May 21, 2018

Erchonia Corporation
% Kevin Walls
Principle Consultant
Regulatory Insight, Inc.
33 Golden Eagle Lane
Littleton, Colorado 80127

Re: K180197
Trade/Device Name: Erchonia® FX-635
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: NHN
Dated: February 17, 2018
Received: February 20, 2018

Dear Mr. Walls:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K180197

Device Name
Erchonia® FX-635

Indications for Use *(Describe)*
The Erchonia® FX-635 laser is indicated for the following two indications:
a. as an adjunct to provide relief of minor chronic low back pain of musculoskeletal origin.
b. as an adjunct to reducing chronic heel pain arising from plantar fasciitis.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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
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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
Regulatory Insight, Inc.
33 Golden Eagle Lane
Littleton, Colorado 80127
Contact: Mr. Kevin Walls, RAC
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Email: kevin@reginsight.com

Date Prepared

1/21/2018

Device Information

Trade Name: Erchonia® FX-635
Model#: HPS
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® FX-635 (Model# HPS) is substantially equivalent to the following predicate device:
Erchonia® Allay (Model# HPS) K132940
The Erchonia® Allay is the same model as the Erchonia® FX-635 with a different tradename. Based on this, Erchonia® FX-635 is substantially equivalent to itself, being previously cleared as an adjunct to reducing chronic heel pain arising from plantar fasciitis.

Device Description

The Erchonia® FX-635 (Model#: HPS) is low level laser system that uses three semi-conductor diodes (visible red-light) 630nm to 650nm. The Erchonia® FX-635 (Model#: HPS) is a variable hertz device. The variable hertz feature of the Erchonia® FX-635 (Model#: HPS) is a pulsed wave, defined as containing a selected series of breaks, variances that are preprogrammed. The Erchonia® FX 635 (Model#: HPS) has been classified by the FDA/EC as a Class II/IIa device and a Class II/2 Laser. Erchonia® FX-635 (Model#: HPS) is indicated for use as an adjunct to provide relief of minor chronic low back pain of musculoskeletal origin. Erchonia® FX-635 (Model#: HPS) is also indicated for use as an adjunct to reducing chronic heel pain arising from plantar fasciitis.

The components of the device include a mobile base which 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 main 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 low back protocol and heel pain protocol is factory set and cannot be altered by the end user, 20 minutes for providing relief of minor chronic low back pain of musculoskeletal origin, or 10 minutes for reducing chronic heel pain arising from plantar fasciitis, prior clearance K132940. The device has an adjustable main arm that is attached to the mobile base with the laser head assembly located at the end. The adjustable main arm is capable to collapse into the mobile base for storage and transporting or extends to position the laser heads above the area of involvement. The laser head assembly that is attached to the adjustable main arm that is manually raised and lowered, utilizes internal mechanics that collects the light emitted from each of the three (3) laser diodes that rotate in a spiraling circle pattern that is totally random and independent of the other diodes. The laser head assembly is positioned 3-4 inches from the patient's skin to deliver treatment for low back pain or treatment for heel pain. This assembly can be rotated 120 degrees for proper positioning to patient for accurate treatment. The laser head assembly includes arms and pivots that allow the three (3) laser output heads to be rotated, tilted, and raised / lowered independently. 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:

- Hospital grade power cord
- Patient protective eyewear
- Power safety lockout keys

Intended Use

The Erchonia® FX-635 laser is indicated for the following two indications:
a. as an adjunct to provide relief of minor chronic low back pain of musculoskeletal origin.
b. as an adjunct to reducing chronic heel pain arising from plantar fasciitis.

NOTE: The Erchonia® FX-635 is the same model as the Erchonia® Allay with a changed tradename. Based on this, the HPS model was previously cleared as an adjunct to reducing chronic heel pain arising from plantar fasciitis. Ref: K132940

Comparison of Technological Characteristics with the Predicate Device

The Erchonia® FX-635 is equivalent to the predicate device, Erchonia® Allay manufactured by Erchonia®. The principles of operation of the Erchonia® FX-635 are identical in every aspect to the previously cleared Erchonia® Allay (Model#: HPS).

