August 19, 2021

Xianning Eco Medical Articles Co., Ltd.
Wei Zhou
General Manager
No.16,Shutai Street High-Tech Industrial Zone
Xianning, Hubei 437000
China

Re: K210698
Trade/Device Name: ECOMA Disposable Surgical Mask (Ear loops)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 14, 2021
Received: July 14, 2021

Dear Wei Zhou:

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,

Clarence W. Murray, III, PhD
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)*
K210698

Device Name
ECOMA Level 2 Disposable Surgical Mask with Ear Loops

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..

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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510(k) SUMMARY

510(k) Premarket Notification for ECOMA Level 2 Disposable Surgical Mask with Ear Loops

In accordance with the requirements set forth in Title 21 CFR §807.92

1. **Submitter**: **XIANNING ECO MEDICAL ARTICLES CO., LTD.**
   No.16, Shutai Street
   High-Tech Industrial Zone
   Xianning, China 437000
   Tel: +86-715-8215222 8018
   Fax: +86-715-8217333
   FDA Registration Number: 3008240985

2. **Manufacturing Location**: **XIANNING ECO MEDICAL ARTICLES CO., LTD.**
   No.16, Shutai Street
   High-Tech Industrial Zone
   Xianning, China 437000
   Registration Number: **3008240985**

3. **Packaging Location**: **Same as Manufacturing Location**

4. **Regulatory Affairs Contact**: **Wei Zhou**
   General Manager
   Tel: +86-715-8215222 8018
   Fax: +86-715-8217333
   Email: zhouwei@ecoma.com.cn

5. **Date Summary Prepared**: Feb-08-2021

6. **Name of Device**: ECOMA Level 2 Disposable Surgical Mask with Ear Loops

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7. Trade Name: ECOMA Level 2 Disposable Surgical Mask with Ear Loops

8. Common/Classification Name: Surgical Mask

9. Regulation Number: 21 CFR §878.4040
10. Device Class: Class II
11. Regulation Name: Surgical Apparel
12. Product Code: FXX

13. Predicate Device: BH Medical Products Co., Ltd. Level 2 Surgical Mask with ear loops (K133070).

14. Device Description: The ECOMA surgical mask is composed of 3-layers and is flat-pleated. The mask materials consist of an outer layer (polypropylene spunbond, blue), filter layer (polypropylene melt blown, white), and inner layer (polypropylene spunbond, white). The three layers of the mask body are collated and sonically welded around the edges. The surgical mask contains ear loops attached by welding to secure the mask over the user's mouth and face and includes a malleable nosepiece to provide a firm fit over the nose. The surgical face mask is a single use, disposable device, provided non-sterile.
Over the counter use: Yes
Duration and type of contact: Direct contact, less than 24 hours, skin contact
Single use disposable device: Yes

15. Packaging: 50 masks/box

16. 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. 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.

17. Technological Characteristics Comparison:

:

For the Surgical Face Masks with Ear loops:

- Surgical Face Mask with Ear Loops

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- K133070
- Submitter of 510(K)/holder: BH Medical Products Co., Ltd

18. Technological Characteristics Comparison Table (Ear loop):

Element of Comparison	Predicted Device K133070	Subject Device	Comparison
Manufacturer	BH Medical Products Co., Ltd	Xianning ECO Medical Articles Co, Ltd.	**N/A**
Proprietary or Model Name	Surgical Face Mask, Ear Loops, Model 101B, 101G, 136B, 136G, 137B, 137G	Surgical Face Mask, Ear Loops, Model LV2001W-B	**N/A**
Intended 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 facemasks 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 nonsterile.	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 facemasks 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 nonsterile.	Same
ASTM Level	1, 2, 3	2	Similar
Design feature	Ear Loops and Tie on	Ear Loops	Similar
Mask styles	3 flat pleated	4 Flat pleated	Similar
Product Performance Specifications	Meet ASTM F1862-07	ASTM F1862/F1862-M-17	Similar
	Meet ASTM F2101-07	Meet ASTM F2101-19 and EN 14683:2019	Similar
	Meet ASTM F2299-03	ASTM F2299/F2299M-17	Similar
	Meet MIL-M-36954C	Meet ASTM F2100-19	Similar
	Meet 16 CFR Part 1610	Meet 16 CFR Part 1610	Similar
16 CFR Part 1610	Class 1	Class 1	similar
Single Use	Yes	Yes	same
Disposable	Yes	Yes	same

