



June 1, 2019

Erchonia Corporation  
% Steven Shanks  
President  
650 Atlantis Road  
Melbourne, FL 32904

Re: K190572

Trade/Device Name: Erchonia® FX-635  
Regulation Number: 21 CFR 890.5500  
Regulation Name: Infrared Lamp  
Regulatory Class: Class II  
Product Code: NHN  
Dated: March 5, 2019  
Received: March 6, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek Pinto, PhD  
Assistant Director, Acute Injury Devices Team  
DHT5B: Division of Neuromodulation  
and Rehabilitation Devices  
OHT5: Office of Neurological  
and Physical Medicine Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K190572

Device Name

Erchonia ® FX-635

Indications for Use (Describe)

The Erchonia® FX-635 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.

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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: Mr. Steven Shanks  
Telephone: 321-473-1251  
Fax: 321-473-1608  
Email: sshanks@erchonia.com

### **Date Prepared**

2/28/2019

### **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 primary predicate device:

Erchonia® FX-635 (Model# HPS) K180197

Additionally the Erchonia® FX-635 (Model# HPS) is substantially equivalent to the following secondary predicate device(s):

Erchonia® Allay (Model# HPS) K132940 as well as the TUCO Erchonia® PL2000 (Model# PL2) K012580

The Erchonia® FX-635 is the same model as the Erchonia® FX-635 previously submitted under K180197.

### **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.

The Erchonia® FX 635, model: HPS laser is indicated for the adjunctive use in providing temporary relief of nociceptive musculoskeletal pain. The Erchonia® Laser is applied externally and has proven through clinical trials to treat the neck, shoulder, low back and 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. 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 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 adjunctive use in providing temporary relief of nociceptive musculoskeletal pain.

**Comparison of Technological Characteristics with the Predicate Device**

The Erchonia® FX-635 is equivalent to the primary predicate device, Erchonia® FX 635 manufactured by Erchonia® as well as the secondary predicate device(s) the Erchonia® Allay as well as the TUCO Erchonia® PL2000. The principles of operation of the Erchonia® FX-635 are identical in every aspect to the previously cleared Erchonia® FX 635.

<b>Device</b>	<b>Erchonia® FX-635 (Model# HPS)</b>	<b>Erchonia® FX-635 (Model# HPS)</b>	<b>Erchonia® Allay (Model# HPS)</b>	<b>TUCO Erchonia® PL2000</b>
<b>510(k) #</b>	N/A	K180197	K132940	K012580
<b>Power (measured at aperture)</b>	17.25mW ± 1.25mW	17.25mW ± 1.25mW	17.25mW ± 1.25mW	<5mW
<b>Wavelength</b>	630nm to 640nm	630nm to 640nm	630nm to 640nm	630nm to 640nm
<b>Energy Source</b>	Multi diode collected then line dispersed (coherent)	Multi diode collected then line dispersed (coherent)	Multi diode collected then line dispersed (coherent)	Single diode collected then line dispersed (coherent)
<b>Treatment time</b>	Variable depending on area being treated – refer to Owner’s Manual	20 minutes for Low Back Pain and 10 minutes for Heel Pain	10 minutes for Heel Pain	0-9.9 minutes
<b>Total Joules Per Minute</b>	1.53 J	1.53 J	1.53 J	.15 J
<b>Power Supply</b>	1.5A/100VAC & 0.5A/240VAC, 50-60Hz electrical outlet	1.5A/100VAC & 0.5A/240VAC, 50/60Hz electrical outlet	1.5A/100VAC & 0.5A/240VAC, 50/60Hz electrical outlet	Rechargeable batteries: (six) nickel–metal hydride 7.2V, 2500mAh
<b>Energy Delivery</b>	Floor model device with probe head	Floor model device with probe head	Floor model device with probe head	Handheld treatment probe
<b>Target Size</b>	Line pattern, electronically scanned over area of treatment	Line pattern, electronically scanned over area of treatment	Line pattern, electronically scanned over area of treatment	Line pattern, manually scanned over area of treatment

