February 2, 2021

EcoGuard Inc.
% Nickita Alexiades
Consultant
mdi Consultants, Inc.
55 Northern Blvd, Suite 200
Great Neck, New York 11021

Re: K202096
Trade/Device Name: 3-ply EcoGuard B with Earloop, 3-ply EcoGuard B with Tie-On
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 5, 2021
Received: January 13, 2021

Dear Nickita Alexiades:

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)*
K202096

Device Name
3-ply EcoGuard B with Earloop; 3-ply EcoGuard B with Tie-on

Indications for Use *(Describe)*
The Following EcoGuard Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. These surgical masks are intended for use in infection control practices to reduce the potential exposure to blood and bodily fluid. These surgical masks are single use, disposable devices provided non-sterile.

3-ply EcoGuard B with Earloop, Model Number: ECO01
3-ply EcoGuard B with Tie-on, Model Number: ECO02

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

The assigned 510(k) number is: K202096.

1. Submitter's Identification:

Manufacturer: EcoGuard Inc.
Address: 700 S BATTLEGROUND AVE, SUITES 103
GROVER, NC 28073

Contact Person: Ms. Fang Wang
Ecoguard Inc.

Date Summary Prepared: January 29, 2021

Official Correspondent: Mr. Nickita Alexiades
mdi Consultants, Inc.

2. Name of the Device:

Device Name(s): 3-ply EcoGuard B with Earloop, Model Number: ECO01
Model Number(s): 3-ply EcoGuard B with Tie-on, Model Number: ECO02

Common Name: Surgical Mask
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX

3. Information for the 510(k) Cleared Device (Predicate Device):

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

4. Device Description:

The proposed surgical masks are available in two models with three-ply pleated earloop or tie-on (EcoGuard B) masks with ear loops and nose piece. Detail configurations of them are presented in Table I: Surgical Masks Description.

Table 1: Surgical Masks Description

Product Model Number:	Product Model	ASTM Level
ECO01	3-Ply EcoGuard B with Earloop	Level 3
ECO02	3-Ply EcoGuard B with Tie-On	Level 3

The inner and outer layers are made of spunbond polypropylene, and the middle layer is made of melt blown polypropylene filter. The ear loops or ties are held in place over the users' mouth and nose by two elastic ear loops or four ties welded to the surgical mask. Neither the elastic ear loops, nor ties are made with natural rubber latex. The nose piece in the layers of surgical mask is to allow the user to fit the surgical

mask around their nose, which is made of malleable polyethylene wire. The surgical masks are sold non-sterile and are intended to be single use, disposable devices.

5. Indications for Use:

The following EcoGuard Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. These surgical masks are intended for use in infection control practices to reduce the potential exposure to blood and bodily fluid. These surgical masks are single use, disposable devices provided non-sterile.

3-ply EcoGuard B with Earloop, Model Number: ECO01
3-ply EcoGuard B with Tie-on, Model Number: ECO02

6. Comparison to the 510(k) Cleared Device (Predicate Device):

Table 2: Comparison to Predicate Device

Item	Subject Device	Predicate Device	Similar or Different
Manufacturer	EcoGuard Inc.	Xiantao Rayxin Medical Products Co., Ltd.	-
510K number	K202096	K153496	-
Model Name	3-ply EcoGuard B with Earloop Model Number: ECO01 3-ply EcoGuard B with Tie-on Model Number: ECO02	Disposable Surgical Face Mask	Similar
Classification	Class II Device Product Code: FXX (21 CFR878.4040)	Class II Device Product Code: FXX (21 CFR878.4040)	Similar
Indications for Use	The Following EcoGuard 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 surgical masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. These surgical masks are single use, disposable	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 nonsterile.	Similar