Device	**Erchonia® FX-635 (Model# HPS)**	**Erchonia® Allay (Model# HPS)**
Power (measured at aperture)	17.25mW ± 1.25mW	17.25mW ± 1.25mW
Wavelength	630nm to 640nm	630nm to 640nm
Energy Source	Multi diode collected then line dispersed (coherent)	Multi diode collected then line dispersed (coherent)
Treatment time	20 minutes for Low Back Pain and 10 minutes for Heel Pain	10 minutes
Total Joules Per Minute	1.53 J	1.53 J
Power Supply	1.5A/100VAC & 0.5A/240VAC, 50-60Hz electrical outlet	1.5A/100VAC & 0.5A/240VAC, 50/60Hz electrical outlet
Energy Delivery	Floor model device with probe head	Floor model device with probe head
Target Size	Line pattern, electronically scanned over area of treatment	Line pattern, electronically scanned over area of treatment
Indication for Use	The Erchonia® FX-635 laser is indicated for the following two indications: a. as an adjunct to provide relief of minor chronic low back pain of musculoskeletal origin. b. as an adjunct to reducing chronic heel pain arising from plantar fasciitis.	The Erchonia® Allay is indicated as an adjunct to reducing chronic heel pain arising from plantar fasciitis
Principles of Operation	Mains power, converted to DC, powering semi-conductor diodes	Mains power, converted to DC, powering semi-conductor diodes
Mechanism of Action	Stimulates the mitochondria to increase the production of ATP	Stimulates the mitochondria to increase the production of ATP

Performance Data

Compliance with Voluntary Standards

The device complies with the 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, 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 a high-low spread that was all-inclusive. The range noted in the Erchonia® FX-635 (Model#: HPS) 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 as a "minor" level of concern.

Clinical Trial Summary

BACKGROUND: The purpose of this clinical study was to determine the effectiveness of the Erchonia® FX-635™, manufactured by Erchonia Corporation (the Company), in providing temporary acute relief of minor episodic chronic low back pain of musculoskeletal origin.

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

SUBJECTS: Fifty-eight (58) subjects completed the study: 29 randomized to the active procedure group and 29 randomized to the placebo group. Subjects were males and females 18 years or older with episodic chronic low back pain of musculoskeletal origin lumbar sprain or strain etiology and rating 40 or greater on the 0 to 100 Visual Analog Pain Scale (VAS).

Average subject age was 45.57 years. Subject gender was evenly distributed amongst males (47%) and females (53%). The majority of subjects were Caucasian (69%); followed by Hispanic (14%), African American (8.5%) and Asian (8.5%).

Average subject duration of low back pain was 97.8 months (approx. 8 years). The majority of subjects (79%) had low back pain on both the right and left sides with an average pain rating at the time of study entry of 59.10 on the 0 to 100 Visual Analog Scale (VAS).

STUDY PROCEDURES: Subjects received eight 20-minute procedure administrations across the lower back region with the Erchonia® FX-635™ laser (active or sham) across a four-week period: two procedures per week, each procedure three to four days apart.

Subjects agreed to use only the study pain relief medication of over-the-counter (OTC) Tylenol to relieve any low back pain, as needed, throughout study participation and to record this usage in a daily diary. Subjects were instructed not to record a VAS pain rating any sooner than six hours after taking a dosage of the study pain relief rescue medication.

STUDY RESULTS

The study primary outcome measure was pre-determined as the difference in the proportion of subjects between test and control groups who achieved a 30% or greater decrease in self-reported VAS low back pain rating from baseline (pre-procedure) to study endpoint (2 months post-procedure evaluation).

