September 4, 2025

Clinical Laserthermia Systems AB
% David Makanani
Regulatory Consultant, OMEDtech LLC
P.O. Box 1345
Frisco, Texas 75034

Re: K251298
Trade/Device Name: Mobile Laser Unit (1001-N2); Thermoguide Workstation (1100-N1); Laser Applicator (4012-N5, 4017-N2, 4017-N4); MR Introducer (4013-N6)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: ONO
Dated: August 3, 2025
Received: August 5, 2025

Dear David Makanani:

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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2025.09.04 08:03:59 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic 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)*
K251298

Device Name
Thermoguide Therapy System

Indications for Use *(Describe)*
The Thermoguide Therapy System is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under magnetic resonance imaging (MRI) guidance in medicine and surgery in neurosurgery for wavelengths of 1064nm.

When therapy is performed under MRI guidance, and when data from compatible MRI sequences is available, the Thermoguide Therapy System can process images using proton resonance-frequency (PRF) shift analysis and image subtraction to relate changes in complex phase angle back to relative changes in tissue temperature during therapy. The image data may be manipulated and viewed in a number of different ways, and the values of data at certain selected points may be monitored and/or displayed over time.

The Thermoguide Therapy System is compatible with 1.5T and 3.0T MR scanner systems: Siemens MRI Magnetom and GE MRI Signa. When interpreted by a trained physician, this device provides information that may be useful in the determination or assessment of thermal therapy. Patient management decisions should not be made solely on the basis of analysis using the Thermoguide Therapy System

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.

Thermoguide Therapy System - 510(k) Summary

A. Device Information

Category	Comments
Sponsor/Submitter	Clinical Laserthermia Systems AB Scheelevägen 2, 223 81 Lund, Sweden Contact: Dan Mogren, CEO Telephone: +46705901140 dan.mogren@clinicallaser.com
Correspondent Contact Information:	OMEDtech, L.L.C. PO Box 1345, Frisco, TX 75034 Contact: David Makanani Telephone: +4058260713 dmakanani@omedtech.com
Device Common Name:	Neurosurgical Laser with MR Thermography
Device Classification Regulation & Name:	21 CFR 878.4810; Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification & Product Code:	Class II, ONO
Device Proprietary Name:	Thermoguide Therapy System

Predicate Device Information:

Category:	Primary predicate device	Secondary predicate device
Predicate Device:	Thermoguide Therapy System	Monteris Medical NeuroBlate® System
Predicate Device Manufacturer:	Clinical Laserthermia Systems AB	Monteris Medical, USA
Predicate Device Common Name:	Neurosurgical Laser with MR Thermography	Neurosurgical Laser with MR Thermography
Predicate Device Premarket Notification Number:	K214125	K240877
Predicate Device Classification Regulation & Name:	21 CFR 878.4810; Laser surgical instrument for use in general and plastic surgery and in dermatology	21 CFR 878.4810; Laser surgical instrument for use in general and plastic surgery and in dermatology
Predicate Classification & Product Code:	Class II, ONO	Class II, ONO

B. Date Summary Prepared

8/28/2025

C. Description of Device

The Thermoguide Therapy System consists of the following three components:

1) Mobile Laser Unit
2) Laser applicator and introducer
3) Thermoguide Workstation

The Thermoguide Therapy System can be used for soft tissue laser ablation procedures by appropriate trained medical professionals only. The Thermoguide Therapy System has received FDA clearance for use with 3T magnetic resonance (MR) scanners (K214125). This submission expands the approval to include both 3T and 1.5T MR field strengths.

The system consists of a medical laser apparatus (Mobile Laser Unit), single use sterile devices (Laser applicator and introducer) and a workstation with software (Thermoguide Workstation) for extracting temperature maps from magnetic resonance (MR) images to calculate thermal dose in the tissue.

The Thermoguide Therapy System can be used for soft tissue laser ablation procedures using MR image guidance in minimal invasive procedures under local or general anesthesia. The system is optimized with advanced functions to control and monitor tissue temperatures within the ablation volume and surrounding tissue.

The Mobile Laser Unit is provided with a laser generator operating at the wavelength of 1064 nm, continuous wave. The generated laser light is locally applied by means of a single use applicator kit (Laser applicator and introducer) through a less invasive surgical or percutaneous procedure. The energy within the laser light is absorbed by the tissue resulting in increased tissue temperature that necrotizes or coagulates soft tissue.

The Laser applicator is a 12 m long optical fiber allowing the laser generator to be placed in the MRI control room. The treatment is monitored using the Thermoguide Workstation to measure temperature changes and estimate thermal damage resulting from the induced temperature increase.

D. Indications for Use

The Thermoguide Therapy System is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under magnetic resonance imaging (MRI) guidance in medicine and surgery in neurosurgery for wavelengths of 1064nm.

When therapy is performed under MRI guidance, and when data from compatible MRI sequences is available, the Thermoguide Therapy System can process images using proton resonance-frequency (PRF) shift analysis and image subtraction to relate changes in complex phase angle back to relative changes in tissue temperature during therapy. The image data may be manipulated and viewed in a number of different ways, and the values of data at certain selected points may be monitored and/or displayed over time.

