December 12, 2025

DMC Importação e Exportação de Equipamentos LTDA
% Tatiana Jabor Botura
Regulatory Affairs Specialist
PR Serviços Regulatórios Administrativos Ltda
Edifício Pórtico Sul - R. José Jaime Delibo, 160,
Nova Aliança
Ribeirão Preto, SP 14026-563
Brazil

Re: K252273
Trade/Device Name: Therapy US
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: NHN
Dated: November 17, 2025
Received: November 17, 2025

Dear Tatiana Jabor Botura:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CHUN XU -S

For 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252273

Device Name
Therapy US

Indications for Use *(Describe)*
Therapy US is generally indicated for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.

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

ADMINISTRATIVE INFORMATION

Sponsor/Manufacturer Name	DMC Importação e Exportação de Equipamentos LTDA. Rua Sebastião de Moraes, 831 – Parque Santa Felícia – São Carlos, SP – Brazil. Phone: +55 (16) 2107-2323
Consultants	Tatiana Jabor Botura and Letícia Teixeira Regulatory Affairs Specialists Passarini Regulatory Affairs PR Serviços Regulatórios Administrativos Ltda Email: tatiana@passarini.com.br Telephone +55 (16) 98217-0125
Date Prepared	December 12, 2025

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Therapy US
Common Name	Infrared Lamp
Classification Name	Powered Light Based Laser Non-Thermal Instrument With Non-Heating Effect For Adjunctive Use In Pain Therapy
Product Code	NHN
Classification Regulation	21 CFR 890.5500, Class II
Review Panel	Physical Medicine

PREDICATE DEVICE INFORMATION

Predicate	K241057 - Enhanced Handheld Pain Relief Laser Instrument (GD-P-E) - Wuhan Guangdun Technology Co.,Ltd.

Indications for Use

Therapy US is generally indicated for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.

Device Description

The Therapy US consists of an ergonomic device that is easy to use and operate. The device has a red laser diode (660 nm) and an infrared laser diode (808 nm). Two optical fibers conduct the laser light emitted by each emitter. The optical power emitted is controlled by the electrical current in the laser diodes.

The Therapy US should be used by doctors, nurses, and physical therapists for adjunctive use in temporary pain relief of minor chronic neck and shoulder pain in patients.

The Therapy US consists of components including a handpiece, handpiece holder, battery charging cable, spacer (3 units), safety glasses, eye protection, and carrying case. The only part that comes into contact with the patient is the spacer. This component is made of polycarbonate, and its function is to create a safe distance between the tip of the therapy device and the patient's skin.

Substantial Equivalence

A comparison between the subject device and predicate is presented in the table below:

Table 1. Substantial equivalence

Contents	Subject device	Predicate device	Equivalence
K number	K252273	K241057	-
Device name	Therapy US	Enhanced Handheld Pain Relief Laser Instrument	-
Design			Equivalent
Product code	NHN	NHN	Equivalent
Regulation number	21 CFR 890.5500	21 CFR 890.5500	Equivalent
Class	Class II	Class II	Equivalent
Indications for use	Therapy US is generally indicated for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.	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;	The indication for use is a subset of the predicate device's indications for use.

