October 22, 2021

Erchonia Corporation
Travis Sammons
Clinical Affairs Manager
650 Atlantis Road
Melbourne, Florida 32904

Re: K211186
Trade/Device Name: Erchonia® XLR8
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: NHN
Dated: September 14, 2021
Received: September 21, 2021

Dear Travis Sammons:

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,

Vivek Pinto, PhD
Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K211186

Device Name

Erchonia® XLR8

Indications for Use *(Describe)*

The Erchonia® XLR8 is generally indicated:

a. as adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin
b. as an adjunct to liposuction procedures of the thighs, hips and stomach for reduction of pain associated with the recovery process
c. for the temporary reduction in post-surgery pain at 24 hours after surgery following bilateral breast augmentation surgery
d. as an adjunctive treatment of postoperative pain

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

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

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Melbourne, FL 32904
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Email: sshanks@erchonia.com

Date Prepared

10/22/2021

Device Information

Trade Name: Erchonia® XLR8 Laser
Model#: HLS
Common Name: Infrared Lamp
Classification Name: Powered Light-Based Laser Non-Thermal Instrument with Non-Heating Effect for Adjunctive Use in Pain Therapy (21 CFR 890.5500)
Classification: Class II
Panel: Physical Medicine
Product Code: NHN

Predicate Device

The Erchonia® XLR8 is the exact same model as the Erchonia® XLR8 which has previously received 510(k) market clearance under K130996 for the intended use: The Erchonia® XLR8™ laser is indicated for the following three indications:
a. adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin
b. as an adjunct to liposuction procedures of the thighs, hips and stomach for reduction of pain associated with the recovery process
c. temporary reduction in post-surgery pain at 24 hours after surgery following bilateral breast augmentation surgery

There have been no technical or design modifications made to the Erchonia® XLR8 since clearance under K130996.

Device Description

The Erchonia® XLR8 (Model# HLS) is a low-level laser system that uses two semi-conductor diodes (visible red light), red: 640nm ±10. The Erchonia® XLR8 (Model# HLS) is a variable hertz device. The variable hertz feature of the Erchonia® XLR8 (Model# HLS) is a pulsed wave, defined as containing a selected series of breaks, variances. The Erchonia® XLR8 (Model# HLS) has been classified by the FDA/EC as a Class II/IIa device and a Class II/2 laser.

The Erchonia® XLR8™ laser is currently indicated for the following three indications:
a. adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin
c. as an adjunct to liposuction procedures of the thighs, hips and stomach for reduction of pain associated with the recovery process
c. temporary reduction in post-surgery pain at 24 hours after surgery following bilateral breast augmentation surgery

This Premarket Notification is requesting expansion of the indications for use to include:
d. as an adjunctive treatment of postoperative pain

The Erchonia® Laser is applied externally and has proven through clinical trials to treat post-surgical pain associated with liposuction and breast augmentation surgery. The Erchonia ® XLR8 laser emits a 640-nanometer wavelength with a tolerance of ±10 nanometer, from each of the two laser diodes. The lasers are powered by an internal battery that is recharged using a separate inductive charging base powered by an external class II medical power supply. This configuration offers portability as well as consistency of power.

The internal battery powers the two specially created and patented electronic diodes with an output of <10mW red laser beam.

The Erchonia® (HLS) laser is manufactured in accordance to the Good Manufacturing Procedures consistent with national regulatory agencies; such as FDA, EU, HC, TGA, and Anvisa. Per ISO and FDA standards the device and laser are classified as Class II.

Each of these governing agencies requires specific labeling. All required labels are affixed according to the relevant codes. Each label is pictured and described in this manual. Additionally, the placement of each label, on the Erchonia ® device, is communicated.

The associated accessories include:

- Charging Base
- Power Supply
- Patient protective eyewear

Intended Use

The Erchonia® XLR8 is generally indicated:
a. as adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin
b. as an adjunct to liposuction procedures of the thighs, hips and stomach for reduction of pain associated with the recovery process
c. for the temporary reduction in post-surgery pain at 24 hours after surgery following bilateral breast augmentation surgery
d. as an adjunctive treatment of postoperative pain

Comparison of Technological Characteristics with the Predicate Device

Device	Erchonia® XLR8 (Model# HLS)	Erchonia® XLR8 Laser (Model# HLS)
510(k) #	Unknown	K130996
	Subject Device	Predicate Device
Technology	Coherent light-based laser non-thermal instrument	Coherent light-based laser non-thermal instrument
Power	7.5mW ± 2mW	7.5mW ± 2mW
Wavelength	640nm ±10	640nm ±10
Energy Source	Multi diode collected then line dispersed (coherent)	Multi diode collected then line dispersed (coherent)
Recommended treatment duration (use time) based on clinical evidence	0 – 12 minutes	0 – 12 minutes
Total Joules Per Minute	0.45 J	0.45 J
Power Supply	External Power Supply – (100-240Vac, 50-60Hz, 0.5A; 12Vdc 1.5A) that connect to the Inductive Charging Base – (1.5A 12V), to charge the Battery (Lithium-ion Polymer 3.7V, 1800mAh, 6.7W)	External Power Supply – (100-240Vac, 50-60Hz, 0.5A; 12Vdc 1.5A) that connect to the Inductive Charging Base – (1.5A 12V), to charge the Battery (Lithium-ion Polymer 3.7V, 1800mAh, 6.7W)
Application	Line pattern, manually scanned 3-6 inches over area of treatment	Line pattern, manually scanned 3-6 inches over area of treatment
Mechanism of Action	Stimulates the mitochondria to increase the production of ATP	Stimulates the mitochondria to increase the production of ATP
Indication for Use	The Erchonia® XLR8 is generally indicated: a. as adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin b. as an adjunct to liposuction procedures of the thighs, hips and stomach for reduction of pain associated with the recovery process c. for the temporary reduction in post-surgery pain at 24 hours after surgery following bilateral breast augmentation surgery d. as an adjunctive treatment of postoperative pain	The Erchonia® XLR8™ laser is indicated for the following three indications: a. adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin c. as an adjunct to liposuction procedures of the thighs, hips and stomach for reduction of pain associated with the recovery process c. temporary reduction in post-surgery pain at 24 hours after surgery following bilateral breast augmentation surgery
Product Code	NHN	NHN

