November 12, 2021

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

Re: K212595
Trade/Device Name: Erchonia® FX-405
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: NHN
Dated: August 12, 2021
Received: August 16, 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,

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K212595

Device Name
Erchonia® FX-405

Indications for Use *(Describe)*
The Erchonia® FX-405 laser is indicated for the adjunctive use in providing temporary relief of nociceptive musculoskeletal 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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**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

Erchonia Corporation
650 Atlantis Road
Melbourne, FL 32904
Contact: Steven Shanks
Telephone: 321-473-1251
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Email: sshanks@erchonia

## Date Prepared

08/11/2021

## Device Information

Trade Name: Erchonia® FX-405
Model#: MLS-AC
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® FX-635 previously cleared under K190572.

## Reference Device:

Erchonia EVRL Laser® (K191257)
The use of this reference device is justified as it points to a previous 510(k) market clearance that was granted to an Erchonia laser that emitted both 635nm red and 405nm violet lasers simultaneously to temporarily reduce minor chronic neck and shoulder pain of musculoskeletal origin. The 635nm red and 405nm violet wavelengths emitted by the Erchonia EVRL Laser® (K191257), are identical to the subject device, Erchonia® FX-405.

The Erchonia EVRL Laser® 510(k): K191257, was based on clinical data from a study that evaluated the safety and efficacy of the Erchonia Laser with both 635nm red and 405nm violet diodes activated simultaneously, in comparison to the efficiency of the Erchonia 635nm red diode only clinical trial whose results successfully supported 510(k) clearance K012580.

## Device Description

The Erchonia® FX-405 (Model#: MLS-AC) is low level laser system that uses three semi-conductor diodes (visible light) 630nm to 650nm with a mean power output of 17.25mW per diode and one semi-conductor diode 395nm to 415nm with a mean power output of 23.00mW. The Erchonia® FX-405 (Model#: MLS-AC) is a variable hertz device. The variable hertz feature of the Erchonia® FX-405 (Model#: MLS-AC) is a pulsed wave, defined as containing a selected series of breaks, variances that are preprogrammed. The Erchonia® FX-405 (Model#: MLS-AC) has been classified by the FDA/EC as a Class II device and a Class 2 Laser.

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. 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 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 four (4) laser diodes and processes each through a proprietary patented lens which redirects the beam with a line refractor. The refracted light is then bent into a spiraling circle pattern that is totally random and independent of the other diodes. 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 four (4) 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 exterior materials consist of 6061 T6 AL, Kydex 430 and Copolymer Acetal with powder coating and carbon fiber finish.
The associated accessories include:

- (1) Hospital grade power cord
- (1) Patient protective eyewear (sufficiently and effectively block the laser light spectrum at OD 2+ @ 635nm, OD 0.75 @ 405nm VLT60)
- (2) Power safety lockout keys

## Indication for Use

The Erchonia® FX-405 laser is indicated for the adjunctive use in providing temporary relief of nociceptive musculoskeletal pain.

## Comparison of Technological Characteristics with the Predicate Device(s)

The Erchonia® FX-405 (MLS-AC) is substantially equivalent to the predicate device, the Erchonia® FX-635 previously submitted under K190572. Both the subject device and the predicate device have identical principles of operation, including wavelength, power, energy source, energy delivery, and treatment times. The only technological difference between the subject and predicate device is the addition of a single 405nm diode laser which does not render the device not substantially equivalent, does not affect the safety or effectiveness, or raise different questions of safety and effectiveness.

Additionally, the mechanism of action of the Erchonia® FX-405 is the exact same as the predicate device, Erchonia® FX-635 which stimulates the mitochondria to increase the production of ATP, as detailed in the substantially equivalent discussion Table 1 below.

**Table 1.**

| **Device** | **Erchonia® FX-405 (Model# MLS-AC)** | **Erchonia® FX-635 (Model# HPS)** |
|---|---|---|
| **510(k) #** | K212595 | K190572 |
| | Subject Device | Predicate Device |
| |  |  |
| **Number of diodes** | (3) Red diodes<br>(1) Violet diode | (3) Red diodes |
| **Power per Diode (measured at aperture)** | Red: 17.25mW ± 1.25mW<br>Violet: 23mW ± 2mW | Red:17.25mW ± 1.25mW |
| **Wavelength** | Red: 630nm to 640nm<br>Violet: 400nm to 410nm | Red: 630nm to 640nm |
| **Energy Source** | Multi diode collected then line dispersed (coherent) | Multi diode collected then line dispersed (coherent) |
| **Treatment time** | Variable depending on area being treated – refer to Owner's Manual | Variable depending on area being treated – refer to Owner's Manual |
| **Total Joules Per Minute** | 2.25J | 1.53J |
| **J/cm$^2$ Per Minute** | Red: .0035 J/cm$^2$<br>Violet: .0045 J/cm$^2$ | Red: .0035 J/cm$^2$ |
| **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-405 laser is indicated for the adjunctive use in providing temporary relief of nociceptive musculoskeletal pain. | The Erchonia® FX-635 laser is indicated for the adjunctive use in providing temporary relief of nociceptive musculoskeletal pain. |
| **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 |
| **Product Code** | NHN | NHN |

## Performance Data

***Compliance with Voluntary Standards***
The Erchonia® FX-405 complies with the following voluntary standards:
IEC 60601-1-2:2014 Edition 4.0
IEC 60601-1:2005 Edition 3.1
IEC 60825-1:2014 Edition 3.0

***Performance Standards***
The Erchonia® FX-405 complies with FDA's performance standards for light-emitting products (21CFR 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.
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.