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Non-sterile	Yes	Yes	Same
Material Composition	Three-layer mask constructed of: Outer layer: spunbond polypropylene Filter layer: melt blown polypropylene Inner layer: spunbond polypropylene Binding: Spunbond Polypropylene Ear loops: Polyester Nose clip: Aluminum Wire	Three-layer mask constructed of: Outer layer: Polypropylene Spunbond Filter layer: Polypropylene Melt blown Inner layer: Polypropylene Spunbond Ear loops: Spandex elastic, polyester Nose Piece: Malleable Iron wire with plastic cover/Polypropylene	Similar
ASTM Level	1, 2, 3	2	Similar
Design feature	Ear Loops and Tie on	Ear Loops	Similar
Mask styles	3 flat pleated	4 Flat pleated	Similar
Color	Blue, Green	Blue	Same
Dimensions(L*W)	6.8” +/-0.25”x 4.2” +/-0.25”	17.5 x 9.5 cm (+/- 0.5cm)	Same
Use	Single Use; Disposable	Single Use; Disposable	Same
Biocompatibility	The surgical mask was tested in accordance with ISO10993 and passed acceptance criteria.	The surgical mask was tested with following standards: • AAMI /ANSI/ ISO 10993-5:2009, Under the testing conditions, the subject surgical mask did not show potential cytotoxicity • AAMI /ANSI/ ISO 10993-10:2010, Under the testing conditions, the subject surgical mask did not cause significant irritation or sensitization reaction to the test animals.	Same

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19. Summary of Non-Clinical Testing (ASTM F2100 Performance Testing and Biocompatibility Testing Results)

Test Methodology	**Purpose**	**Acceptance Criteria**	**Test Results**
ASTM F2101-Bacterial Filtration Efficiency (BFE)	To measure the bacterial filtration efficiency (BFE) of medical face mask materials, employing a ratio of the upstream bacterial challenge to downstream residual concentration to determine filtration efficiency of medical face mask materials.	≥ 98% Average BFE for all samples tested	96 /96 samples passed ≥ 98% Average BFE (3 lots, 32 samples per lot with a lot size of 200,000 each)
ASTM F2299-Particulate Filtration Efficiency	To determine the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex. Spheres	≥ 98% Average PFE for all samples tested	96 /96 samples passed ≥ 98% Average PFE (3 lots, 32 samples per lot with a lot size of 200,000 each)
Differential Pressure	To determine the pressure required to breathe through the final manufactured face mask	Samples must be < 6.0 mm H_2O/cm^2	96 /96 samples passed differential pressure < 6.0 mm H_2O/cm^2 (3 lots, 32 samples per lot with a lot size of 200,000 each)
ASTM F1862-Fluid Resistance	To evaluate the resistance of medical face masks to penetration by the impact of a small volume (~2mL) of a high-velocity stream of synthetic blood.	At least 29 out of 32 specimens per lot show passing results at 120 mmHg	95 /96 samples passed fluid resistance at 120 mmHg (3 lots, 32 samples per lot with a lot size of 200,000 each)
16 CFR 1610-Flammability	The purpose of this standard is to reduce danger of injury and loss of life by providing, on a national basis, standard methods of testing and rating the flammability of textiles and textile products for clothing use, thereby prohibiting the use of any dangerously	All samples must be Class I	96 /96 samples passed Class I flammability test （96 /96 samples passed Class I flammability test）

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Sensitization	Under the research conditions, determine whether the non-polar and polar extracts of the target device are irritating.	The sample is non-sensitizing.	The device was tested in accordance with ISO 10993 and passed acceptance criteria
Irritation	Under the research conditions, determine whether the non-polar and polar extracts of the target device are sensitive.	The sample is non-irritating.	
Cytotoxicity	Under the research conditions, determine whether the target device extract is cytotoxic.	The sample is non-cytotoxic.	

20. Conclusion

The conclusion drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, BH Medical Products Surgical Face Mask cleared under K133070.