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

August 8, 2019

Re: K191257
Trade/Device Name: Erchonia EVRL
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: NHN, GEX
Dated: May 8, 2019
Received: May 10, 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,

Neil R.P. Ogden, M.S.
Acting Team Assistant Director
Light Based Devices Team
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191257

Device Name
Erchonia® EVRL

Indications for Use *(Describe)*

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.

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
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Melbourne, FL 32904
Telephone: 321-473-1251
Fax: 321-473-1608

Establishment Registration Number
2032513

Name and Address of Official Correspondent
Erchonia Corporation
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Melbourne, FL 32904
Contact: Mr. Steven Shanks
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Email: sshanks@erchonia.com

Date Prepared

05/08/2019

Device Information

Trade Name: Erchonia® EVRL
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, GEX

Predicate Device

The Erchonia® EVRL (Model# EVRL) is substantially equivalent to the following predicate device:
Erchonia® EVRL (Model# EVRL) K152196

The Erchonia® EVRL is the same model as the Erchonia® EVRL previously submitted under K152196.

Device Description

The Erchonia® EVRL (Model# EVRL) is a low-level laser system that uses two semi-conductor diodes (visible red and violet light), red: 630-650 nm and violet: 380-450 nm. The Erchonia® EVRL (Model# EVRL) is a variable hertz device. The variable hertz feature of the Erchonia® EVRL (Model# EVRL) is a pulsed wave, defined as containing a selected series of breaks, variances. The Erchonia® EVRL (Model# EVRL) has been classified by the FDA/EC as a Class II/IIa device and a Class II/2 laser.

The Erchonia® EVRL (Model# EVRL) is indicated for use:
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.
The Erchonia® Laser is applied externally and has proven through clinical trials to treat neck and shoulder pain with the red diode.

The components of the device consist of:
An ultra-slim hand-held battery-operated control device with a docking station providing two laser diodes a 640 nanometer and a 405 nanometer. Each laser diode emits its wavelength with a tolerance of ±10 nanometer. 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 7.5mW ± 1mW red and <5mW violet non-convergent beam and is classified as a Class 2 laser in accordance IEC 60825-1 (Complies with 21CFR 1040.10 and 21 CFR 1040.11 by Laser Notice #50).
The separate inductive charging base runs on AC power of 120 Volt 60 Hz or 220 Volt 50 Hz by plugging to main power.
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 Erchonia® EVRL (Model# EVRL) as designed contains user protocols. The user protocols are defined and saved by the user in one of ten memory locations and can be changed at any time. The protocols consist of activating the lasers to emit predefined frequencies for a predetermined length of time.
The Acne protocol is factory set and cannot be altered by the end user.
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:

- Charging Base
- Power Supply

- Patient protective eyewear

Intended Use

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.

Comparison of Technological Characteristics with the Predicate Device

The Erchonia® EVRL is equivalent to the predicate device, Erchonia® EVRL manufactured by Erchonia®. The principles of operation of the Erchonia® EVRL are identical in every aspect to the previously cleared Erchonia® EVRL.

Device	Erchonia® EVRL (Model# EVRL)	Erchonia® EVRL (Model# EVRL)
510(k) #	UN	K152196
Power (measured at aperture)	Red: 7.5Mw± 1Mw Violet: <5Mw	Red: 7.5Mw± 1Mw Violet: <5Mw
Wavelength	Violet: 405nm Red: 640nm	Violet: 405nm Red: 640nm
Energy Source	diode laser energy collected then dispersed via line generating optics	diode laser energy collected then dispersed via line generating optics
Treatment Time	Acne: approx. 24 min. Neck and Shoulder Pain: 0-13 min.	Acne: approx. 24 min. Neck and Shoulder Pain: 0-13 min.
Total Joules Per Minute	Red: .45 Violet: .30	Red: .45 Violet: .30
Power Supply	Lithium ion Polymer 3.7V, 3000mAh, 11.2W, rechargeable batteries	Lithium ion Polymer 3.7V, 3000mAh, 11.2W, rechargeable batteries
Energy Delivery	Device hand-held, probe on top	Device hand-held, probe on top
Target Size	Line pattern, manually scanned over area of treatment	Line pattern, manually scanned over area of treatment

Indications for Use	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.	The Erchonia® EVRL laser is generally indicated: a. while using the red diode, 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.
Principles of Operation	DC, powering semi-conductor diodes	DC, powering semi-conductor diodes

Performance Date

Compliance with Voluntary Standards

The device complies with IEC 60601-1, IEC 60601-2 and IEC 60825-1 standards.

Performance Standards

The device complies with 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, 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 a high-low spread that was all-inclusive. The range noted in the Erchonia® EVRL (Model# EVRL) Owner's Manual (between 14 to 140°F (-10 to 60°C) relative humidity <95%) 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

Submission for Software Contained in Medical Devices." The software for this device was considered as a "minor" level of concern.

Clinical Data

BACKGROUND: The purpose of this clinical study was to determine the effectiveness of the Erchonia® EVRL, manufactured by Erchonia Corporation (the Company), when both the red and violet diodes are activated simultaneously, in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.