***Software***
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.
The Erchonia® FX-405 does not store any patient data. Cybersecurity is not considered a security or safety risk to users, nor does it pose a risk of safety or effectiveness. The Erchonia® FX-405 Laser does not contain wireless communication interfaces (Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.).

***Performance Testing-Clinical***

No new clinical study results are being submitted as part of this submission. Clinical data previously reviewed in 510(k) submissions of the predicate device, the Erchonia® FX-635 Laser K190572, as well as the reference device, the Erchonia® EVRL Laser K191257 were provided to demonstrate safety of using the red and violet diodes simultaneously.

### Treatment Protocol Comparison of the FX-405 (Subject device) and FX-635 (Predicate device)

The treatment protocols of the subject device, Erchonia® FX-405, are identical to the protocols of the predicate device Erchonia® FX-635 (K#190572), which received FDA market clearance for adjunctive use in providing temporary relief of nociceptive musculoskeletal pain. Table 2 below provides a comparison of treatment protocols:

**Table 2. Comparison of Treatment Protocols**

| Condition | Treatment Duration and Frequency | Laser Wavelength | Power Output (mW) | Total Joules Per Minute | Duty cycle | Frequency (Hz) |
|---|---|---|---|---|---|---|
| **Chronic Neck and Shoulder Pain** | Single treatment to the sagittal suture, shoulder, cerebral, cervical and torso regions for a combined total of 13 minutes. | **Erchonia FX-635** (3) Red 635nm | **Erchonia FX-635** 635nm: 17.25mW | **Erchonia FX-635** 1.53J | 50% | The variable hertz is a pulsed wave, containing a selected series of breaks, variances that are preprogrammed. |
| | | **Erchonia FX-405** (3) Red 635nm (1) Violet 405nm | **Erchonia FX-405** 635nm: 17.25mW 405nm: 23mw | **Erchonia FX-405** 2.25J | | |
| **Chronic Low Back Pain** | 8 20-minute treatments 2 times/week for 4 weeks across the lower back region and hip flexors. | **Erchonia FX-635** (3) Red 635nm | **Erchonia FX-635** 635nm: 17.25mW | **Erchonia FX-635** 1.53J | 50% | The variable hertz is a pulsed wave, containing a selected series of breaks, variances that are preprogrammed. |
| | | **Erchonia FX-405** (3) Red 635nm (1) Violet 405nm | **Erchonia FX-405** 635nm: 17.25mW 405nm: 23mw | **Erchonia FX-405** 2.25J | | |
| **Chronic Heel Pain arising from Plantar Fasciitis** | 6 10-minute treatments 2 times/week for 3 weeks to the top of foot, myofascial junction of the heel, and the plantar aspect of the heel. | **Erchonia FX-635** (3) Red 635nm | **Erchonia FX-635** 635nm: 17.25mW | **Erchonia FX-635** 1.53J | 50% | The variable hertz is a pulsed wave, containing a selected series of breaks, variances that are preprogrammed. |
| | | **Erchonia FX-405** (3) Red 635nm (1) Violet 405nm | **Erchonia FX-405** 635nm: 17.25mW 405nm: 23mw | **Erchonia FX-405** 2.25J | | |

## Substantially Equivalent Discussion

The Erchonia® FX-405 (MLS-AC) is substantially equivalent to the predicate device, the Erchonia® FX-635 previously submitted under K190572. Both the subject device and the predicate device have identical principles of operation, including wavelength, power, energy source, energy delivery, and treatment time. The only technological difference between the subject and predicate device is the addition of a single 405nm diode laser which 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 has documented the safety of simultaneously administering the combination of 635nm red and 405nm violet diodes, in clinical data previously reviewed under K191257. In particular, the provided reference device (Erchonia® EVRL) provides clinical data that demonstrated the use of the Erchonia 635nm red and 405nm violet laser diodes when administered simultaneously to be safe when “providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin”, under FDA market clearance K191257.

### Conclusion

The subject device and predicate device have identical power, wavelength, energy source, and treatment time. The only technological difference between the subject and the predicate devices (i.e., slightly greater energy to be delivered [2.25 vs. 1.53 Joules per minute] by including one extra violet diode) does not render the subject device not substantially equivalent to the predicate device, affect the safety or effectiveness, or raise questions regarding the safety and effectiveness.

The physiological effect of the Erchonia 635nm red laser is as safe and as effective for providing temporary relief of nociceptive musculoskeletal pain as the predicate device, cleared under K190572. Erchonia clinical data previously reviewed in K190572 demonstrated when administering the Erchonia 635nm diode simultaneously with the Erchonia 405nm diode, the synergistic effects of both laser wavelengths maintains the same safety profile as when the 635nm diode is use alone. Therefore, the subject device is substantially equivalent to the predicate device.