



January 24, 2025

Wuhan Guangdun Technology Co.,Ltd.  
% Boyle Wang  
Manager  
Shanghai Truthful Information Technology Co., Ltd.  
Room 1801, No. 161 East Lujiazui Rd., Pudong  
Shanghai, 200120  
China

Re: K241057

Trade/Device Name: Enhanced Handheld Pain Relief Laser Instrument (GD-P-E)  
Regulation Number: 21 CFR 890.5500  
Regulation Name: Infrared Lamp  
Regulatory Class: Class II  
Product Code: NHN  
Dated: December 24, 2024  
Received: December 30, 2024

Dear Boyle Wang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

**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

## Indications for Use

510(k) Number (if known)

K241057

Device Name

Enhanced Handheld Pain Relief Laser Instrument (GD-P-E)

Indications for Use (Describe)

The GD-P-E Enhanced Handheld Pain Relief Laser Instrument generally indicated:

- adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin;
- adjunctive use in providing temporary relief of minor chronic pain associated with Carpal Tunnel Syndrome (CTS)

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 requirements of 21 CFR 807.92.

### **Submitter's Information**

Name: Wuhan Guangdun Technology Co.,Ltd.  
 Applicant address: No.1,Floor 3, Building 2-05,Optics Valley Chip Center II, NO.303,Optics Valley Avenue,East Lake New Technology Development Zone,Wuhan,Hubei P.R.China  
 Telephone: +86-27-59368661  
 Contact: Suzy Pan

### **Designated Submission Correspondent**

Contact: Mr. Boyle Wang  
 Name: Shanghai Truthful Information Technology Co., Ltd.  
 Address: Room 1801, No. 161 East Lujiazui Rd., Pudong Shanghai, 200120 China  
 Tel: +86-21-50313932  
 Email: [Info@truthful.com.cn](mailto:Info@truthful.com.cn)

Date of Preparation: January 21, 2025

### **Device Information**

510(k) Number: K241057  
 Trade name: Enhanced Handheld Pain Relief Laser Instrument  
 Common name: Infrared lamp  
 Classification name: Powered Light Based Laser Non-Thermal Instrument With Non-Heating Effect for Adjunctive Use in Pain Therapy  
 Model(s): GD-P-E  
 Production code: NHN  
 Regulation number: 21 CFR 890.5500  
 Classification: Class II  
 Panel: Physical Medicine

### **Predicate Devices**

**Primary Predicate Device:**

Manufacturer: GRT Solutions, Inc.  
Trade/Device Name: GRT LITE Model PRO-8A  
510(k) number: K050668

**Predicate Device 2:**

Manufacturer: TUCO Innovations, Inc.  
Trade/Device Name: TUCO Erchonia® PL2000  
510(k) number: K012580

**Predicate Device 3:**

Manufacturer: THØR International Ltd.  
Trade/Device Name: THØR DDII 830CL3 Laser System  
510(k) number: K030226

**Predicate Device 4:**

Manufacturer: Erchonia Corporation  
Trade/Device Name: Erchonia® XLR8  
510(k) number: K130996

**Device Description**

The GD-P-E Enhanced Handheld Pain Relief Laser Instrument consists of a LCD, button, battery, power charger jack. Accessories include a power cords, a power adapter. It is a handheld, non-invasive, non-heating infrared cold laser instrument designed to be used as an adjunct treatment for managing the temporary relief of pain associated with Carpal Tunnel Syndrome. A key feature of the device is its ability to produce multiple laser wavelengths (808nm and 650nm).

A key feature of the device is its ability to emit dual laser wavelengths (808nm and 650nm), providing targeted low-level light therapy to the affected area. This "cold" laser therapy enables body tissue to absorb the light, facilitating a temporary reaction within the cells that promotes minor pain relief.

**Indication for Use Statement**

The GD-P-E Enhanced Handheld Pain Relief Laser Instrument generally indicated:

- adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin;
- adjunctive use in providing temporary relief of minor chronic pain associated with Carpal Tunnel Syndrome (CTS).

