September 8, 2020
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: K202354
Trade/Device Name: Surgical Mask-Model Number CW01
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 13, 2020
Received: August 19, 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.
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)*
K202354

Device Name
Surgical Mask

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. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: K202354

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

Contact person: Tao Jingfeng
Position: QC Manager
Tel.: ++86-18774961605
E-mail: taojingfeng@hcyy.com

Preparation date: Aug. 27, 2020

II Proposed Device

Trade Name of Device:	Surgical Mask
Common name:	Surgical Mask
Regulation Number:	21 CFR 878.4040
Regulatory Class:	Class II
Product code:	FXX
Review Panel:	General Hospital
510(k) Number:	K202354

III Predicate Devices

510(k) Number:	K153496
Trade name:	Disposable Surgical Face Mask
Common name:	Surgical Mask
Classification:	Class II
Product Code:	FXX
Manufacturer	Xiantao Rayxin Medical Product Co., Ltd.

IV Device description

The Surgical Masks are Flat Pleated type mask, utilizing Ear Loops way for wearing, and they all have Nose Piece design for fitting the face mask around the nose. The Face Masks are manufactured with three layers. The outer layer is made of spun-bonded polypropylene (PP) non-woven fabric. The middle layer with filtration function is made of melt blown polypropylene (PP) non-woven fabric. The inner layer

contact with face is made of polypropylene (PP) fabric.
The Surgical Masks are single use, disposable device, provided non-sterile/sterile.

V Indication 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. 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

Item		**Proposed device (K202354)**	**Predicate device (K153496)**
Product name		Surgical Mask	Disposable Surgical Face Mask
Product Code		FXX	FXX
Regulation No.		21 CFR 878.4040	21 CFR 878.4040
Class		Class II	Class II
Mask style		Flat-pleated, ear loop, 3 layers	Flat-pleated, ear loop, tie-on, 3 layers
Indication 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. 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 Disposable 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(s), provided non-sterile.
Material	Inner	Spun-bond polypropylene	Spun-bond polypropylene

	layer		
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter
	Outer layer	Spun-bond polypropylene	Spun-bond polypropylene
	Ear loop	Spandex + Polyester	Polyester
	Nose piece	malleable polyethylene	Malleable aluminum wire
Color		Blue	blue
Length		17.5 cm±5%	17.5±1cm
Width		9.5 cm±5%	9.5±1cm
OTC use		Yes	Yes
sterile		Non-sterile, sterile	Non-sterile
Sterilization method		EO	/
Single for use		Yes	Yes
ASTM F2100 Level		Level 1	Level 2
Biocompatibility		Confirm to the requirements of ISO 10993 series standards	Confirm to the requirements of ISO 10993 series standards

VII Summary of 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 test 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	≥95%	95.8~96.8%
ASTM F2101-19	Bacterial Filtration Efficiency	≥95%	98.3~99.2%

EN 14683:2019 Annex C	Differential Pressure	< 5.0mmH2O/cm²	3.7~3.8 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 Summary of 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 or better than the predicate device, Disposable Surgical Face Mask (K153496).