It was pre-determined that the study would be considered a success if the difference in the proportion of individual subject successes between procedure groups was 35% or greater.

72.4% of subjects who received the active procedures with the Erchonia® FX-635™ attained a 30% or greater decrease in low back pain VAS rating from baseline to endpoint compared with 27.6% of subjects who received the 'fake' (placebo) procedures. A Fischer's Exact Test for two independent proportions found this 44.8% difference to be statistically significant at $p<0.005$.

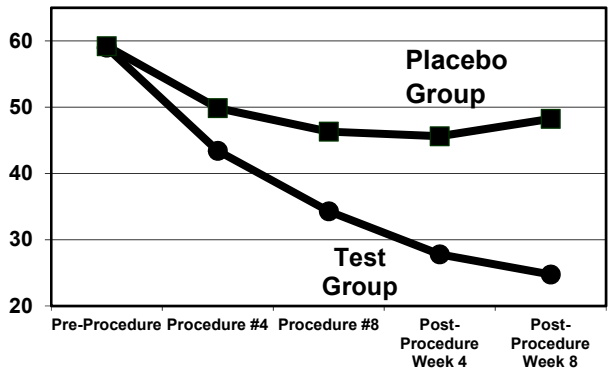
The magnitude of mean change in low back pain VAS rating was a decrease of 34.24 points for subjects who received the actual Erchonia® FX-635™ procedures and a decrease of 10.97 points for subjects who received the placebo procedures. ANCOVA analysis found the 23.37-point difference in mean change in low back pain VAS ratings between procedure groups to be statistically significant independent of baseline low back pain VAS rating ($F=12.76$; $p<0.001$).

Table 1 and Chart 1 below show the mean change in low back pain VAS ratings across study duration.

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

Evaluation Visit	Test Group	Placebo Group
Pre-Procedure	59.00	59.21
Procedure #4	43.41	49.86
Procedure #8	34.28	46.31
Post-Procedure Week 4	27.79	45.62
Post-Procedure Week 8	24.76	48.24

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



For test subjects, mean low back pain VAS ratings decreased progressively from pre-procedure through endpoint evaluation, indicating a progressive and cumulative treatment effect of the laser. For placebo subjects, there was a slight initial placebo effect with low back pain ratings returning to near baseline levels by endpoint.

The secondary measure of change in per cent total index score on the Oswestry Disability Index (ODI) found the 12.27% mean decrease from study Baseline to Endpoint for test group subjects to be about two and a half times greater than the relative 5.18% mean decrease for placebo group subjects and to exceed the minimal detectable change of -10% indicative of clinically meaningful positive improvement.

The secondary measure of flexion, extension, and right and left lateral flexion range of motion (ROM) measurements recorded across study duration found changes in ROM to be minimal and essentially negligible for both test and placebo group subjects.

At completion of the procedure administration phase and again at study endpoint, subjects were asked to rate satisfaction with any perceived overall change in low back pain on a 5-point scale. At both evaluations, 45% of test subjects and 17% of placebo subjects were 'Very Satisfied' with study outcome.

SAFETY: No adverse event was reported for any subject throughout study duration, and no other safety issues occurred; therefore, device safety is supported through these study results.

SUMMARY: These study results demonstrate that the Erchonia® FX-635™ is an effective tool for reducing episodic chronic low back pain of musculoskeletal origin, progressively reducing low back pain over a 3-month period to minimal levels, including a 2-month period of time during which no additional procedures with the Erchonia® FX-635™ Laser were administered.

Conclusion

Any differences between the subject device and predicate do not render the device NSE, do not affect safety or effectiveness, or raise different questions of safety and effectiveness due to the fact that that total light energy delivered per treatment is identical to the predicate. The new and

predicate device has identical technology and provides the same outputs. The new and predicate device treatment protocols went through clinical trials to demonstrate that they are each equally effective in providing relief of minor chronic low back pain and reducing chronic heal pain arising from plantar fasciitis..