Erchonia Corporation
Mr. Steven Shanks
President
650 Atlantis Road
Melbourne, Florida 32904

Re: K192544
Trade/Device Name: Erchonia Emerald
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use
Regulatory Class: Class II
Product Code: OLI
Dated: September 13, 2019
Received: September 16, 2019

Dear Steven Shanks:

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,

Jessica Mavadia-Shukla
Acting Assistant Director
DHT4A: Division of General 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K192544

Device Name
Erchonia Corporation

Indications for Use *(Describe)*
Erchonia® Emerald (Model # SHL) Laser is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference in individuals with a Body Mass Index (BMI) up to 40 kg/m^2.

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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K 192544 --- 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Owner Information

Name and Address of Sponsor / Manufacturer
Erchonia Corporation
650 Atlantis Rd.
Melbourne, FL. 32904
Telephone: 321-473-1251
Fax: 321-473-1608

Establishment Registration Number
2032513

Name and Address of Official Correspondent
Erchonia Corporation
650 Atlantis Road
Melbourne, FL 32904
Contact: Mr. Steven Shanks
Telephone: 321-473-1251
Fax: 321-473-1608
Email: sshanks@erchonia.com

Date Prepared

01/10/2020

Device Information

Trade Name: Erchonia® Emerald Laser
Model#: SHL
Common Name: Fat Reducing Low-Level Laser
Classification Name: Low-level laser energy for the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for noninvasive aesthetic use. (21 CFR 878.5400)
Classification: Class II
Panel: General & Plastic Surgery
Product Code: OLI

Predicate Device

The Erchonia® Emerald Laser (Model#: SHL) is substantially equivalent to the primary predicate device, the Erchonia® SHL Laser (Model# SHL) K142042. Additionally, the Erchonia® Emerald Laser (Model#: SHL) is substantially equivalent to the secondary predicate device, the Erchonia® Zerona™ 2.0 Laser (Model# GLS) K123237.

The principles of operation of the Erchonia® Emerald Laser (Model#: SHL) are identical to the previously cleared Erchonia® SHL Laser (Model# SHL) with the exception of a design change.

Reference Device

As part of this 510(k) submission, there is a reference device, which is the Erchonia® Zerona Z6 (Model# SHR) K162578.

The use of the reference device is rationalized as it points to a previous 510(k) application in which an FDA market clearance was granted for overall body contouring with another Erchonia Corporation device (Erchonia® Zerona Z6) that has the same intended use as the subject device; "the non-invasive reduction in fat layer for body contouring."

Device Description

The Erchonia® Emerald (Model#: SHL) is low-level laser system that uses ten (10) semi-conductor diodes (visible green-light) 522nm to 542nm. The Erchonia® Emerald (Model#: SHL) has been classified by the FDA as a Class II device and a Class II Laser in accordance with IEC 60825-1 (Complies with 21 CFR 1040.10 and 21 CFR 1040.11 by laser notice #50. The performance parameters and intended use of the Erchonia® Emerald (Model#: SHL) are compliant to the internationally recognized safety testing standards for medical devices. The testing of the Erchonia® Emerald (Model#: SHL) device includes functional performance, electrical, safety and component verification, in accordance with the FDA QS requirement, validated annually through ISO 13485 and MDSAP audits. The software incorporated into the operation of the Erchonia® Emerald (Model#: SHL) complies with FDA and ISO Software Development and Validation regulations.

The components of the device include a mobile base that plugs into the wall, using a hospital grade power cord, equipped with a medical-grade transformer. The device runs on AC power of 120 Volt 60 Hz or 220 Volt 50 Hz by plugging to mains power. Four (4) antistatic wheels that enable ease for maneuverability. A touch screen that functions as a display screen and input panel. The touch screen communicates with the PCB to initiate, stop or pause the energy flow to the laser diodes. The laser diodes can only be on or off; there is no user interface that allows the end-user to alter the laser diode output. The protocol is factory set and cannot be altered by the end-user. The device has an adjustable main arm that is attached to the mobile base with the laser head assembly located at the end. The laser head assembly that is attached to the adjustable main arm utilizes internal mechanics that collects the light emitted from each of the ten (10) laser diodes that rotate in a spiraling circle pattern that is totally random and independent of the other diodes. The laser head assembly can be manually adjusted for positioning the lasers 3-4 inches from the patient's skin to deliver treatment for body contouring. The device laser head assembly can be moved vertically (raised or lowered) over the subject for proper height placement of lasers for treatment. The device laser head assembly can be moved horizontally (left or right) over the patient for proper placement of lasers for treatment. The device laser head assembly has two adjustable outside laser arms with each arm housing two (2) laser diodes that can be moved in and out for proper positioning to the patient for accurate treatment distance.

The device contains software that is loaded into the PCB drivers. This data includes the touch screen images (GUI), and the command prompts that activate the screen icons; work in conjunction with the component platform to ensure the device operates as intended.