STUDY DESIGN: The study was a single (active treatment only) group non-inferiority design to evaluate equivalency or superiority of the Erchonia® EVRL in red/violet diode combination application with red diode only application in the temporary reduction of neck and shoulder pain of musculoskeletal origin. The comparative active data for the Erchonia® EVRL red diode only therapy was attained in the 2001 trial whose results successfully supported 510(k) clearance (K050672) of application of the EVRL in red diode mode only for the identical indication being sought through the results of this clinical trial.

SUBJECTS: Forty-four (44) subjects completed the study. Subjects were predominantly Caucasian (82%) males (39%) and females (61%) of average age 54.07 years with chronic neck and/or shoulder pain of musculoskeletal origin: osteoarthritis, chronic muscle spasms or cervical and thoracic spine sprain strain who rated 50 or greater on the 0 to 100 Visual Analog Pain Scale (VAS). Average subject duration of neck and shoulder pain was 76.58 months with the location of pain quite evenly distributed across the right and left sides. Average VAS pain rating at study entry was 65.00. In the 2001 comparative trial, 43 subjects received the active Erchonia® EVRL red diode only procedure administration.

STUDY PROCEDURES: Each subject received a single 13-minute active procedure administration with the Erchonia® EVRL at the investigator's test site as in the 2001 trial, differing only in dual-diode (red and violet) versus single-diode (red only) application, respectively.

STUDY RESULTS: Study primary outcome measure was change in Visual Analog Scale (VAS) neck and shoulder pain rating from baseline to study endpoint evaluation. Individual subject success criteria was established as a 30% or greater decrease in VAS rating at endpoint relative to baseline. The study was pre-established as a non-inferiority study (equivalency or superiority) of the EVRL in red/violet diode combination therapy compared to the red diode only therapy as based upon the comparative data from the 2001 trial. Overall study success criteria was established as 65±5% of individual subject successes in the current trial.

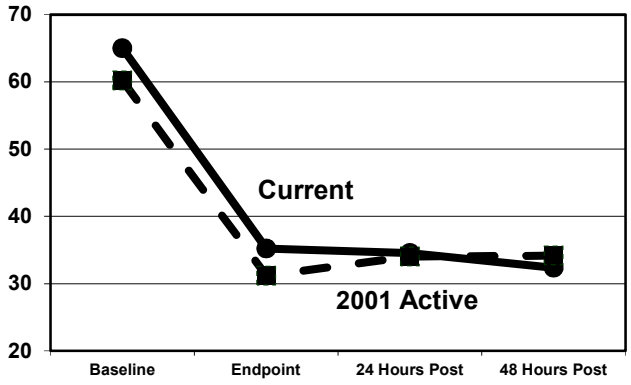
Seventy-five per cent (75%) of subjects in this study attained individual subject success compared with 65.1% of actively treated subjects in the 2001 trial, exceeding the overall study success criteria by 5%.

The 29.80-point mean decrease (from 65.00 to 35.20) in neck and shoulder VAS pain rating from study Baseline to Endpoint for subjects in the Current study is comparable to (slightly above) the respective 29.02-point mean decrease (from 60.21 to 31.19) for 2001 Active study subjects.

T-test for correlated samples found the 29.80-point mean decrease for Current study subjects to be statistically significant at $p<0.0001$.

Chart 1: Mean neck and shoulder pain VAS ratings across study duration

Chart 1 to the right demonstrates that the statistically significant decreases in mean neck and shoulder pain VAS ratings from Baseline to Endpoint evaluation for both Current and 2001 Active group subjects was maintained comparably across the subsequent 48-hour evaluation period.



The secondary measure of change in neck and shoulder range of motion (ROM) demonstrated sizable improvements. Mean shoulder ROM in Seated Passive Abduction improved 27.95 degrees on each of the right and left sides. Mean shoulder ROM measurements in relaxed position improved 30.11 degrees on the right side and 28.52 degrees on the left side. Mean neck ROM measurements improved 22.68 and 23.36 degrees for the right and left sides, respectively.

At completion of the procedure administration (endpoint) and again at 24- and 48-hours post-procedure, subjects were asked to rate satisfaction with any perceived overall change in neck and shoulder pain on a 5-point scale. Subjects who were 'Very Satisfied' with the study procedure increased from 41% at endpoint evaluation to 46% at 48 hours post-procedure evaluation. Seventy-one per cent (71%) of subjects remained 'Satisfied' ('Very Satisfied' or 'Somewhat Satisfied') across the 48 hours post-procedure evaluation period.

ADVERSE EVENTS: No adverse event occurred for any subject throughout study duration.

Patient Accountability

Stage	Investigational Device Arm Total	Control (Placebo) Arm Total	Total
Enrollment	44	NA	44
Treatment	44	NA	44
Primary Effectiveness Endpoint Analysis	44	NA	44
Primary Safety Endpoint Analysis	44	NA	44

SUMMARY: These study results demonstrate that the Erchonia® EVRL in dual red/violet diode application is as effective in reducing neck and shoulder pain of musculoskeletal origin as the Erchonia® EVRL in red diode only mode.

Conclusion

Any differences between the subject device and predicate do not render the device not

substantially equivalent, do not affect safety or effectiveness, or raise different questions of safety and effectiveness despite the fact that total light energy delivered per treatment is marginally greater to the predicate. The new and predicate device has identical technology and provides the same outputs. The predicate device treatment protocol went through a clinical trial to demonstrate that it is effective in providing relief of chronic neck and shoulder pain.