The Thermoguide Therapy System is compatible with 1.5T and 3.0T MR scanner systems: Siemens MRI Magnetom and GE MRI Signa. When interpreted by a trained physician, this device provides information that may be useful in the determination or assessment of thermal therapy. Patient management decisions should not be made solely on the basis of analysis using the Thermoguide Therapy System.

E. Comparison to Predicate Devices

A table comparing the key features of the subject and predicate devices is provided in Table 1 at the end of this 510(k) summary.

The Intended Use/Indications for Use has been expanded to include both 3T and 1.5T MR field strengths, as compared to the primary predicate device that is cleared for use with 3T MR field strength. There is no difference in intended use between the subject device and primary predicate device apart from the expansion of MRI modalities. The intended use of the secondary predicate device is in essence the same as for the subject device.

The minor differences do not raise different questions of safety and effectiveness. Bench testing and animal testing according to the Intended Use/Indications for Use have been performed showing that the differences do not affect the safety and effectiveness of the device when used as labeled. The technological characteristics of the devices are essentially identical. All technological components and operating parameters are the same between the subject device and the primary predicate.

The secondary predicate device, Monteris Medical NeuroBlate® System, cleared in K240877, has similar technical characteristics, uses the same Proton-Resonance-Frequency (PRF) shift analysis and image subtraction for temperature calculation and consecutively the CEM43 algorithm for calculation of the thermal does as the Thermoguide Therapy System. The Monteris Medical NeuroBlate® System is cleared for use in both field strengths, 1.5T and 3T, and its Indications for use are essentially identical

to the Thermoguide Therapy System.

Based on the comparison of technical and device specific parameters between the subject device and primary and secondary predicate devices, it is concluded that the minor differences do not raise different questions of safety and effectiveness and do not adversely affect the safety and effectiveness of the Thermoguide Therapy System device as compared to the predicate devices.

F. Summary of Supporting Data

The Thermoguide Therapy System has been designed and tested for compliance with applicable ISO, IEC and FDA safety and performance standards that include functional safety, basic safety, and essential performance and effectiveness as well as laser safety requirements.

To demonstrate the safety and effectiveness of the Thermoguide Therapy System in a 1.5T MRI environment, the company has done comparative testing in 3.0T and 1.5T environments. The performance testing has been conducted using similar protocols and acceptance criteria as were used to support the original submission (K214125).

Thermoguide Therapy System was tested addressing:

- Intraoperability between the different devices of the system and MRI scanners.
- Correct operation of the thermometry algorithm as determined by correlation to physical measurements.
- Evaluation of near real time behavior of temperature measurements. When using a commercially available scanner sequence, for the chosen scanner, determine offset from real time and update rate of temperature maps.
- Verification that the products fulfill product requirement specifications.

G. Conclusion

The results of the performance testing show that the Thermoguide Therapy System when used with 1.5T MRI systems is as safe and effective as the predicate system cleared for use with 3.0T MRI systems (K214125). Thus, the Thermoguide Therapy System (1.5T and 3.0T) is substantially equivalent to the Thermoguide Therapy System (3.0T).

Table 1. Substantial Equivalence

	Subject device *Thermoguide Therapy System, **1.5T and 3.0T***	**Primary predicate device** *Thermoguide Therapy System, 3.0T (K214125)*	**Secondary predicate device** *Monteris Medical NeuroBlate® System (K240877)*
Manufacturer	**Clinical Laserthermia Systems AB, Sweden**	**Clinical Laserthermia Systems AB, Sweden**	**Monteris Medical, USA**
Intended use / Indications for use	The Thermoguide Therapy System is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under magnetic resonance imaging (MRI) guidance in medicine and surgery in neurosurgery for wavelengths of 1064nm. When therapy is performed under MRI guidance, and when data from compatible MRI sequences is available, the Thermoguide Therapy System can process images using proton resonance-frequency (PRF) shift analysis and image subtraction to relate changes in complex phase angle back to relative changes in tissue temperature during therapy. The image data may be manipulated and viewed in a number of different ways, and the values of data at certain selected points may be monitored and/or displayed over time. The Thermoguide Therapy System is compatible with 1.5T and 3.0T MR scanner systems: Siemens MRI Magnetom and GE MRI Signa. When interpreted by a trained physician, this device provides	The Thermoguide Therapy System is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under magnetic resonance imaging (MRI) guidance in medicine and surgery in neurosurgery for wavelengths of 1064nm. When therapy is performed under MRI guidance, and when data from compatible MRI sequences is available, the Thermoguide Therapy System can process images using proton resonance-frequency (PRF) shift analysis and image subtraction to relate changes in complex phase angle back to relative changes in tissue temperature during therapy. The image data may be manipulated and viewed in a number of different ways, and the values of data at certain selected points may be monitored and/or displayed over time. The Thermoguide Therapy System is compatible with 3.0T MR scanner systems: Siemens MRI Magnetom and GE MRI Signa. When interpreted by a trained physician, this device provides	The Monteris Medical NeuroBlate System is a neurosurgical tool and is indicated for use to ablate, necrotize, or coagulate intracranial soft tissue, including brain structures (e.g., brain tumor, radiation necrosis, and epileptogenic foci as identified by non-invasive and invasive neurodiagnostic testing, including imaging), through interstitial irradiation or thermal therapy in medicine and surgery in the discipline of neurosurgery with 1064 nm lasers. The Monteris Medical NeuroBlate System is intended for planning and monitoring thermal therapies under MRI visualization. It provides MRI-based trajectory planning assistance for the stereotaxic placement of MRI compatible (conditional) NeuroBlate Laser Delivery Probes. It also provides near real-time thermographic analysis of selected MRI images. When interpreted by a trained physician, this System provides information that may be useful in the determination or assessment of thermal therapy. Patient