The associated accessories include:

Device Accessories:

- Laser safety glasses (1) Patient & (1) Operator
- Tape measure
- Manual
- Power cord

Assembly Accessories:

- Large Screws (2)
- 1/8 (Large) Allen Driver
- Small Screws (4)
- 1/16 (Small) Allen Driver
- Wire Cover
- Arm Cover

Intended Use / Indications for Use

The Erchonia® Emerald (Model # SHL) Laser is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference in individuals with a Body Mass Index (BMI) up to 40 kg/m²

Design Change

The principles of operation of the Erchonia® Emerald (Model# SHL) are identical to the primary predicate device, Erchonia® SHL Laser (Model# SHL), with the exception of a design change. Below is a table that details the comparison of the technology between the subject device and the primary predicate device.

Erchonia® SHL (K142042)	Erchonia® Emerald	Changes
Materials: Kydex T ABS, Acetal, 6061-T6 AL Aluminum 	**Materials:** PT8952 Polyurethane, Kydex T ABS, Acetal, 6061-T6 AL Aluminum, 5052 Aluminum 	Device enclosure: updated appearance
The main arm, or boom arm, adjustment mechanism is designed using spring tension. The adjustment of the main arm is by manual movement from the end user. This allows the end user to lower and raise the Laser Output Heads for proper positioning to patient for accurate treatment distance. The device is also designed with an arm lock to manually lock the main arm adjustment in place. **Boom Arm:** Surgi-Med Solutions – EM 0908.1 **Arm Lock (provided w/ Boom Arm)**	The main arm adjustment mechanism is designed using an electric motor (arm motor). The adjustment of the main arm is performed by the end user moving the device arm control switch (this powers the arm motor). This allows the end user to lower and raise the Laser Output Heads for proper positioning to patient for accurate treatment distance. Once a protocol has ended the main arm will automatically raise up and away from the patient. **Arm Motor:** Mcmaster – 6409K18 **Control Switch:** C&K – 7205J61ZQE22	Main arm height adjustment mechanism: electric motor with control switch

Erchonia® SHL (K142042)	Erchonia® Emerald	Changes
The PLC & touchscreen are off the shelf components. The device has an 8" touchscreen. **PLC:** Automation Direct – DL-205 PLC/D2-06BDC1-1, DL-250-1, F2-16TD2P, H2-CTRIO **Touchscreen:** Automation Direct – EA9-T8	The PLC (also known as PCB) is a custom component, designed specifically for Erchonia. The touchscreen is off the shelf. The device has an 10.4" touchscreen. **PLC:** Communication Systems Solutions – ERCSS4/HPS2 Main PCB/ER-E-00302 **Touchscreen:** NLT Technologies – NL10276BC20-18BD, PTPW10	PLC & touchscreen: custom PLC & larger touchscreen
PSU: Condor/SL Power – MINT3110A1908K01	**PSU:** Condor/SL Power – MINT3110A0508K01	AC to DC power supply (PSU): a different PSU is required for power demands of arm motor, updated PLC & updated touchscreen
Device is designed with a mechanical key-switch with a removable key. The key must be inserted into the key-switch and turned to the ON position to operate the lasers.	Device is designed with 4 digit passcode within device software. The correct 4 digit passcode must be entered into the device software via the touchscreen to operate the lasers.	Device lockout mechanism: passcode within software
Erchonia® SHL (K142042)	**Erchonia® Emerald**	**Areas that Remain Unchanged**
10	10	Quantity of diodes per device
16mW ± 2mW	16mW ± 2mW	Power (measured at aperture) per diode
522nm to 542nm	522nm to 542nm	Wavelength
Multi diode collected then line dispersed (coherent)	Multi diode collected then line dispersed (coherent)	Energy Source
0 - 30 minutes	0 - 30 minutes	Treatment time
288 J	288 J	Total Joules Per Treatment

Comparison of Technological Characteristics with the Predicate Device(s)

The Erchonia® Emerald Laser (Model#: SHL) is substantially equivalent to the primary predicate device, the Erchonia® SHL Laser (Model# SHL) K142042. Additionally, the Erchonia® Emerald Laser (Model#: SHL) is substantially equivalent to the secondary predicate device, the Erchonia® Zerona™ 2.0 Laser (Model# GLS). Additionally, as part of this submission, there is a reference device, which is the Erchonia® Zerona Z6 (Model# SHR) K162578.
The principles of operation of the Erchonia® Emerald Laser (Model#: SHL) are identical to the previously cleared Erchonia® SHL Laser (Model# SHL) with the exception of a design change that was detailed above.

