September 1, 2022

Erchonia Corporation
Travis Sammons
Contact Address

Re: K221987
Trade/Device Name: Erchonia® GVL
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: NHN, GEX
Dated: June 30, 2022
Received: July 6, 2022

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,

Jianting Wang
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221987

Device Name
Erchonia® GVL

Indications for Use *(Describe)*
The Erchonia® GVL laser is generally indicated:
a. while using the green 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.

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510(k) Summary
K221987

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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Date Prepared

09/01/2022

Device Information

Trade Name: Erchonia® GVL
Model#: GVL
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

Erchonia® EVRL (Model# EVRL) cleared under K191257.

Reference Device

Erchonia® EVRL (Model# EVRL) cleared under K152196.

The use of this reference device provides the regulatory background of the safety and effectiveness of Erchonia low-level lasers in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.

The Erchonia® PL2000, a red (635 nm) diode laser was evaluated for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin in a double-blinded, sham-controlled, randomized clinical trial, the results of which successfully supported an

FDA clearance under K012580 for the following indication:

"The TUCO Erchonia PL2000 is indicated for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin."

The TUCO Erchonia PL2000 was subsequently renamed the Erchonia® EVRL (reference device), and its indications updated under K152196 to include both the treatment of neck and shoulder pain as well as acne vulgaris, as follows:

"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, and
b. while using the blue diode, to treat dermatological conditions, and specifically indicated to treat moderate inflammatory Acne Vulgaris"

Device Description

The Erchonia® GVL (Model# GVL) is identical to the predicate device, the Erchonia® EVRL cleared under K191257, including device enclosure, functionally and software. The only difference between the Erchonia® GVL and the Erchonia® EVRL is the color of laser emission (green and violet as a replacement for red and violet).

The Erchonia® GVL (Model# GVL) is a low-level laser system that uses two semi-conductor diodes (visible green and violet light), green: 520 nm and violet: 405 nm ± 10. The Erchonia® GVL (Model# GVL) is a variable hertz device. The variable hertz feature of the Erchonia® GVL (Model# GVL) is a pulsed wave, defined as containing a selected series of breaks, variances. The Erchonia® GVL (Model# GVL) has been classified by the FDA/EC as a Class II/IIa device and a Class II/2 laser.

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 520 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 green 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 Erchonia® GVL (Model# GVL) 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. User instructions are provided in the Erchonia® GVL Operation & Maintenance Manual for proper touchscreen interface operation for the user to set laser diode variable hertz and length of treatment time. There is no interface that allows the end user to alter the laser power output (milliwatts) or the laser wavelength (nanometers).
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® GVL laser is generally indicated:
a. while using the green 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.

Device Comparison Table

Device	Erchonia® GVL (Model# GVL)	Erchonia® EVRL (Model# EVRL)	Erchonia® EVRL (Model# EVRL)
510(k) #	K221987	K191257	K152196
	Subject Device	Predicate Device	Reference Device
			
Power (measured at aperture)	Green: 7.5mW± 1mW Violet: <5mW	Red: 7.5mW± 1mW Violet: <5mW	Red: 7.5mW± 1mW Violet: <5mW
Wavelength	Violet: 405nm ± 10 Green: 520nm ± 10	Violet: 405nm ± 10 Red: 640nm ± 10	Violet: 405nm ± 10 Red: 640nm ± 10
Energy Source	diode laser energy collected then dispersed via line generating optics	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.	Acne: approx. 24 min. Neck and Shoulder Pain: 0-13 min.
Total Joules Per Minute	Green: .45 Violet: .30	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	Lithium ion Polymer 3.7V, 3000mAh, 11.2W, rechargeable batteries
Energy Delivery	Device hand-held, probe on top	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	Line pattern, manually scanned over area of treatment
Indications for Use	The Erchonia® GVL laser is generally indicated: a. while using the green 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 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.
Mechanism of Action	Stimulates the mitochondria to increase the production of ATP	Stimulates the mitochondria to increase the production of ATP	Stimulates the mitochondria to increase the production of ATP
Principles of Operation	DC, powering semi-conductor diodes	DC, powering semi-conductor diodes	DC, powering semi-conductor diodes

Technological Characteristics Summary

The Erchonia® GVL (subject device) and the Erchonia® EVRL (predicate device) have identical principles of operation, power, energy source, energy delivery, mechanism of action, and treatment times. The only technological difference between the subject and the predicate device is substitution of a red laser diode with a green laser diode of identical power.

Performance Standards

The Erchonia® GVL 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® GVL, Model#: GVL 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

The Erchonia® GVL utilizes the same components as the predicate device, Erchonia® EVRL cleared under K191257, with the exception of the color of laser emission. The Erchonia® GVL emits violet/green light and the Erchonia® EVRL emits violet/red light, the change does not alter the safety and EMC testing previously conducted on the Erchonia® EVRL. Therefore, the safety and EMC testing which was conducted on the Erchonia® EVRL device (K191257) applies to the Erchonia® GVL. The device testing complies with the current IEC 60601-1, IEC 60601-2 and IEC 60825-1 standards. Furthermore, Erchonia has provided in this submission independent testing of the Erchonia GVL according to consensus standards.