<b>Indication for Use</b>	<p>The Erchonia® FX-635 laser is indicated for the adjunctive use in providing temporary relief of nociceptive musculoskeletal pain.</p>	<p>The Erchonia® FX-635 laser is indicated for the following two indications:</p> <ol style="list-style-type: none"> <li>a. as an adjunct to provide relief of minor chronic low back pain of musculoskeletal origin.</li> <li>b. as an adjunct to reducing chronic heel pain arising from plantar fasciitis.</li> </ol>	<p>The Erchonia® Allay™ laser is indicated as an adjunct to reducing chronic heel pain arising from plantar fasciitis.</p>	<p>The TUCO Erchonia® PL2000 is indicated for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.</p>
<b>Principles of Operation</b>	<p>Mains power, converted to DC, powering semi-conductor diodes</p>	<p>Mains power, converted to DC, powering semi-conductor diodes</p>	<p>Mains power, converted to DC, powering semi-conductor diodes</p>	<p>DC, powering semi-conductor diodes</p>
<b>Mechanism of Action</b>	<p>Stimulates the mitochondria to increase the production of ATP</p>	<p>Stimulates the mitochondria to increase the production of ATP</p>	<p>Stimulates the mitochondria to increase the production of ATP</p>	<p>Stimulates the mitochondria to increase the production of ATP</p>

## **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 Data**

Clinical testing of the Erchonia FX-635™ Laser device included three pivotal studies evaluating reduction of chronic neck and shoulder pain, chronic low back pain and heel pain arising from plantar fasciitis,. A total of 213 subjects were evaluated across all three studies. Each of these pivotal studies was used to support clearance of the respectively evaluated indications. Substantial equivalence is based in part on these three pivotal studies.

**Pivotal Study 1:** Study of the Effectiveness of the TUCO Erchonia PL2000 in Providing Temporary Relief of Minor Neck and/or Shoulder Pain of Chronic Origin

The pivotal study was a prospective, multi-center, randomized, double-blinded and placebo controlled multi-arm study of 100 subjects, of which 86 were available for primary endpoint analysis. Each of the 14 excluded subjects failed the study qualification evaluation.

The device was administered to the sagittal suture (top of head); left and right cervical, shoulder and torso areas; right and left shoulders during each of passive external rotation and passive adduction of the arm and shoulder; right and left cervical muscles and trapezius muscles during passive left lateral flexion of the cervical spine; and the right and left sternocleidomastoid and scalene muscles during passive range of motion, for a total of 13 minutes during a single treatment administration.

Subjects were adults with neck and shoulder pain of musculoskeletal origin (osteoarthritis, chronic muscle spasms and cervical and thoracic spine sprain strain) ongoing for at least 30 days, and a rating of 50 or greater on the 0-100 Visual Analog Pain scale (VAS). Average duration of neck and/or shoulder pain at study entry was about 6 years. Demographic data was not collected for subjects in this study.

All subjects were followed for a period of 48 hours at 3 sites, each in the United States only.

**Patient Accountability**

Stage	Investigational Device Arm Total	Control (Placebo) Arm Total	Total
Enrollment	50	50	100
Treatment	43	43	86



Primary Effectiveness Endpoint Analysis	43	43	86
Primary Safety Endpoint Analysis	43	43	86

### Primary effectiveness endpoint

The primary efficacy endpoint was immediately following the single device treatment administration relative to baseline. The primary efficacy measure was the change in neck and shoulder pain rating as recorded on the 0-100 VAS.

Individual subject success was defined as a 30% or greater improvement (decrease) in the primary efficacy measure from baseline to endpoint. Study success was defined as a minimum 30% difference between treatment groups, comparing the proportion of individual successes.

Study results demonstrated that 65.1% of actively treated subjects attained individual success compared with 11.6% of control (placebo) subjects, resulting in a 53.5% difference between treatment groups, exceeding the 30% criteria by 23.5% ( $p < 0.0001$ ). Hence the study met its primary efficacy endpoint.

The magnitude of the mean change in neck and shoulder pain VAS rating at endpoint relative to baseline was -29.02 for actively-treated subjects and -4.91 for control (placebo) subjects, a 20.08 difference ( $p < 0.0005$ ).

### Primary safety endpoint:

The primary safety endpoint consisted of all treatment-related adverse events.

No treatment-related adverse event was reported or observed for any subject throughout study duration, and no other safety issues occurred; therefore, device safety is supported through these study results.

### Summary

Based on the clinical performance as documented in pivotal study 1, the Erchonia PL2000 was found to have a safety and effectiveness profile that supported clearance of K012580, indicated for “adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.”

