June 30, 2022

Sparta East, LLC
℅ Dallas L. Thomas, RAC, MHA, MPA, SSYB
Medical Device Regulatory Consultant
Thomas Regulatory Resolutions, Inc.
1069 Piccadilly St.
Palm Beach Gardens, Florida 33418

Re: K220378
Trade/Device Name: Sparta 3-Ply Surgical Disposable Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 13, 2022
Received: June 17, 2022

Dear Dallas L. Thomas:

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,

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K220378

Device Name
Sparta 3-Ply Surgical Disposable Face Mask

Indications for Use *(Describe)*
The Sparta 3-Ply Surgical Disposable Face Mask is intended to be worn to protect both the patient and healthcare professional from transfer of microorganisms, body fluids, and particulate material. The Sparta 3-Ply Surgical Disposable Face Mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, non-sterile, disposable device

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

5.1 General Information

Preparation Date: 5 February 2022

Submitter/Holder / Applicant

Ricardo Samayoa

General Manager

Sparta East LLC

8830 NW 102 Street, Medley, FL 33178

Contact Phone#: 305-924-3610

Email: resamayoa@yahoo.com

Primary Submission Contact

Dallas L. Thomas, RAC, MHA, MPA, SSYB
Medical Device Regulatory Consultant
Thomas Regulatory Resolutions
5613 Tiger Way Winter Garden, FL 34787
Mobile +1 801 556 6809
Email: dallas@thomasregulatory.com

5.2 Regulatory Information

Subject Device Name	Sparta 3-Ply Surgical Disposable Face Mask
Classification Names	Surgical apparel.
Device Classification	II
Common Name	Sparta 3-Ply Surgical Disposable Face Mask
FDA Product Code	FXX
CFR References	21 CFR 878.4040
Review Panel	General Hospital

5.3 Identification of Predicate Device

The predicate device for this submission has been identified as the Disposable Surgical Mask K202463.

5.4 Subject Device Description

The Sparta 3-Ply Surgical Disposable Face Mask is a flat-pleated mask with ear loops and nose piece for fitting and securing the mask to the to the user's face. The mask outward facing layer is blue in color, using color master batch.

The device is manufactured with three layers:

Outer Layer: Spunbond polypropylene

Middle Layer: Melt Blown polypropylene

Inner Layer: Spunbond polypropylene

The subject device is provided non-sterile and is a single use, disposable device.

A visual representation of the device can be found in the following figure.

Figure 1: Sparta 3-Ply Surgical Disposable Face Mask Product Image

5.5 Subject Device Specification

Design specifications:

- Size/Dimensions:

Dimensions-Width	3.74in (9.5 cm)
Dimensions-Length	6.89in (17.5cm)

- Materials of subject device are as listed below.

Outer Layer (Blue)	Spunbond polypropylene
Middle Layer (White)	Melt blown polypropylene
Inner Layer (White)	Spunbond polypropylene
Nose Wire	Polypropylene and galvanized steel
Ear Band	Spandex

5.6 Indications for Use

Per the current proposed product labeling, the indications for use for the Sparta 3-Ply Surgical Disposable Face Mask are quoted as follows:

The Sparta 3-Ply Surgical Disposable Face Mask is intended to be worn to protect both the patient and healthcare professional from transfer of microorganisms, body fluids, and particulate material. The Sparta 3-Ply Surgical Disposable Face Mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, non-sterile, disposable device.

Please note that the above indication is slightly reworded compared to the already cleared indications for the predicate Disposable Surgical Mask K202463 and updated accordingly per current FDA Guidance. The indications for use statement also provides further clarification that is complementary to the cleared predicate indications for use.

5.7 Substantial Equivalence Discussion

Below is a summary table of the Substantial Equivalence between the subject and predicate devices. The review of the indications for use and comparison characteristics provided in **Table 1** demonstrate that Sparta 3-Ply Surgical Disposable Face Mask is substantially equivalent to the predicate device, Disposable Surgical Mask K202463.