**Comparison to the Predicate Device**

| Item                                   | Subject Device<br>(K241057)                                                                                                                                                                                                                                                                                                                                                                         | Primary<br>Predicate Device<br>(K050668)                                                                                                                                                                                                                                                                                                                                                                                                            | Predicate<br>Device 2<br>(K012580)                                                                                                                        | Predicate<br>Device 3<br>(K030226)                                                                                                                       | Predicate<br>Device 4<br>(K130996)                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Trade Name                             | Enhanced<br>Handheld Pain<br>Relief<br>Laser Instrument                                                                                                                                                                                                                                                                                                                                             | GRT LITE Model<br>PRO-8A                                                                                                                                                                                                                                                                                                                                                                                                                            | TUCO<br>Erchonia®<br>PL2000                                                                                                                               | THØR DDII<br>830CL3<br>Laser System                                                                                                                      | Erchonia®<br>XLR8                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Class<br>Product<br>Code<br>Regulation | Class II<br>NHN<br>21 CFR 890.5500                                                                                                                                                                                                                                                                                                                                                                  | Class II<br>NHN<br>21 CFR 890.5500                                                                                                                                                                                                                                                                                                                                                                                                                  | Class II<br>NHN<br>21 CFR<br>890.5500                                                                                                                     | Class II<br>NHN<br>21 CFR<br>890.5500                                                                                                                    | Class II<br>NHN<br>21 CFR<br>890.5500                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Indications<br>for Use                 | The GD-P-E<br>Enhanced<br>Handheld Pain<br>Relief Laser<br>Instrument<br>generally<br>indicated:<br><ul style="list-style-type: none"> <li>• adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin;</li> <li>• adjunctive use in providing temporary relief of minor chronic pain associated with Carpal Tunnel Syndrome (CTS).</li> </ul> | The GRT LITE Model PRO-8A is a non-heating lamp, infrared as described under the provisions of 21 CFR §890.5500 and is clinically indicated for:<br><ul style="list-style-type: none"> <li>• Adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.</li> <li>• Adjunctive use in providing temporary relief of minor chronic pain associated with Carpal Tunnel Syndrome (CTS).</li> </ul> | The TUCO Erchonia PL2000 is indicated for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin. | The THØR DDII 830CL3 Laser System is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome. | The Erchonia® XLR8™ laser is indicated for the following three indications:<br>a. adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin<br>b. as an adjunct to liposuction procedures of the thighs, hips and stomach for reduction of pain associated with the recovery process<br>c. temporary reduction in post-surgery pain at 24 hours after surgery following bilateral breast augmentation surgery |
| Type of Use                            | Prescription Use Only                                                                                                                                                                                                                                                                                                                                                                               | Prescription Use Only                                                                                                                                                                                                                                                                                                                                                                                                                               | Prescription Use Only                                                                                                                                     | Prescription Use Only                                                                                                                                    | Prescription Use Only                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Wavelength                             | 650nm (±10nm)<br>808nm (±10nm)                                                                                                                                                                                                                                                                                                                                                                      | 628nm (±5nm)<br>850nm (±5nm)                                                                                                                                                                                                                                                                                                                                                                                                                        | Not Publicly Available                                                                                                                                    | 830nm                                                                                                                                                    | Not Publicly Available                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Aiming Beam                            | Laser Diodes, Class 3R                                                                                                                                                                                                                                                                                                                                                                              | Visible LEDs (628nm)<br>Infrared LEDs (850nm)                                                                                                                                                                                                                                                                                                                                                                                                       | Not Publicly Available                                                                                                                                    | Laser Diodes                                                                                                                                             | Not Publicly Available                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Terminal Output                        | 13 x 650nm (Laser Diodes)<br>4 x 808nm (Laser Diodes)                                                                                                                                                                                                                                                                                                                                               | 2 x 628nm (Visible LEDs)<br>2 x 850nm (Infrared LEDs)                                                                                                                                                                                                                                                                                                                                                                                               | Not Publicly Available                                                                                                                                    | 3 x 830nm (Laser Diodes)                                                                                                                                 | Not Publicly Available                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Timing Range                           | 5 or 8 minutes                                                                                                                                                                                                                                                                                                                                                                                      | Not Publicly Available                                                                                                                                                                                                                                                                                                                                                                                                                              | Not Publicly Available                                                                                                                                    | Not Publicly Available                                                                                                                                   | Not Publicly Available                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Max Power                              | 650nm x 5mW<br>808nm x 3mW                                                                                                                                                                                                                                                                                                                                                                          | Not Publicly Available                                                                                                                                                                                                                                                                                                                                                                                                                              | Not Publicly Available                                                                                                                                    | 3 x 30mW                                                                                                                                                 | Not Publicly Available                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Energy Fluence                         | 1773.15 mJ/mm²                                                                                                                                                                                                                                                                                                                                                                                      | Not Publicly Available                                                                                                                                                                                                                                                                                                                                                                                                                              | Not Publicly Available                                                                                                                                    | Not Publicly Available                                                                                                                                   | Not Publicly Available                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Irradiance                             | 3.43 mW/mm² to 4.95 mW/mm²                                                                                                                                                                                                                                                                                                                                                                          | Not Publicly Available                                                                                                                                                                                                                                                                                                                                                                                                                              | Not Publicly Available                                                                                                                                    | Not Publicly Available                                                                                                                                   | Not Publicly Available                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Spot Size                              | 1.16 mm² (Avg.)                                                                                                                                                                                                                                                                                                                                                                                     | Not Publicly Available                                                                                                                                                                                                                                                                                                                                                                                                                              | Not Publicly Available                                                                                                                                    | Not Publicly Available                                                                                                                                   | Not Publicly Available                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Power Mode                             | Pulsed & Continuous Modulation                                                                                                                                                                                                                                                                                                                                                                      | Pulsed & Continuous Modulation                                                                                                                                                                                                                                                                                                                                                                                                                      | Not Publicly Available                                                                                                                                    | Not Publicly Available                                                                                                                                   | Not Publicly Available                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Energy Delivery                        | Handheld treatment probe                                                                                                                                                                                                                                                                                                                                                                            | Hand-held, non-invasive, pain therapy system                                                                                                                                                                                                                                                                                                                                                                                                        | Not Publicly Available                                                                                                                                    | Handheld, non-invasive, low energy,                                                                                                                      | Not Publicly Available                                                                                                                                                                                                                                                                                                                                                                                                                                             |