Contents	Subject device	Predicate device	Equivalence
		- adjunctive use in providing temporary relief of minor chronic pain associated with Carpal Tunnel Syndrome (CTS).	
Type of use	Prescription Use Only	Prescription Use Only	Equivalent
Emitters technology	Diode Laser	Not Publicly Available	Equivalent to the predicate device.
Optical power	100 mW	Not Publicly Available	Equivalent to the predicate device.
Wavelengths	660 nm (±10 nm) 808 nm (±10 nm)	650 nm (± 10 nm) 808 nm (± 10 nm)	The subject device is equivalent to the predicate device
Spacer Dimensions & Weight	14 mm (0.55 in.): length 13.5 mm (0.53 in.): outer diameter 11.74 mm (0.46 in.): inner diameter 0.230 g (0.0081 oz.): weight	Not Publicly Available	Equivalent to the predicate device.
Handpiece Dimensions & Weight	210 mm (8.27 in.): height 30 mm (1.18 in.): width 50 mm (1.97 in.): depth 200 g (7.05 oz.): weight	Not Publicly Available	Equivalent to the predicate device.
Anatomical sites of use	Neck and shoulder	Not Publicly Available	The subject device is intended for use on the neck and shoulder, similar to the predicate device.
Timing range per session	1 – 8 minutes	5 or 8 minutes	The timing range per session for the subject device is similar to the predicate device, with both devices sharing the same maximum session duration.
Aiming beam	NA (contact application)	Laser Diodes, Class 3R	The subject device does not include an “aiming beam” by definition, as it is intended for contact applications only; however, it incorporates a Class 2 visible beam (emitted by a 660 nm laser diode),

Contents	Subject device	Predicate device	Equivalence
			which represents a lower hazard level to human eyes and skin compared to the Class 3R aiming beam of the predicate device.
Terminal output	1 × 660 nm (Laser diode) 1 × 808 nm (Laser diode)	13 × 650 nm (Laser diodes) 4 × 808 nm (Laser diodes)	Both the subject device and the predicate device use red laser light (660 nm for the subject device and 650 nm for the predicate device, both within the red spectrum) as well as infrared laser light (808 nm for both devices). Although the number of emitters differs between the devices, the safety of use is primarily determined by the amount of optical power (P) delivered per unit area (A) – that is, its irradiance (E = P/A). As presented in the "Irradiance" line of this same table, the irradiance values of the subject device are lower than those of the predicate device.
Power (measured at aperture)	660 nm × 100 mW 808 nm × 100 mW	650 nm × 5 mW 808 nm × 3 mW	The subject device has one red laser diode with 100 mW and one infrared laser diode with 100 mW, whereas the predicate device has 13 red laser diodes with 5 mW each (totaling 65 mW) and 4 infrared laser diodes with 3 mW each (totaling 12 mW). Although the subject device presents a higher optical power than the predicate device, its irradiance is significantly lower (as presented in the "Irradiance" line of this same table). Irradiance is the parameter used to evaluate the safety of laser light, as it depends on the amount of optical power delivered per

Contents	Subject device	Predicate device	Equivalence
			unit area rather than on the device's overall output power.
Energy fluence	583 mJ/mm² (1 x 8 minute session) 1748.16 mJ/mm² (3 x 8 minute consecutive sessions)	1773.15 mJ/mm²	Considering the irradiance value of 1.214 mW/mm² for each emitter of the subject device and an application time of 8 minutes (480 s), the energy fluence (H) of the subject device is: $H = (1.214 \times 10^3\ W/m^2) \times 480\ s = 583\ mJ/mm^2$. In other words, the energy fluence of the predicate device is approximately three times higher than that of the subject device for an 8 minute treatment session. To reach an equivalent fluence level, the subject device is intended to be applied for 24 minutes (3 x 8 min sessions consecutively) as stated in the instructions for use.
Irradiance	1.214 mW/mm² (660 nm) 1.214 mW/mm² (808 nm)	3.43 mW/mm² to 4.95 mW/mm²	The irradiance of the K241057 predicate device is approximately 2.8 to 4.1 times higher than that of the subject device. The lower irradiance of the subject device represents a more conservative level of optical power per unit area, ensuring safety of the subject device.
Spot size	82 mm²	1.16 mm² (avg.)	The primary predicate device has an average beam area of 1.16 mm², compared to 82 mm² for the subject device. The significantly smaller beam

Contents	Subject device	Predicate device	Equivalence
			area of the predicate device results in a higher concentration of power, which represents a more demanding safety condition than that required for the subject device.
Power mode (pulsed/continuous)	Continuous modulation	Pulsed & Continuous Modulation	Equivalent to the predicate device.
Power supply	3.7 V – 2420 mAh Lithium-ion battery	3.7 V – 1950 mAh Lithium-ion battery	Both batteries operate at the same voltage and use the same lithium-ion chemistry, differing only in capacity. The higher capacity of the subject device's battery (2420 mAh vs. 1950 mAh) provides longer operating time without altering the safety of the device.