	devices provided non-sterile.		
Model(s) & Style	**EcoGuard B** Ear Loops Flat Pleated, 3 layers ECO01 Tie-On Flat Pleated, 3 layers ECO02	Ear Loops Tie-On Flat Pleated 3 layers	Similar
Outer Facing Layer	Spun-bond polypropylene	Spun-bond polypropylene	Similar
Middle Layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Similar
Inner Facing Layer	Spun-bond polypropylene	Spun-bond polypropylene	Similar
Nose Piece	Malleable Polyethylene wire	Malleable Aluminum wire	Different
Ear Loops or Tie-On	**Earloops:** Polyester Nylon/Spandex **Tie-On:** Polypropylene	**Earloops:** Polyester	Similar
Color	Blue	Blue	Similar
Dimension (Width)	17.5cm±2cm 6.89" ± 0.40"	17.5cm±1cm	Similar
Dimension (Length)	9.5cm±2cm 3.74" ± 0.40"	9.5cm±1cm	Similar
OTC use	Yes	Yes	Similar
Sterility	Non-Sterile	Non-Sterile	Similar
Use	Single Use, Disposable	Single Use, Disposable	Similar
ASTM F2100 Level	Level 3	Level 2	Similar
Non-Clinical Testing	ASTM F1862 ASTM F2299 ASTM F2101 ASTM F2100 MIL-M369454C 16 CFR 1610	ASTM F1862 ASTM F2299 ASTM F2101 ASTM F2100 MIL-M369454C 16 CFR 1610	Similar
Biocompatibility Testing	Cytotoxicity Irritation Sensitization	Cytotoxicity Irritation Sensitization	Similar

The difference in the materials does not raise additional questions for safety and effectiveness. Performance testing including biocompatibility evaluation has been performed on the final finished device

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The EcoGuard Surgical Masks have been tested accordance with ASTM 2100-11 Standard Specification for Performance of Materials Used in Medical Face Masks. See Table 2 for a summary of other non-clinical testing.

Table 2: Summary of Non-Clinical Testing

Test	Purpose	Acceptance Criteria per ASTM F2100-11 Level 3 (AQL = 4.0%)	Subject Device Test Results- EcoGuard B	
			ASTM F2100-11 Level 3	Average
ASTM F1862 Synthetic Blood	Determine synthetic blood penetration resistance	Level III	Pass at 160 mmHg (95/96) 32 Samples each from 3 non-consecutive lots	N/A
ASTM F2101 BFE	Determine the bacterial filtration efficiency	≥ 98%	Pass (96/96) 32 Samples each from 3 non-consecutive lots	99.9%
ASTM F2299 PFE at 0.1 micron	Determine submicron particulate filtration efficiency	≥ 99%	Pass (96/96) 32 Samples each from 3 non-consecutive lots	99.8%
Mil-M-36954C Delta P	Determine breathing resistance or differential pressure	< 6.0 mm H2O/cm2	Pass (96/96) 32 Samples each from 3 non-consecutive lots	4.4 mm H20/cm2
16 CFR 1610 Flammability	Determine flammability or flame spread	Class 1	Class 1 Pass (96/96) 32 Samples each from 3 non-consecutive lots	N/A

All testing results have met ASTM F2100-11 2019 Level 3 acceptance criteria. The testing information demonstrates that the safety and effectiveness of the EcoGuard B Surgical Masks in their intended environment of use is supported by testing that was conducted in accordance with the FDA 2004 guidance "Surgical Masks - Premarket Notification [510(k)] Submissions", which outlines performance requirements for surgical masks.

Table 3: Summary of Biocompatibility testing

Test	Testing Findings	Result
Cytotoxicity (Standard)	Under the conditions of the study, the device is noncytotoxic.	EcoGuard B: **Pass**
Irritation (Standard)	Under the conditions of the study, the device is nonirritating.	EcoGuard B: **Pass**
Sensitization (Standard)	Under the conditions of the study, the device is nonsensitizing	EcoGuard B: **Pass**

None of the biocompatibility testing results demonstrated any safety hazards or any design characteristics that violated the requirements set forth in the Guidance for Industry regarding Premarket Notification Submissions of Surgical Masks. It was our conclusion that both 3-ply EcoGuard B with Earloop and 3-ply EcoGuard B with Tie-on surgical masks met all relevant testing requirements.

8. Discussion of Clinical Tests Performed:

No Clinical testing was performed.

9. Conclusions:

Based on the comparison and analysis above and the nonclinical tests performed, the subject device, EcoGuard B Surgical Masks, are as safe, as effective, and performs as well as the legally marketed predicate device, Xianto Rayxin Medical Products Disposable Surgical Mask cleared under K153496.