August 11, 2023

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

Re: K231409
Trade/Device Name: Erchonia FX-405
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: NHN
Dated: May 8, 2023
Received: May 15, 2023

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231409

Device Name
Erchonia® FX-405

Indications for Use *(Describe)*
The Erchonia® FX-405 laser is generally indicated:
a. while using the red and violet diodes, for the adjunctive use in providing temporary relief of nociceptive musculoskeletal pain.
b. and while using the red diodes, as an adjunctive treatment of postoperative 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.

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510(k) Summary
K231409

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

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Date Prepared

8/10/2023

Device Information

Trade Name: Erchonia® FX-405
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 Devices

Primary Predicate Device: Erchonia® FX-405 cleared under K212595.
Secondary Predicate Device: Erchonia® XLR8 cleared under K211186.

Device Description

Erchonia® FX-405 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 400nm to 410nm with a mean power output of 23.00mW. The Erchonia® FX-405 is a variable hertz device. The variable hertz feature of the Erchonia® FX-405 is a pulsed wave, defined as containing a selected series of breaks, variances that are preprogrammed. The Erchonia® FX-405 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

Indications for Use

The Erchonia® FX-405 laser is generally indicated:

a. while using the red and violet diodes, for the adjunctive use in providing temporary relief of nociceptive musculoskeletal pain.

b. and while using the red diodes, as an adjunctive treatment of postoperative pain.

Comparison of Technological Characteristics with the Predicate Devices

The subject device (Erchonia® FX-405) is the exact same model as the primary predicate device (Erchonia® FX- 405) previously cleared under K212595. The subject device (Erchonia® FX-405) and secondary predicate device (Erchonia® XLR8) have identical wavelength, energy source, and mechanism of action. There are no differences between the subject device and predicate devices that render the subject device not substantially equivalent nor affect safety or effectiveness.

Device	**Erchonia® FX-405**	**Erchonia® FX-405**	**Erchonia® XLR8**	**Difference Between Subject Device and Secondary Predicate Device**
510(k) #	K231409	K212595	K211186	
	Subject Device	Primary Predicate Device	Secondary Predicate Device	
Wavelength	Red: 630nm to 640nm Violet: 400nm to 410nm	Red: 630nm to 640nm Violet: 400nm to 410nm	Red: 640 ± 10	Both devices emit identical red wavelength
Number of Diodes	3 Red 1 Violet	3 Red 1 Violet	2 Red	The subject device enables the user to select the application of one to three diodes, therefore the number of diodes is identical or equivalent (does not affect safety or effectiveness) to the application of two diodes with the secondary predicate device.
Power (measured at aperture)	Red: 17.25mW ± 1.25mW Violet: 23mW ± 2mW	Red: 17.25mW ± 1.25mW Violet: 23mW ± 2mW	Red: 7.5mW ± 2mW	Difference in power is negligible (does not affect safety or effectiveness) when applied over the treatment area.
Energy Source	Diode collected then line dispersed (coherent)	Diode collected then line dispersed (coherent)	Diode collected then line dispersed (coherent)	Same
Total Joules Per Minute (50% duty cycle)	2.25	2.25	.45	Difference in total joules per minute is negligible (does not affect safety or effectiveness) when applied over the treatment area.
Recommended treatment duration	0 – 20 minutes	0 – 20 minutes	0 – 12 minutes	Both devices have the same recommended treatment time for the IFU, as an adjunctive treatment of postoperative pain.
J/cm^2 per minute	Red: .0035 J/cm2 Violet: .0045 J/cm2	Red: .0035 J/cm2 Violet: .0045 J/cm2	Not Publicly Available	Infomation not publicly available
Power Supply	1.5A/100VAC & 0.5A/240VAC, 50-60Hz electrical outlet	1.5A/100VAC & 0.5A/240VAC, 50-60Hz electrical outlet	External Power Supply –(100- 240Vac, 50-60Hz, 0.5A; 12Vdc 1.5A) that connect to the Inductive Charging Base –(1.5A 12V), to charge the Battery (Lithium-ion Polymer 3.7V, 1800mAh, 6.7W)	Safety and EMC testing conducted.
Energy Delivery	Floor model device with probe head	Floor model device with probe head	Handheld treatment probe	Difference in energy delivery does not affect treatment safety or effectiveness
Target Size	Line pattern, electronically scanned over area of treatment	Line pattern, electronically scanned over area of treatment	Line pattern, manually scanned over area of treatment	No difference in line pattern beam. The difference in electronically scanned or manually scanned does not change the physiological mechanism of the Erchonia Corporation 635nm diode laser for providing pain reduction and does not affect safety or effectiveness.

Indication for Use	The Erchonia® FX-405 laser is generally indicated: a. while using the red and violet diodes, for the adjunctive use in providing temporary relief of nociceptive musculoskeletal pain. b. and while using the red diodes, as an adjunctive treatment of postoperative pain.	The Erchonia® FX-405 laser is indicated for the adjunctive use in providing temporary relief of nociceptive musculoskeletal pain.	The Erchonia® XLR8 is generally indicated: a. as adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin. b. as an adjunct to liposuction procedures of the thighs, hips and stomach for reduction of pain associated with the recovery process. c. for the temporary reduction in post-surgery pain at 24 hours after surgery following bilateral breast augmentation surgery. d. as an adjunctive treatment of postoperative pain	No difference in IFU. Both devices are indicated while using red diodes, as an adjunctive treatment of postoperative pain.
Principles of Operation	Mains power, converted to DC, powering semi-conductor diodes	Mains power, converted to DC, powering semi-conductor diodes	DC, powering semi-conductor diodes	Safety and EMC testing conducted.
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	Same
Product Code	NHN	NHN	NHN	Same

Substantially Equivalent Discussion

The subject device (Erchonia® FX-405) is the exact same model as the primary predicate device (Erchonia® FX-405) previously cleared under K212595, “for the adjunctive use in providing temporary relief of nociceptive musculoskeletal pain”. The subject device (Erchonia® FX-405) and secondary predicate device both emit the Erchonia Corporation 635nm diode laser with identical wavelength, energy source, and mechanism of action.

The treatment for postoperative pain with the Erchonia® FX-405 and Erchonia® XLR8 is established upon the utilization of the Erchonia Corporation 635nm diode laser with identical wavelength and laser characteristics. The difference in output of Joules per minute and J/cm^2 per minute is negligible and does not affect the safety or effectiveness of the treatment.

The difference in application of treatment (manually or electronically scanned) device does not change the physiological mechanism of the Erchonia Corporation 635nm diode laser for providing pain reduction.

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 clinical data was used to establish Substantial Equivalence

Conclusion

The subject device is as safe, as effective, and performs as well as the legally marketed devices Erchonia® FX-405 and Erchonia® XLR8. The subject device is substantially equivalent to the Erchonia® FX-405 and Erchonia® XLR8.