Comparison of Technological Characteristics with the Predicate Device(s)

Device	Erchonia® Emerald Laser (Model# SHL)	Erchonia® SHL Laser (Model# SHL)	Erchonia® Zerona 2.0 (Model# GLS)	Erchonia® Zerona Z6 (Model# SHR)
510(k) #	Unknown	K142042	K123237	K162578
	Subject Device	Primary Predicate	Secondary Predicate	Reference Device
Power (measured at aperture)	16mW ± 2mW	16mW ± 2mW	16mW ± 2mW	17.25mW ± 1.25mW
Wavelength	522nm to 542nm	522nm to 542nm	522nm to 542nm	630nm to 650nm
Energy Source	Multi diode collected then line dispersed (coherent)	Multi diode collected then line dispersed (coherent)	Multi diode collected then line dispersed (coherent)	Multi diode collected then line dispersed (coherent)
Treatment time	0 - 30 minutes	0 - 30 minutes	0 - 30 minutes	0 - 40 minutes
Total Joules Per Treatment	288 J	288 J	173 J	248 J
Power Supply	100-240VAC, 50-60Hz electrical outlet	100-240VAC, 50-60Hz electrical outlet	100-240VAC, 50-60Hz electrical outlet	100-240VAC, 50-60Hz electrical outlet
Energy Delivery	Floor model device with probe head	Floor model device with probe head	Floor model device with probe head	Floor model device with probe head
Target Size per diode	Line pattern, electronically scanned over area of treatment	Line pattern, electronically scanned over area of treatment	Line pattern, electronically scanned over area of treatment	Line pattern, electronically scanned over area of treatment
Indication for Use	The Erchonia® Emerald (Model#: SHL) Laser is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference in individuals with a Body Mass Index (BMI) up to 40 kg/m²	The Erchonia® SHL Laser is indicated for use as a non-invasive dermatological aesthetic treatment for reduction of circumference of hips, waist and upper abdomen when applied to individuals with a Body Mass Index (BMI) between 30 kg/m² and 40 kg/m²	The Erchonia® Zerona™ 2.0 Laser is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reductions of circumference of hips, waist, and thighs	The Zerona Z6 Laser is indicated for us as a non-invasive dermatological aesthetic treatment for the reduction of body circumference
Product Code	OLI	OLI	OLI	OLI
Principles of Operation	Mains power, converted to DC, powering semi-conductor diodes	Mains power, converted to DC, powering semi-conductor diodes	Mains power, converted to DC, powering semi-conductor diodes	Mains power, converted to DC, powering semi-conductor diodes

Performance Data

Compliance with Voluntary Standards

The device complies with the following standards:

Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance IEC 60601-1:2005 3rd Edition,

General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests IEC 60601-1-2:2014 4th Edition, and

Safety of Laser Products IEC/EN 60825-1:2007 2nd Edition

Performance Standards

The device complies with the FDA's performance standards for light-emitting products (21 CFR 1040.10 and 21 CFR 1040.11 by Laser Notice #50).

Biocompatibility

Not applicable. The device does not come in contact with the patient's skin or any other bodily tissue.

Sterilization and Shelf-Life

The device is not provided sterile. As an electromechanical device containing no biodegradable materials, such as chemical or biologic, and no mechanical componentry subject to degradation, such as batteries, the aging rationale is based on only the acceptable transportation parameters of time and conditions. The transportation range was assessed by evaluating each component's acceptable temperature and humidity parameters, then identifying an all-inclusive high-low spread. The range noted in the Erchonia® Emerald (Model#: SHL) Owner's Manual was considered and determined acceptable as part of the IEC 60601-1 Safety Testing and is in compliance with the FDA guidance document "Shelf-Life of Medical Devices."

Software Verification and Validation Testing

Software verification and validation testing was conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered a "minor" level of concern.

Clinical Data

Erchonia Corporation did not perform a clinical study for the indication for use proposed in this premarket notification. Substantial equivalence is based on the primary predicate device, the Erchonia® SHL Laser (Model# SHL) K142042, as well as the secondary predicate device, the Erchonia® Zerona™ 2.0 Laser (Model# GLS) K123237.

Conclusion

Any technological differences between the subject device and predicate do not render the device not substantially equivalent, do not affect the safety or effectiveness, or raise questions regarding the safety and effectiveness due to the fact the total light energy delivered per treatment is equivalent to the predicate(s). The new and predicate device(s) have equivalent technology and provides the same wavelength. The predicate device(s) treatment protocols went through clinical trials to demonstrate that

they are safe and effective in providing a non-invasive dermatological aesthetic treatment for the reduction of body circumference in individuals with a Body Mass Index (BMI) up to 40 kg/m²

Therefore, based on the equivalent predicate device(s), the physiological mechanism of action provided by the Erchonia Corporation 532nm diode laser has demonstrated safety and effectiveness to support the proposed indication of use “as a non-invasive dermatological aesthetic treatment for the reduction of body circumference in individuals with a Body Mass Index (BMI) of up to 40 kg/m².”