September 17, 2020

Qiqihar Hengxin Medical Supplies, Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
China

Re: K201691
Trade/Device Name: Single-Use Surgical Mask With Ear Loop
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 18, 2020
Received: August 21, 2020

Dear Ray 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201691

Device Name
Single-Use Surgical Mask with Ear Loop

Indications for Use *(Describe)*

The Single-Use Surgical Mask with Ear Loop is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The Single-Use Surgical Mask with Ear Loop 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.
Model: M and L, blue color, and Level 2 barrier level as ASTM F2100.

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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K201691

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Preparation: 2020/09/17

2. Sponsor Identification

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3. Designated Submission Correspondent

Mr. Ray Wang

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Fax: +86-10-56335780
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4. Identification of Proposed Device

Trade Name: Single-Use Surgical Mask with Ear Loop
Common Name: Surgical Face Mask
Model(s): M, L;

Regulatory Information
Classification Name: Surgical Face Mask
Classification: II
Product Code: FXX
Regulation Number: 878.4040
Review Panel: Surgical Apparel

Indication for use Statement:
The Single-Use Surgical Mask with Ear Loop is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The Single-Use Surgical Mask with Ear Loop 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. Model: M and L, blue color, Level 2 barrier level as ASTM F2100.

Device Description
The proposed device(s) are Blue color, and Flat Pleated type mask, utilizing Ear Loops' way for wearing, and they all have Nose Piece design for fitting the facemask around the nose.

The proposed device(s) are manufactured with three layers, the inner and outer layers are made of PP spun-bond non-woven fabric, and the middle layer is made of Melt-blown non-woven fabric.
The blue colorant is bule masterbatch.

The Single-Use Surgical Mask with Ear Loop is held in place over the user's mouth and nose by two elastic ear loops welded to the facemask.
The elastic ear loops are made with Polyester.

The nose piece contained in the proposed device(s) is in the layers of the facemask to allow the user to fit the facemask around their nose, which is made of malleable aluminum wire.

The proposed device(s) are sold non-sterile and are intended to be single-use, disposable devices.

There are two models included, Model M and L. The two models share the same indication for use, instruction for use, material used, and structure. The only difference is the dimension.

5. Identification of Predicate Device(s)

Predicate Device
K153496
Disposable Surgical Face Mask
Xiantao Rayxin Medical Products Co., ltd.

6. Substantially Equivalent (SE) Comparison

Table 2 General Comparison

ITEM		Proposed Device K201691	Predicate Device K153496	Remark
Intended Use		The Single-Use Surgical Mask with Ear Loop is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The Single-Use Surgical Mask with Ear Loop 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 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.	SAME
Basic Design		Ear Loops, Flat Pleated, 3 layers	Ear Loops, Tie-On, Flat Pleated, 3 layers	SAME
Materials	Outer Facing Layer	Spun-bond non-woven fabric	Spun-bond polypropylene	SAME
	Middle Layer	Melt blown non-woven fabric	Melt blown polypropylene filter	
	Inner Facing Layer	Spun-bond non-woven fabric	Spun-bond polypropylene	
	Nose Piece	Malleable aluminum wire	Malleable aluminum wire	
	Ear Loops	Polyester	Polyester	
Color		Blue	Blue	SAME
Dimension (Length)		Model M: 14 cm +/- 1cm Model L: 18 cm +/- 1cm	17.5 cm +/- 1cm	SIMILAR
Dimension (Width)		9 cm +/- 1cm	9.5 cm +/- 1cm	
OTC use		Yes	Yes	SAME
Single Use		Yes	Yes	SAME
Sterile		No	No	SAME
ASTM F2100 Level		Level 2	Level 2	SAME

Table 3 Performance Characteristic Comparison

ITEM	Proposed Device K201691	Predicate Device K153496	ASTM F2100 Requirements for Level 2 Classification	Remark
Fluid Resistance Performance ASTM F1862	31 out of 32 pass at 120 mmHg	31 out of 32 pass at 120 mmHg	29 out of 32 pass at 120 mmHg	SIMILAR
Particulate Filtration Efficiency ASTM F2299	>99%	98.46%	⩾ 98%	
Bacterial Filtration Efficiency ASTM	>99%	98.7%	⩾ 98%	

F2101				
Differential Pressure (Delta P) MIL-M-36954C	< 5.0 mmH2O/cm^2	4.2 mmH2O/cm^2	< 6.0 mmH2O/cm^2	
Flammability 16 CFR 1610	Class 1	Class 1	Class 1	SAME

Table 4 Biocompatibility Comparison

ITEM	Proposed Device K201691	Predicate Device K153496	Remark
Cytotoxicity	Under the conditions of the study, no cytotoxicity effect	Comply with ISO 10993-5	SAME
Irritation	Under the conditions of the study, no irritation effect	Comply with ISO 10993-10	SAME
Sensitization	Under conditions of the study, no sensitization effect		SAME

7. Summary of Non-Clinical Testing

The following performance data has been provided to demonstrate that the subject device meet the acceptance criteria in the standard.

Table 1 Non-Clinical Testing

Name of the Test Methodology/standard	Purpose	Acceptance Criteria	Results
ASTM F1862	Resistance to penetration by synthetic blood	120 mm Hg	120 mm Hg
ASTM F2299	Sub-micron particulate filtration efficiency at 0.1 micron	≥ 98%	>99%
ASTM F2101	Bacterial Filtration Efficiency	≥ 98%	>99%
MIL-M-36954C	Differential Pressure	< 6.0 mm H_2O/cm^2	< 5.0 mm H_2O/cm^2
16 CFR 1610	Flammability	Class 1	Class 1
ISO 10993-5	Irritation	No irritation effect	Under the conditions of the study, no irritation effect
	Sensitization	No sensitization effect	Under conditions of the study, no sensitization effect
ISO 10993-10	Cytotoxicity	No cytotoxicity effect	Under the conditions of the study, no cytotoxicity effect

8. Summary of Clinical Testing

No clinical study is included in this submission.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Single-Use Surgical Mask with Ear Loop, is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Disposable Surgical Face Mask (K153496).