, provided non-sterile/sterile.

V. Indication for use

The Protective Face Mask for Medical Use is intended to worn by the healthcare personnel during procedure to protect both the patient and the healthcare personnel from the 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/sterile.

VI. Comparison of technological characteristics with the predicate devices

Table 1-Comparison of proposed device and predicate devices

Item	Proposed device (K202358)	Predicate device (K143287)	Reference device (K160271)	Discussion
Product name	Protective Face Mask for Medical Use	FLUIDSHIELD Surgical Mask with Expanded Chamber	N95 Particulate and Surgical Mask, Models TN01-11 and TN01-12	-
Product Code	FXX	FXX	MSH	Similar
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	21 CFR 878.4040	Same
Class	Class II	Class II	Class II	Same

Mask style		Flat-fold, ear loop, three layers	Expanded Chamber (Duckbill) Flat-fold, headband ties , 4 Layers	Flat-fold, Headband, 4 Layers	Similar[1]
Indication for use		The Protective Face Mask for Medical Use is intended to worn by the healthcare personnel during procedure to protect both the patient and the healthcare personnel from the 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/sterile.	The Expanded Chamber Surgical 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.	The N95 Particulate Respirator and Surgical Mask, Models TN01-11 and TN01-12 are single use , disposable devices, provided non-sterile and are intended to be worn by operating room personnel or other healthcare workers to protect both the patient and operating room personnel from of microorganisms, body fluids and particulate material.	Similar to predicate device Different from reference device
Material	Inner layer	Spun-bond polypropylene	Polyethylene/Polyester	Polypropylene and polyethylene	Different[2]
	Middle layer	Melt blown polypropylene filter	Middle layer #1: polypropylene Spunbond Middle layer #2: Polypropylene Meltblown	Two filter layers Polypropylene meltblown	Similar
	Outer layer	Spun-bond polypropylene	Top Half: Blue Polypropylene Spunbond (w Print) Bottom Half: White Polypropylene	Polypropylene spunbond	Similar

			Spunbond		
	Ear loop/ head band	Spandex + Polyester	Polyester Spunlace or Polypropylene Spunbond	Polyurethane, not made with natural rubber latex	Different[2]
	Nose piece	Outer plastic, inner aluminum wire, Sponge strips	Unknown	Polyethylene coated steel wire	Different[2]
Offered with Visor		No	Yes	No	Different
Color		White	Top Half: Blue Bottom Half: White	Orange / White	Different[2]
Dimensions		Length: 16cm Width: 20cm	Length: 19cm Width: 21cm	TN01-12 (Small): Length: 205 ± 5 mm Width: 75 ± 5 mm Band length: 205 ± 5 mm TN01-11 (Medium): Length: 240 ± 5 mm Width: 75 ± 5 mm Band length: 240 ± 5 mm	Different[3]
OTC use		Yes	Yes	Yes	Same
Sterility		Non-sterile/sterile	Non-sterile	Non-sterile	Different[4]
For single use		Yes	Yes	Yes	Same
ASTM F2100 Level		ASTM F 2100-19, Level 2	ASTM F2100-11, Level 2	ASTM F2100-11, Level 3	Similar[4]
Fluid Resistance Performance		pass at 120mmHg	pass at 120mmHg	pass at 160mmHg	Same as the predicate device
Particulate Filtration Efficiency		≥98%	≥98%	NIOSH Certification #TC 84A-3348 (includes TN01-11 & TN01-12)	Same as the predicate device
Bacterial		≥98%	≥98%	NIOSH Certification	Same as the

Filtration Efficiency			#TC 84A-3348 (includes TN01-11 & TN01-12)	predicate device
Differential Pressure	<6.0mmH_2O/cm^2	<5.0mmH_2O/cm^2	NIOSH Certification #TC 84A-3348 (includes TN01-11 & TN01-12)	Similar[4]
Flammability	Class I non flammable	Class I non flammable	Class I non flammable	Same
Biocompatibility	Confirm to the requirements of ISO 10993 series standards	Confirm to the requirements of ISO 10993 series standards	Confirm to the requirements of ISO 10993 series standards	Same

[1] The physical feature of the proposed device has minor difference from the predicate device. But the proposed device has similar mask shape with the reference device, which it is a surgical respirator. Both of them have the similar indications. The conclusion can be drawn out that the different mask style does not affect the indications of the device.

[2] The difference in the materials does not raise additional questions for safety and effectiveness of the device. The biocompatibility evaluation test of the subject devices have been performed on the final finished device. The test results shows pass the requirements.

[3] Compare with the predicate and reference device, the different of the physical feature or size does not affect the intended use of the subject device.

[4] The subject device (sterile or non-sterile) has performed performance test according to the ASTM F 2100-19. The test results demonstrate that meet the acceptance criteria.

VII. Non-Clinical Testing

Non clinical performance tests were conducted to verify that the proposed device met all design specifications. The below table shows the test results of tests article, which demonstrated that the proposed device complies with the following standards:

Methodology	Purpose	Acceptance Criteria	Results
ASTM F1862M-17	Fluid Resistance Performance	29 out of 32 pass at 120mmHg	32 out of 32 pass at 120mmHg
ASTM F2299	Particulate Filtration Efficiency	≥98%	98.9~99.9%
ASTM F2101-19	Bacterial Filtration Efficiency	≥98%	98.9~99.9%
EN 14683:2019 Annex C	Differential Pressure	<6.0mmH2O/cm²	4.0~5.6 mmH2O/cm²
16 CFR 1610	Flammability	Class I non flammable	non flammable

- ISO 10993-5: 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 F2100-19, Standard Specification for Performance of Materials Used In Medical Face Masks.
- ASTM 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)
- EN 14683:2019, Medical Face Mask-Test-Requirements and Test Methods
- 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;
- ASTM F2299-03, Stand 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;

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusion

The conclusion drawn from the non-clinical performance testing data demonstrates that the subject device is as safe, as effective, and performs as well as the predicate

device, FLUIDSHIELD Surgical Mask with Expanded Chamber (K143287).