Technological Characteristics Summary

The subject device (Erchonia® XLR8 Laser, Model# HLS) is the exact same model as the predicate device (Erchonia® XLR8 Laser, Model# HLS) previously submitted under K130996. There are no differences between the subject device and predicate that render the device not substantially equivalent nor affect safety or effectiveness, as the devices have the same design, material, energy source, power, wavelength, and based on same mechanism of action. There have been no technical or design modifications made to the Erchonia® XLR8 since clearance under K130996. This 510k submission is to expand the indication of use.

Performance Standards
The Erchonia® XLR8 Laser complies with FDA's performance standards for light-emitting products (21CFR 1040.10 and 21 CFR 1040.11 by Laser Notice #50).

Risk Assessment
The Erchonia® XLR8, Model#: HLS is acceptable in accordance with IEC 60601 edition 3.1, by virtue of Engineering and third-party verification. All identified risks have been mitigated to ensure the lowest acceptable risk possible using the ISO 14971 standard framework.

Electromagnetic Compatibility and Electrical Safety
Safety and EMC testing was conducted on the Erchonia® XLR8™ (Model#:HLS) device. The device complies with the IEC 60601-1, IEC 60601-2 and IEC 60825-1 standards.

Compliance with Voluntary Standards
The Erchonia® XLR8 complies with the following voluntary standards:
IEC 60601-1-2:2014
IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
IEC 60825-1:2014 (Third Edition)

Performance Testing- Bench
Not Applicable, as the subject device and predicate are exactly the same

Performance Testing-Animal
No animal testing conducted

Performance Testing-Clinical
No clinical study results are being submitted as part of this submission.

Summary of Clinical Testing

Seven randomized controlled clinical trials published in scientific peer-reviewed journal publications were identified wherein low-level laser therapy (LLLT) was evaluated for its therapeutic ability to reduce post- operative pain following surgical procedures. These studies evaluated post-surgical pain related to:

- Coronary artery bypass graft surgery
- Coronary bypass surgery with internal mammary artery grafts
- Tibial fracture surgery
- Cesarean section (2 studies)
- Endodontic surgery
- Tonsillectomy

No new clinical data is being submitted in this 510(k) submission.

Comparison of Erchonia® XLR8 Laser (Model# HLS) & Erchonia EML Laser

The Erchonia® XLR8 Laser, Model# HLS (predicate & subject device) has previously received substantial equivalence to the Erchonia EML Laser by the FDA, reference 510(k) #K130996. Any technological differences between the Erchonia® XLR8 Laser (subject & predicate device) and Erchonia EML Laser did not render the device not substantially equivalent, did not affect the safety or effectiveness, or raise questions regarding the safety and effectiveness due to the fact the laser wavelength and total light energy delivered per treatment is identical.

Device	Erchonia® XLR8 Laser (Model# HLS)	Erchonia EML Laser
	Subject & Predicate Device	
510(k)	Unknown, K130996	K041139, K072206
Output – at aperture	7.5mW	7.5mW
Wavelength	640nm ±10	640nm ±10
Waveform	Pulsed	Pulsed
Energy Source	Multi diode collected then line dispersed (coherent)	Multi diode collected then line dispersed (coherent)
Power Supply	External Power Supply – (100-240Vac, 50-60Hz, 0.5A; 12Vdc 1.5A) that connect to the Inductive Charging Base – (1.5A 12V), to charge the Battery (Lithium-ion Polymer 3.7V, 1800mAh, 6.7W)	115/220 V ac 50/60 Hz electrical outlet, rechargeable batteries
Energy Delivery	Device hand-held, probe on top	Handheld treatment probe
Target Size	Line pattern, manually scanned over area of treatment	Line pattern, manually scanned over area of treatment
Mechanism of Action	Stimulates the mitochondria to increase the production of ATP	Stimulates the mitochondria to increase the production of ATP

Conclusion

The subject device (Erchonia® XLR8 Laser, Model# HLS) is the exact same model as the predicate device (Erchonia® XLR8 Laser, Model# HLS) previously submitted under K130996. There are no differences between the subject device and predicate that render the device not substantially equivalent nor affect safety or effectiveness, as the devices have identical technology, provides the same outputs, and based on same mechanism of action. Therefore, this 510k submission is to expand the indication of use.

Based on Erchonia Lasers previous received FDA 510(k) market clearances for post-operative use (K072206 & K041139), and supportive published literature of low level laser therapy (LLLT) effectively reducing postoperative pain across various body locations and surgical procedures, the proven physiological mechanism of action provided by the Erchonia® XLR8™ laser has substantially equivalent safety and effectiveness to support the proposed Indication for Use:

The Erchonia® XLR8 is generally indicated:
a. as adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin
b. as an adjunct to liposuction procedures of the thighs, hips and stomach for reduction of pain associated with the recovery process
c. for the temporary reduction in post-surgery pain at 24 hours after surgery following bilateral breast augmentation surgery
d. as an adjunctive treatment of postoperative pain