February 19, 2026

Erchonia Corporation
Travis Sammons
Clinical Affairs Manager
112 Southchase Blvd.
Fountain Inn, South Carolina 29644

Re: K251903
Trade/Device Name: Erchonia DPN Laser (Model# EVRL)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: NHN
Dated: January 19, 2026
Received: January 20, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

AMBER T. BALLARD -S

Amber Ballard, PhD
Assistant 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251903

Device Name
Erchonia® DPN Laser (Model# EVRL)

Indications for Use *(Describe)*
The Erchonia® DPN Laser is indicated while using the red and violet diode simultaneously for prescription home use as an adjunctive treatment in providing temporary relief of diabetic peripheral neuropathy foot 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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
112 Southchase Blvd.
Fountain Inn, SC 29644
Telephone: 321-473-1251
Fax: 321-473-1608

Establishment Registration Number

2032513

Name and Address of Official Correspondent

Erchonia Corporation
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Fountain Inn, SC 29644
Contact: Travis Sammons
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Email: tsammons@erchonia.com

Date Prepared

02/19/2026

Device Information

Trade Name: Erchonia® DPN Laser
Model#: EVRL
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

Erchonia® EVRL cleared under K191257

Device Description

The Erchonia® DPN Laser (Model# EVRL) is a handheld, self-contained, lightweight, battery-operated low-level laser therapy (LLLT) device designed for use in prescription home environments. It delivers non-thermal, non-invasive laser light at specific wavelengths to provide a therapeutic benefit without generating heat. The DPN Laser builds upon the red and violet laser technology of the predicate Erchonia® EVRL (K191257), which is indicated for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin under product code NHN.

The DPN Laser device utilizes two semiconductor laser diodes that emit visible red (640 nm ± 10 nm) and violet (405 nm ± 10 nm) light, each delivering 7.5 mW.

The DPN Laser incorporates a single, non-adjustable neuropathy treatment protocol, which is pre-programmed into the device and not accessible for modification by the end user. There is no interface available that permits alteration of the laser output power or wavelength, ensuring consistent and controlled therapeutic delivery.

The laser is powered by an internal rechargeable battery. Recharging is accomplished via a separate inductive charging base, which operates using an external medical-grade power supply compatible with 120V/60Hz or 220V/50Hz AC mains power. The DPN Laser system features a user-friendly touchscreen interface that functions as both a display and control panel. The touchscreen communicates with the internal printed circuit board (PCB) to initiate or pause laser energy delivery. Detailed operating instructions for touchscreen use and treatment application are provided in the Erchonia DPN Laser Proper Use Reference guide.

The associated accessories include:

(1) DPN Laser (no assembly required)
(1) Proper Use Reference Guide
(1) Laser Safety Goggles
(1) Charger Base
(1) Charger Base Power Supply Connector

Indications for Use

The Erchonia® DPN Laser is indicated while using the red and violet diode simultaneously for prescription home use as an adjunctive treatment in providing temporary relief of diabetic peripheral neuropathy foot pain.

Device Comparison Table

Device	Erchonia® DPN Laser (Model #EVRL)	Erchonia® EVRL (Model #EVRL)	Device Comparison
510(k) #		K191257	n/a
	Subject Device	Predicate Device	n/a
Manufacturer	Erchonia	Erchonia	Same
Power (measured at aperture)	Red: 7.5mW± 1mW Violet: 7.5mW± 0.5mW	Red: 7.5mW± 1mW Violet: 5mW	The violet diode power of the subject device (7.5 mW) represents a 2.5 mW increase over the predicate device (5 mW). This difference does not impact safety or effectiveness for the following reasons: 1. Both devices are non-thermal, low-level laser products. The increased violet power does not change the laser safety classification or the risk profile of the device. 2. Clinical data collected using the subject device at the 7.5 mW violet power output demonstrated substantially equivalent safety and effectiveness for the intended use. (refer to Performance Testing – Clinical)
Wavelength	Red: 640nm ± 10 Violet: 405nm ± 10	Red: 640nm ± 10 Violet: 405nm ± 10	Same
Energy Source	Diode laser energy collected then dispersed via line generating optics	Diode laser energy collected then dispersed via line generating optics	Same
J/cm² Per Minute	Red: 0.09 J/cm² Violet: 0.09 J/cm²	Red: 0.09 J/cm² Violet: 0.06 J/cm²	The violet diode J/cm² per minute of the subject device (0.09 J/cm²) represents a 0.03 J/cm² increase over the predicate device (0.06 J/cm²). This difference does not impact safety or effectiveness for the following reasons: 1. The increase in J/cm² per minute is a direct and proportional result of the increased violet diode power (from 5 mW to 7.5 mW) described above. The energy source and energy delivery remain the same as the predicate device. Therefore, the safety rationale provided for the power increase applies equally to the corresponding J/cm² per minute increase. 2. Clinical data collected using the subject device at 0.09 J/cm² per minute violet demonstrated substantially equivalent safety and effectiveness for the intended use. (refer to Performance Testing – Clinical)
Power Supply	Lithium-ion Polymer 3.7V, 3000mAh, 11.2W, rechargeable batteries	Lithium-ion Polymer 3.7V, 3000mAh, 11.2W, rechargeable batteries	Same
Energy Delivery	Hand-held device with probe on top	Hand-held device with probe on top	Same
Laser Application	Line pattern, manually scanned over area of treatment	Line pattern, manually scanned over area of treatment	Same

Intended Use	Non-thermal light-based device for adjunctive use in pain therapy	Non-thermal light-based device for adjunctive use in pain therapy	Same
Indications for Use	The Erchonia® DPN Laser is indicated while using the red and violet diode simultaneously for prescription home use as an adjunctive treatment in providing temporary relief of diabetic peripheral neuropathy foot pain.	The Erchonia® EVRL laser is generally indicated: a. while using the red and violet diode simultaneously, for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin b. and while using the violet diode, to treat dermatological conditions, and specifically indicated to treat moderate inflammatory Acne Vulgaris.	Difference supported by clinical data (refer to Performance Testing-Clinical)
Materials	Machined billet aluminum enclosure	Machined billet aluminum enclosure	Same
Product Code	NHN	NHN	Same

Technological Characteristics Summary

The Erchonia® DPN Laser (Model #EVRL) represents a redesigned iteration of the predicate device, the Erchonia® EVRL. Both devices maintain the same or similar core technological characteristics, including power output, energy source, method of energy delivery, and intended use.