### **Pivotal Study 2:** A Double-Blind, Placebo-Controlled, Randomized Evaluation of the Effect of The Erchonia® Allay™ Laser on Chronic Heel Pain.

The pivotal study was a prospective, multi-center, randomized, double-blinded and placebo controlled multi-arm study of 69 subjects, of which all 69 were available for primary endpoint analysis. The device was administered across the top of the foot (dorsal aspect), the myofascial junction of the heel, and the plantar aspect of the heel, simultaneously, for ten minutes per treatment: two treatments per week, each three of four days apart, across a consecutive three-week period, for a total of six treatments.

Subjects were adults with unilateral mechanical plantar heel pain of at least three months duration and a rating of 50 or greater on the Visual Analog Pain scale (VAS) with failure to respond to prescription non-steroidal anti-inflammatory drugs (NSAIDs) and two or more additional conservative treatment approaches. Subjects averaged 56.29 years, were

predominantly Caucasian (90%), with a 2:3 ratio of females to males (39% versus 61%). Average duration of heel pain at study entry was 12.29 months.

All subjects were followed for a period of two weeks after treatment end, and 23 of the active treatment subjects were followed for 12 months, at 2 sites, both in the United States only.

**Patient Accountability**

Stage	Investigational Device Arm Total	Control (Placebo) Arm Total	Total
Enrollment	37	32	69
Treatment	37	32	69
Primary Effectiveness Endpoint Analysis	37	32	69
Primary Safety Endpoint Analysis	37	32	69

**Primary effectiveness endpoint**

The primary efficacy endpoint was two weeks after treatment end relative to baseline. The primary efficacy measure was the change in 2-day average first steps of the day heel pain as recorded on the 0-100 VAS.

Individual subject success was defined as a 30% or greater improvement (decrease) in the primary efficacy measure from baseline to endpoint. Study success was defined as a minimum 35% difference between treatment groups, comparing the proportion of individual successes.

Study results demonstrated that 62% of actively treated subjects attained individual success compared with 12.5% of control (placebo) subjects, resulting in a 49.5% difference between treatment groups, exceeding the 30% criteria by 19.5% (p<0.00005). Hence the study met its primary efficacy endpoint.

The magnitude of the mean change in 2-day average first steps of the day heel pain VAS rating at endpoint relative to baseline was -29.47 for actively-treated subjects and -5.38 for control (placebo) subjects, a 24.09 difference (p<0.0001).

For actively-treated subjects followed through to 12 months post-treatment, mean change in 2-day average first steps of the day heel pain VAS rating relative to baseline decreased 62.94 points to 6.94 (p<0.0001).

**Primary safety endpoint:**

The primary safety endpoint consisted of all treatment-related adverse events.

No treatment-related adverse event was reported or observed for any subject throughout study duration, and no other safety issues occurred; therefore, device safety is supported through these study results.

**Summary**

Based on the clinical performance as documented in pivotal study 4, the Erchonia Allay™ was found to have a safety and effectiveness profile similar to the predicate device. The results of this

pivotal study supported clearance for K132940, indicated as “an adjunct to reducing chronic heel pain arising from plantar fasciitis.”

**Pivotal Study 3:** A double-blind, placebo-controlled randomized evaluation of the effect of the Erchonia® FX-635™ on low back pain

The pivotal study was a prospective, multi-center, randomized, double-blinded and placebo controlled multi-arm study of 58 subjects, of which all 58 were available for primary endpoint analysis. The device was administered across the lower back region for twenty minutes per treatment: two treatments per week, each three of four days apart, across a consecutive four-week period, for a total of eight treatments.

Subjects were adults with episodic chronic low back pain of musculoskeletal origin of lumbar sprain or strain etiology and a low back pain rating of 40 or greater on the 0 to 100 VAS.

Subjects averaged 45.57 years, were predominantly Caucasian (69%) followed by Hispanic (14%), African American (8.5%) and Asian (8.5%), with equal distribution of males and females (47% versus 53%). Average duration of low back pain at study entry was just over 8 years.

Subjects were followed for a period of three months at 3 sites, each in the United States only.