Table 1. Summary Comparison of Characteristics

Device Characteristic	**Proposed Subject Device: 3-ply disposable face mask**	**Primary Predicate Device 3-ply EcoGuard B with Earloop, 3-ply EcoGuard B with Tie-On K202096**	**Comparison Analysis:** *Identical / Substantially Equivalent / Modified / Cannot Be Determined / Not Applicable*
Product Name	**Surgical Disposable Face Masks**	**3-ply EcoGuard B with Earloop, 3-ply EcoGuard B with Tie-On**	N/A- Differences do not impact safety or efficacy.
Manufacturer	Sparta East, LLC	EcoGuard Inc.	N/A- Differences do not impact safety or efficacy.
FDA Product Code	FXX	FXX	Identical
CFR Reference	878.4040	878.4040	Identical
Device Class	II	II	Identical
510(k) reference	TBD	K202096	N/A- Differences do not impact safety or efficacy.
Implanted Device	No	No	Identical

Device Characteristic	**Proposed Subject Device: 3-ply disposable face mask**	**Primary Predicate Device 3-ply EcoGuard B with Earloop, 3-ply EcoGuard B with Tie-On K202096**	**Comparison Analysis:** *Identical / Substantially Equivalent / Modified / Cannot Be Determined / Not Applicable*
Indications for use statement	The SPARTA Disposable Surgical Mask is intended to be worn to protect both health care practitioners and patients from transfer of microorganisms, body fluids and particulate material. The masks are intended for use in infection control practices to reduce the potential exposure to blood and bodily fluids. This is a single use, disposable device, which is provided non-sterile	The Following EcoGuard Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from the transfer ofmicroorganisms, 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: ECOOI 3-ply EcoGuard B with Tie-on, Model Number: ECO02	Substantially Equivalent, minor wording differences do not impact safety or efficacy.
Device Generic Raw Materials	Outer Facing Layer: Spunbond nonwoven polypropylene Middle Layer: Melt Blown nonwoven polypropylene filter Inner facing layer: Spunbond nonwoven polypropylene Ear loop: Polyester and Spandex Nose wire: Polypropylene and galvanized steel	Outer Facing Layer: Spunbond polypropylene Middle Layer: Melt Blown polypropylene filter Inner facing layer: Spunbond polypropylene Ear loop: Polyester Nylon and Spandex Nose wire: Malleable Polyethylene wire	Substantially Equivalent, minor wording differences do not impact safety or efficacy.

Sparta 3-Ply Surgical Disposable Face Mask

Device Characteristic	**Proposed Subject Device: 3-ply disposable face mask**	**Primary Predicate Device 3-ply EcoGuard B with Earloop, 3-ply EcoGuard B with Tie-On K202096**	**Comparison Analysis:** *Identical / Substantially Equivalent / Modified / Cannot Be Determined / Not Applicable*
Color (outward facing Layer)	Blue	Blue	Identical
Color (middle Layer)	White	Not publically available	Modified - Minor differences do not impact safety or efficacy.
Color (inward facing Layer)	White	Not publically available	Modified - Minor differences do not impact safety or efficacy.
Colorant(s) -ALL Needed in terms of Material Name / Chemical Name	N/A	Not publically available	Modified - Minor differences do not impact safety or efficacy.
Patient Anatomical Site for Use of Device	Nose and Mouth	Nose and Mouth	Identical
Mode of Operation	Protective Mask	Protective Mask	Identical
Reusable or Single Use	Single Use	Single Use	Identical
Sold Sterile or Non-Sterile	Non-Sterile	Non-Sterile	Identical
Prescription Status	OTC	OTC	Identical
Fluid Resistance Performance ASTM F1862-13 (how many passing)	96 Passed (3 batches of 32)	Not publically available	Substantially Equivalent