|                        |                                                               |                                                                                              |                           |                                                                        |                           |
|------------------------|---------------------------------------------------------------|----------------------------------------------------------------------------------------------|---------------------------|------------------------------------------------------------------------|---------------------------|
|                        |                                                               |                                                                                              |                           | non-heating<br>infrared<br>therapeutic<br>medical laser                |                           |
| Power                  | 3.7V -1950mAh<br>Lithium-ion<br>battery                       | Not Publicly<br>Available                                                                    | Not Publicly<br>Available | Not Publicly<br>Available                                              | Not Publicly<br>Available |
| Performance<br>Testing | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60825-1<br>IEC 60601-1-11 | 21 CFR –<br>Subchapter J – Part<br>1010<br>FCC Standard - 47<br>CFR Part 15B<br>UL® Approved | Not Publicly<br>Available | EN 60601-<br>1:1993<br>EN 60601-2-<br>22:1996<br>EN 60601-1-<br>2:1994 | Not Publicly<br>Available |

### **Non-Clinical Test Data**

Non clinical tests were conducted to verify that the subject devices met all design specifications as were Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1: 2020 Medical Electrical Equipment -- Part 1: General Requirements for Basic Safety and essential performance
- IEC 60601-1-2:2020 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60825-1:2014 Safety of Laser products-Part 1: Equipment classification and requirements
- IEC 60601-1-11:2020 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

In addition, the Output Parameters including Output wavelength(s), Power, Energy fluence, Irradiance and the Beam Focus and Energy Distribution Test of the candidate device have been performed. The results of these tests demonstrated that the device performs as intended and meets its specifications:

Software Information:

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA guidance

“Content of Premarket Submissions for Device Software Functions”, issued on June 14, 2023

### **Clinical Test Conclusion**

No clinical study is included in this submission.

### **Conclusion**

Performance testing contained in this submission demonstrates the minor differences in technological characteristics between the subject device and the predicate do not raise different questions of safety and effectiveness. And based on the performance testing and compliance with acceptable voluntary standards, we believe the subject device is substantially equivalent to its predicate device.