Sterilization and Shelf-Life

The device is not provided sterile.

The device is not affected by shelf-life because it is an electro-mechanical device that is not sterile and whose components will not degrade over time while simply sitting in storage prior to initial use.

Performance Testing-Animal

No animal testing conducted

Performance Testing-Clinical

The clinical protocol and associated documentation refer to the investigational device as “EVRL,” reflecting the model number of the device used at the time of study initiation. For the purposes of this 510(k) submission, the investigational device is marketed under the trade name “Erchonia® DPN Laser,” with the same model designation (EVRL).

Clinical Data

BACKGROUND: The purpose of this clinical study was to determine the safety and effectiveness of the Erchonia® DPN Laser (Model #EVRL) in providing prescription home use application for temporary adjunctive relief of diabetic peripheral neuropathy foot pain.

STUDY DESIGN: The study was a prospective, placebo-controlled, randomized, double-blind, parallel group, multi-center design.

SUBJECTS: Sixty-four (64) subjects with a diagnosis of diabetes induced peripheral neuropathy with constant feet pain of 28 or greater on the 0 to 100 Visual Analog Scale (VAS) on-going over at least the prior 3 months completed the study to endpoint assessment: 33 randomized to the active treatment group and 31 randomized to the placebo treatment group. Subjects were 55% male (18/33) and 45% female (15/33) in the active treatment group and 52% male (16/31) and 48% female (15/31) in the placebo treatment group. The average subject age was 67.39 years for active treatment group subjects and 64.74 years for placebo treatment group subjects. Overall, subjects were predominantly Caucasian (56%), and Hispanic (23%).

The average duration of foot pain was 93.33 months for active treatment group subjects and 79.52 months for placebo group subjects, while duration since diabetes diagnosis averaged 186.17 months for the active treatment group and 122.06 months for the placebo treatment group.

STUDY PROCEDURES: Subjects self-administered two (2) treatments with the Erchonia® DPN Laser (active or placebo) on each consecutive day of the three-week treatment phase for a total of 42 self-administered treatments. Each individual treatment administration lasted five (5) minutes per foot. The placebo laser device appeared to the subject to be an active device but did not produce any therapeutic light output. Subjects maintained use of their usual medications and treatments for their diabetic peripheral neuropathy symptoms, including pain, as needed, while in the study, but did not try anything else new.

STUDY RESULTS: Primary efficacy outcome measure was predefined as the difference in the proportion of subjects between active and placebo treatment groups who recorded a 30% or greater decrease (≥30%) in self-reported pain rating on the 0 to 100 Visual Analog Scale (VAS) at study endpoint (Week 3) relative to baseline. Overall study success was predefined as at least a 35% difference in the proportion of individual subject successes between treatment groups. 72.73% of subjects who received active treatments with the Erchonia® DPN Laser met the individual subject success criteria compared with 32.26% of placebo treatment group subjects. As the difference in the proportion of individual subject successes between treatment groups met the pre-established minimum criteria of 35%, overall study success was established.

Secondary outcomes assessed between treatment groups across all applicable study assessments of Baseline, Day 10, Endpoint (Week 3) and Follow-up (Week 7), included diabetic peripheral neuropathy foot pain ratings on the VAS, and total Neuropathic Pain Symptom Inventory (NPSI) and Dimension scores. Secondary outcome findings showed improvement for the active over the placebo treatment group over time and were consistent and supportive of the primary outcome findings.

ADVERSE EVENTS: There were no serious study device- or treatment-related adverse events reported in this clinical study. There were two non-serious adverse events related to internal tingling and warmth during device use that occurred in 3% (2/64) of study subjects that were deemed possibly device and/or treatment related.

Biocompatibility

Not applicable. The device does not come in contact with the skin or any other bodily tissue. Users are instructed to wear gloves during treatment.

Performance Data

Safety and EMC testing was conducted on the Erchonia® DPN Laser (Model #EVRL). The device complies with the IEC 60601-1, IEC 60601-1-6, IEC 60601-1-1-11, IEC 60601-1-2 and IEC 60825-1 standards.

Compliance with Voluntary Standards

The Erchonia® DPN Laser (Model #EVRL) complies with the following voluntary standards:

IEC 60601-1-2:2014+AMD1:2020 Edition 4.1
IEC 60601-1:2005+AMD1:2012+AMD2:2020 Edition 3.2
IEC 60601-1-11:2015+AMD1:2020 Edition 2.1
IEC 60825-1:2014 Edition 3.0

Conclusion

The subject device, Erchonia® DPN Laser, is determined to be substantially equivalent to the predicate device previously cleared under submission K191257. Both devices exhibit identical core technological characteristics, including power output, energy source, method of energy delivery, and mechanism of action.

Additionally, both the subject device and the predicate share the same intended use . Accordingly, the differences in IFU do not alter the intended therapeutic purpose of the device, and they raise no additional questions of safety or effectiveness. The Erchonia® DPN Laser is therefore substantially equivalent to the Erchonia® EVRL (K191257).