**Patient Accountability**

Stage	Investigational Device Arm Total	Control (Placebo) Arm Total	Total
Enrollment	29	29	58
Treatment	29	29	58
Primary Effectiveness Endpoint Analysis	29	29	58
Primary Safety Endpoint Analysis	29	29	58

**Primary effectiveness endpoint**

The primary efficacy endpoint was two months after treatment end relative to baseline. The primary efficacy measure was the change in low back pain rating as recorded on the 0-100 VAS. Individual subject success was defined as a 30% or greater improvement (decrease) in the primary efficacy measure from baseline to endpoint. Study success was defined as a minimum 35% difference between treatment groups, comparing the proportion of individual successes.

Study results demonstrated that 72.4% of actively treated subjects attained individual success compared with 27.6% of control (placebo) subjects, resulting in a 44.8% difference between treatment groups, exceeding the 30% criteria by 14.8% (p<0.005). Hence the study met its primary efficacy endpoint.

The magnitude of the mean change in low back pain VAS rating at endpoint relative to baseline was -34.24 for actively-treated subjects and -10.97 for control (placebo) subjects, a 23.37 difference (p<0.001).

**Primary safety endpoint:**

The primary safety endpoint consisted of all treatment-related adverse events.

No treatment-related adverse event was reported or observed for any subject throughout study duration, and no other safety issues occurred; therefore, device safety is supported through these study results.

**Summary**

Based on the clinical performance as documented in pivotal study 3, the Erchonia FX-6535™ was found to have a safety and effectiveness profile similar to the predicate device. The results of this pivotal study supported clearance for K180197, indicated as an “adjunct to provide relief of minor chronic low back pain of musculoskeletal origin.”

**Conclusion**

Any technological differences between the subject device and predicate do not render the device not substantially equivalent, do not affect the safety or effectiveness, or raise questions regarding the safety and effectiveness due to the fact the total light energy delivered per treatment is equivalent to the predicate(s). The new and predicate device(s) have equivalent technology and provides the same wavelength. The predicate device(s) treatment protocols went through clinical trials to demonstrate that they are safe and effective in providing relief of nociceptive pain of musculoskeletal origin; specifically, chronic neck and shoulder pain (K012580) and low back pain (K180197) as well as chronic heel pain arising from plantar fasciitis (K132940).

The table below provides a comparison of study design and results for each of the respective clinical studies with their associated nociceptive musculoskeletal pain reduction clearance:

510(k) #	Device Name	IFU	Study Design	# Subjects	# Sites	Treatment Administration	Primary Outcome	Blinding Assessment	Results
K012580	PL2000	adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.	Double-blind, randomized, placebo-controlled.	86: Test: 43 Placebo: 43	3	Single treatment to the sagittal suture, shoulder, cerebral, cervical and torso regions for a combined total of 13 minutes.	Change in 0-100 VAS pain rating pre- to post-treatment. Individual Success Criteria: 30%+ VAS decrease Study Success Criteria: 30% difference between groups.	Yes.	Individual Subject Success: Test: 65.1%. Placebo: 11.6%. Overall Study Success: 53.5% difference.
K132940	Allay	adjunct to reducing chronic heel pain arising from plantar fasciitis.	Double-blind, randomized, placebo-controlled.	69: Test: 37 Placebo: 32	2	6 10-minute treatments 2 times/week for 3 weeks to the foot.	Change in 0-100 VAS pain rating pre- to post-treatment. Individual Success Criteria: 30%+ VAS decrease Study Success Criteria: 30% difference between groups.	Yes.	Individual Subject Success: Test: 62%. Placebo: 12.5%. Overall Study Success: 49.5% difference.
K180197	FX-635	adjunct to provide relief of minor chronic low back pain of musculoskeletal origin.	Double-blind, randomized, placebo-controlled.	58: Test: 29 Placebo: 29	3	8 20-minute treatments 2 times/week for 4 weeks across the lower back region	Change in 0-100 VAS pain rating pre- to post-treatment. Individual Success Criteria: 30%+ VAS decrease Study Success Criteria: 35% difference between groups.	Yes.	Individual Subject Success: Test: 72.4%. Placebo: 27.6%. Overall Study Success: 44.8% difference.

Therefore, based on the collective clinical performance of the equivalent predicate devices, the physiological mechanism of action provided by the Erchonia Corporation 635nm diode laser has demonstrated safety and effectiveness to support the proposed indication of use “for the adjunctive use in providing temporary relief of nociceptive musculoskeletal pain.”