Sparta 3-Ply Surgical Disposable Face Mask

Device Characteristic	**Proposed Subject Device: 3-ply disposable face mask**	**Primary Predicate Device 3-ply EcoGuard B with Earloop, 3-ply EcoGuard B with Tie-On K202096**	**Comparison Analysis:** *Identical / Substantially Equivalent / Modified / Cannot Be Determined / Not Applicable*
Particulate Filtration Efficiency ASTM F2299 % Passing	≥98%	≥ 99%	Substantially Equivalent
Bacterial Filtration Efficiency ASTM F2101 % Passing	0.999	≥ 98%	Substantially Equivalent
Differential Pressure (Delta P) EN 14683 Results / Conclusion	<6.0 mmH 2 O/cm 2	< 6.0 mm H2O/cm2	Modified - Both the predicate and the subject device passed as per the Standard. No additional concerns related to efficacy are presented.
Flammability 16 CFR 1610	Class 1	Class 1	Identical
Cytotoxicity	Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic.	Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic.	Identical
Irritation	Under the conditions of the study, the proposed device non-polar and polar extracts were determined to be non-irritating.	Under the conditions of the study, the proposed device non-polar and polar extracts were determined to be non-irritating.	Identical
Sensitization	Under the conditions of the study, the proposed device non-polar and polar extracts were determined to be non-sensitizing.	Under the conditions of the study, the proposed device non-polar and polar extracts were determined to be non-sensitizing.	Identical

Device Characteristic	**Proposed Subject Device: 3-ply disposable face mask**	**Primary Predicate Device 3-ply EcoGuard B with Earloop, 3-ply EcoGuard B with Tie-On K202096**	**Comparison Analysis:** *Identical / Substantially Equivalent / Modified / Cannot Be Determined / Not Applicable*
Dimensions-Width	3.74 in (95 mm)	9.5cm±2cm 3.74" ± 0.40"	Substantially Equivalent – Subject device is within range of the predicate device.
Dimensions-Length	6.89 in (175 mm)	17.5cm±2cm 6.89" ± 0.40"	Substantially Equivalent – Subject device is within range of the predicate device.
ASTM F2100 Level Tested / Passed	Level 3	Level 3	Identical
Non-Clinical Testing	ASTM F1862 ASTM F2299 ASTM F2101 ASTM F2100 EN 14683 16 CFR 1610	ASTM F1862 ASTM F2299 ASTM F2101 ASTM F2100 MIL-M369454C 16 CFR 1610	Substantially Equivalent

5.8 Sterilization and Shelf Life

Sterilization and Shelf Life are not applicable to the Sparta 3-Ply Surgical Disposable Face Mask subject device. The device is provided non-sterile and there is no claimed shelf life.

5.9 Biocompatibility

Biocompatibility tests of Sparta 3-Ply Surgical Disposable Face Mask have been performed on representative finished, sterilized devices as outlined in **Table 2**. The results from the

biocompatibility testing demonstrate that Sparta 3-Ply Surgical Disposable Face Mask is safe and effective for its intended use and biocompatible.

Table 2. Biocompatibility Summary & Standards Applied

Study	File Name	Attachment No.	Test Method / Standard
Sensitization	ATT-15-1_KMH003-SE11_Final_Report	15-1	ISO 10993-10:2013 ISO 10993-12:2021
Cytotoxicity	ATT-15-2_Cytoxicity_AMERICAN_PRECLINICAL	15-2	ISO 10993-5:2009 ISO 10993-12:2021
Irritation	ATT-15-3_Animal_Irritation-American_Preclinical	15-3	ISO 10993-10:2013 ISO 10993-12:2021

5.10 Performance Testing - Bench

Performance bench tests of Sparta 3-Ply Surgical Disposable Face Mask have been performed, see **Table 3**. The results from the performance bench testing demonstrate that Sparta 3-Ply Surgical Disposable Face Mask has met the functional requirements and is substantially equivalent to the predicate device.

Table 3. Performance Testing Summary And Standards Applied

Study	File Name	Attachment No.	Test Method / Standard
Bacterial Filtration Efficiency (BFE)	ATT-18-1_Test_RESULTS-Performance-INTERTEK-Complete	18-1	ASTM F2101-19
Differential Pressure (Delta P)	ATT-18-1_Test_RESULTS-Performance-INTERTEK-Complete	18-1	EN 14683:2019
Synthetic Blood Penetration Resistance	ATT-18-1_Test_RESULTS-Performance-INTERTEK-Complete	18-1	ASTM F1862
Latex Particle Challenge	ATT-18-1_Test_RESULTS-Performance-INTERTEK-Complete	18-1	ASTM F2299
Flammability of Clothing Textiles	ATT-18-1_Test_RESULTS-Performance-INTERTEK-Complete	18-1	16 CFR Part 1610

5.11 Conclusion

The conclusions drawn from the performance data demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed device K202463, Disposable Surgical Mask by Unisources Group, LLC.