The comparative evaluation between the Therapy US device, which is the subject of this submission, and its predicates device, Enhanced Handheld Pain Relief Laser Instrument – GD-P-E (K241057), demonstrates substantial equivalence in the following fundamental aspects:

A) Product Code and Regulatory Classification

Both devices share the product code NHN and are regulated under 21 CFR 890.5500, belonging to Class II.

B) Operating Principle

The subject device uses a Diode Laser to emit infrared radiation. This mode of action is consistent with the predicate device K232813, which also uses a diode laser (semiconductor). This technological alignment supports that no new mechanisms of risk or clinical efficacy are introduced

C) Indications for Use

Therapy US is indicated for temporary relief of mild chronic pain in the neck and shoulders, of musculoskeletal origin.

Thus, the clinical scope of Therapy US is fully covered by the indications of the predicate and does not represent new clinical purposes.

D) Technical Parameters

Optical Power: Therapy US has 100 mW of optical power, equivalent to the predicate device.

Wavelengths: Therapy US operates at 660 nm ±10 nm and 808 nm ±10 nm, which are equivalent to the predicate device.

Non-Clinical Data

The Therapy US device is part of a validated family of therapeutic laser systems that share identical design architecture, manufacturing processes, and materials of construction.

Compliance with applicable requirements for basic safety, essential performance, and electromagnetic compatibility has been demonstrated through testing of a representative configuration from the same product platform, selected as the worst-case model due to its higher optical output and equivalent electronic circuitry.

This approach ensures that the conclusions obtained are conservative and fully applicable to the Therapy US.

- Electrical Safety and Essential Performance

Evaluated in accordance with IEC 60601-1 and IEC 60601-1-6. Testing performed on a representative configuration from the Therapy product family demonstrated full compliance with applicable requirements.

- Electromagnetic Compatibility (EMC)

The results obtained demonstrate that the Therapy US laser system meets the defined optical performance specifications and operates safely within the established limits. Furthermore, EMC tests performed on a representative model from the Therapy product family confirmed full compliance with IEC 60601-1-2:2014 + A1:2020 standards, with no hazardous conditions, instability, or degradation of essential performance identified.

- Laser Safety and Performance

Conducted in accordance with IEC 60601-2-22, IEC 60825-1:2014, and IEC/TR 60825-13:2011. Parameters evaluated included optical power, spatial profile, irradiance, divergence angle, and beam safety. All testing demonstrated compliance with applicable requirements.

- Software Verification and Validation

The Therapy US software was developed under a controlled life-cycle process. Verification and validation were performed following the approved Software Development Plan and Validation Report. All unit, integration, and system tests met acceptance criteria, and no unresolved anomalies were identified.

Cybersecurity verification was conducted covering firmware integrity, update control, and USB port isolation.

All software and cybersecurity evaluations confirmed compliance with applicable FDArecognized consensus standards and essential performance requirements.

- Biocompatibility

Biocompatibility evaluation for the subject device was conducted in accordance with ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by the FDA. The Blue Spacer component, the only patient-contacting part, was tested for:

- Cytotoxicity
- Sensitization
- Irritation

All results confirmed that the material is non-cytotoxic, non-sensitizing, and non-irritating.

Clinical Performance Data:

No clinical data was included in this submission.

Conclusion:

The documentation submitted in this premarket notification demonstrates that Therapy US performance testing conducted shows that minor differences in technological characteristics between the subject device and its predicate do not raise new or different questions of safety or effectiveness. All non-clinical performance endpoints were achieved using validated methods, and results confirmed performance equivalent to the predicate device. Based on these outcomes and compliance with FDA-recognized voluntary consensus standards, the subject device is considered as safe, as effective, and substantially equivalent to its predicate.