Compliance with Voluntary Standards

The Erchonia® GVL complies with the following voluntary standards:
IEC 60601-1-2:2014
IEC 60601-1:2005 (Third Edition)
IEC 60825-1:2014 (Third Edition)

Performance Testing-Clinical

Clinical Data

BACKGROUND: The purpose of this clinical study was to determine the effectiveness of the Erchonia® GVL, manufactured by Erchonia Corporation (the Company), when both the green 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 group non-inferiority design to evaluate equivalency or superiority of the Erchonia® GVL when applied in simultaneous green / violet dual diode mode to that of application of the Erchonia® EVRL when applied in simultaneous red / violet dual diode mode. The comparative data for the Erchonia® EVRL red / violet laser device was attained in the 2019 trial whose results successfully supported 510(k) clearance (K191257).

SUBJECTS: Forty-three (43) subjects completed the study.

STUDY PROCEDURES: Each subject received a single 13-minute active procedure administration with the Erchonia® GVL at the investigator's test site identical to the 2019 Erchonia® EVRL trial.

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 pre-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 of the Erchonia® GVL laser compared to the Erchonia® EVRL laser comparative data from the 2019 trial. Overall study success criteria was established as 75±5% of individual subject successes in the current trial.

Eighty-one-point four per cent (81.4%) of subjects in this study attained individual subject success compared with 75.0% of subjects treated in the 2019 Erchonia® EVRL trial.

The 37.77-point mean decrease (from 71.79 to 34.02) in neck and shoulder VAS pain rating from study Baseline to Endpoint for subjects in the current GVL study is comparable to the respective 29.80-point mean decrease for subjects in the 2019 EVRL study. T-test for correlated samples found the 37.77-point mean decrease for GVL study subjects to be statistically significant at $p<0.0001$.

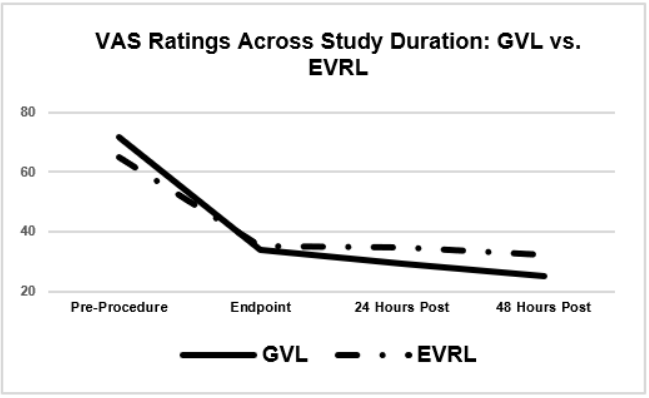

Chart 1: Mean low back pain VAS ratings across study duration

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

Substantially Equivalent Discussion

The Erchonia® GVL is substantially equivalent to the predicate device, the Erchonia® EVRL previously submitted under K191257. Both the subject device and the predicate device have identical principles of operation, power, energy source, energy delivery, mechanism of action, and treatment times. The only technological difference between the subject and the predicate device is the substitution of a red laser diode with a green laser diode of identical power, while the second diode consistently emits a violet wavelength in both devices. This difference does not render the device not substantially equivalent, does not affect the safety or effectiveness, or raise different questions of safety and effectiveness.
Erchonia Corporation maintains extensive clinical data establishing safety and effectiveness for "providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin" with low level laser diodes in the visible light spectrum, including red laser diode only (K012580, K152196), red and violet laser diode (K191257), and green and violet laser diode (this submission). The clinical data provided in this submission demonstrates simultaneously administering the combination of green and violet diode yields comparable (equivalent) or better (superior) results with respect to decrease in subjects' neck and shoulder pain, while maintaining the same safety profile as the predicate device, Erchonia EVRL (K191257) while simultaneously administering red and violet diodes, and the reference device Erchonia EVRL (K152196, K012580) while administrating red laser only. (See Table 1)

Table 1: Individual Success Criteria Met: Subjects who met the study individual subject success criteria of a 30% or greater decrease in VAS neck and shoulder pain ratings from baseline to endpoint evaluation.

	Erchonia® GVL	**Erchonia® EVRL**	**Erchonia® PL2000, Erchonia® EVRL**
510(k) Number	Current Submission	K191257	K012580, K152196
Laser Diode	Green/ Violet	Red/ Violet	Red Only
n	43	44	43
n meeting success criteria	35	33	28
% Meeting success criteria	**81.4%**	**75.0%**	**65.1%**
Side Effects	None	None	None

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. Therefore, the Erchonia® GVL (subject device) is substantially equivalent to the Erchonia® EVRL (predicate device), indicated for use while using the green and violet diode simultaneously for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin and while using the violet diode, to treat dermatological conditions, and specifically indicated to treat moderate inflammatory Acne Vulgaris.