



December 19, 2024

DMC Importacao e Exportacao de Equipamentos LTDA  
Homero Santiago Antunes and Tatiana Jabor Botura  
Regulatory Affairs Specialist  
PR Servicos Regulatorios Administrativos Ltda  
Rua Alice Alem Saadi, 855/2402  
Ribeirao Preto, Sao Paulo 14096570  
Brazil

Re: K232813

Trade/Device Name: Therapy EC, Therapy XT  
Regulation Number: 21 CFR 890.5500  
Regulation Name: Infrared Lamp  
Regulatory Class: Class II  
Product Code: NHN  
Dated: November 18, 2024  
Received: November 18, 2024

Dear Homero Santiago Antunes and 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Amber T. Ballard -S**

Amber Ballard, PhD  
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DHT5B: Division of Neuromodulation and  
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Enclosure

## Indications for Use

510(k) Number (if known)  
K232813

Device Name  
Therapy EC and Therapy XT

Indications for Use (Describe)

Therapy EC and Therapy XT are non-heating infrared lamps and are indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.

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 – K232813

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**Date Prepared:** December 17, 2024

**Device Trade Name:** Therapy EC and Therapy XT

**Regulation and Classification Description:** 21 CFR 890.5500, Infrared lamp

**Class:** II

**Product Code:** NHN

**Predicate Device:** TH0R DDII 830CL3 Laser System (K030226)

### Indications for Use

Therapy EC and Therapy XT are non-heating infrared lamps and are indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.

### Device Description

Therapy EC and Therapy XT are made up of ergonomic equipment that is easy to use and operate. They have one infrared laser diode (808nm). 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.

Therapy EC and Therapy XT are designed to emit infrared laser light. Additionally, they are intended to be used by health care professionals such as physicians, nurses, and physical therapists, for adjunctive use in the temporary relief of hand of wrist pain associated with Carpal Tunnel Syndrome.

Therapy EC and Therapy XT are consisted of components including handpiece, handpiece holder, battery charging cable, battery, spacer (3 units), safety glasses, eye protector, and transportation case. The only part that touches the patient is the spacer. This component is made of polycarbonate and has the function of creating a safe distance between the Therapy tip and the patient's skin.

## Comparison of Technological Characteristics with the Predicate Device

Table 1: Comparison of Subject and Predicate Devices

Contents	Subject device	Primary Predicate (K030226)
Device name	Therapy EC and Therapy XT	TH0R DDII 830CL3 Laser System
Product code	NHN	NHN
Regulation Number	21 CFR 890.5500	21 CFR 890.5500
Class	Class II	Class II
Indications for use	Therapy EC and Therapy XT are non-heating infrared lamps and are indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.	The TH0R DDII 830CL3 Laser System is a non-heating infrared lamp and is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.
Operation principle	Light emission	Light emission
Emitters technology	Diode Laser (Semiconductor)	Diode Laser (Semiconductor)
Optical power	100 mW per emitter	Three 30 mW Gallium Aluminum Arsenide (GaAIAs) laser diodes delivering a total output power of 90 mW
Wavelengths	808 nm	830 nm
Interaction with the patient	Luminous energy absorption	Luminous energy absorption

The indication for use (IFU) statements of the subject and the predicate devices are identical. The subject and the predicate devices are non-heating infrared laser as defined in 21 CFR 890.5500. Both the subject and the predicate devices use diode lasers to emit photonic energy to tissue. The differences between the subject device and predicate are explained below:

**Optical power:** According to 60601-2-22 Edition 3.1 2012-10 (Recognition Number 12-268), a tolerance of 20% is accepted, justifying the difference between the subject (100 mW) and the predicate (90 mW) devices.

**Wavelength:** The absorption coefficient of laser light by melanin, hemoglobin and water at wavelengths 808 and 830 nm are similar.

## **Non-clinical Performance Testing**

The following nonclinical performance testing was conducted to demonstrate substantial equivalence.

- IEC 60825-1 Edition 2.0 2007-03 - Safety of laser products - Part 1: Equipment classification, and requirements
- IEC 60601-1 - Edition 3.2 2020-08 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- IEC 60601-2-22: 2019 - Edition 4.0 2019-11 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 62304:2006+AMD1:2015 - Edition 1.1 2015-06 Medical device software - Software life cycle processes
- ISO 10993-1 - Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

## **Clinical Testing**

Substantial equivalence of the subject device to the predicate has been established through the results of nonclinical testing.

## **Conclusion**

The Therapy EC and Therapy XT have the same intended use, indications for use, and principles of operation, and highly similar technological characteristics as the predicate device. The technological differences identified do not raise new questions of safety or effectiveness compared to the predicate device. Therefore, the subject device is substantially equivalent to the predicate device.