	information that may be useful in the determination or assessment of thermal therapy. Patient management decisions should not be made solely on the basis of analysis using the Thermoguide Therapy System.	information that may be useful in the determination or assessment of thermal therapy. Patient management decisions should not be made solely on the basis of analysis using the Thermoguide Therapy System.	management decisions should not be made solely on the basis of the NeuroBlate System analysis. The intended patients are adults and pediatric from the age of 2 years and older.
Device Regulatory Classification	CFR878.4810 (ONO)	CFR878.4810 (ONO)	CFR878.4810 (ONO) CFR882.4560
Classification Product code	ONO (Neurosurgical Laser With MR Thermography)	ONO (Neurosurgical Laser With MR Thermography)	ONO (Neurosurgical Laser With MR Thermography)
Device class	2	2	2
Laser wavelength	1064nm	1064nm	1064nm
Laser class	Class 4 laser unit that has been tested according to IEC 60825-1:2014 and IEC60601-2-22:2019	Class 4 laser unit that has been tested according to IEC 60825-1:2014 and IEC60601-2-22:2019	Class 4 laser product in accordance with IEC 60825-1:2014 and IEC 60601-2-22:2019.
Output power	Up to 10 W depending on laser applicator type	Up to 7 W depending on laser applicator type	12 W
Maintenance	The recommended maintenance frequency is every 6 months if the unit is used frequently (daily use) or at least every 12 months if the unit is used less frequently. Service, security tests, or system updates may only be performed by the manufacturer or by qualified personnel expressly authorized by the manufacturer.	The recommended maintenance frequency is every 6 months if the unit is used frequently (daily use) or at least every 12 months if the unit is used less frequently. Service, security tests, or system updates may only be performed by the manufacturer or by qualified personnel expressly authorized by the manufacturer.	Annual (minimum) specified maintenance and calibration schedules for non-disposable equipment must be performed by trained Monteris representatives
Thermometry software system	Thermoguide Workstation software	Thermoguide Workstation software	Fusion-S software
MRI Compatibility	1.5T and 3.0T Siemens, GE Types are defined in the IFU.	3.0T Siemens, GE Types are defined in the IFU.	1.5T and 3.0T Siemens, GE, Philips Types are defined in the IFU and supplement material.
Image import	Magnitude and phase maps	Magnitude and phase maps	Magnitude and phase maps

Image processing	Proton-Resonance-Frequency (PRF) shift analysis and image subtraction Image processing results in T-maps and damage prediction maps as overlays on anatomical MR images.	Proton-Resonance-Frequency (PRF) shift analysis and image subtraction Image processing results in T-maps and damage prediction maps as overlays on anatomical MR images.	Proton-Resonance-Frequency (PRF) shift analysis and image subtraction Image processing results in T-maps and damage prediction maps as overlays on anatomical MR images.
Thermometry processing	Relative changes in temperature calculated from complex phase angle.	Relative changes in temperature calculated from complex phase angle.	Relative changes in temperature calculated from complex phase angle.
Temperature monitoring	2D color-coded temperature map. Additionally, up to 6 Region of interest (ROIs as point, line or area) user definable. Temperature values are displayed.	2D color-coded temperature map. Additionally, up to 6 Region of interest (ROIs as point, line or area) user definable. Temperature values are displayed.	2D color-coded temperature map. Additionally, up to 10 Regions of interest (ROIs with three contouring algorithms to choose from; General - used for less-complicated, spherical structures, Irregular - used for complicated, non-spherical structures or Freehand)
Thermal dose	Thermal Dose, expressed as equivalent minutes of exposure at 43 °C (CEM_{43})	Thermal Dose, expressed as equivalent minutes of exposure at 43 °C (CEM_{43})	Thermal Dose, expressed as equivalent minutes of exposure at 43 °C (CEM_{43})
User Population	Trained medical professionals	Trained medical professionals	Trained medical professionals
Patient Population	The products described in this IFU are for adult and pediatric use from 2 years of age.	The products described in this IFU are for adult and pediatric use from 2 years of age.	The intended patients are adults and pediatricians from the age of 2 years and older.