September 22, 2022

Clinical Laserthermia Systems AB
% John Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
555 13th Street NW
Washington, District of Columbia 20004

Re: K214125
Trade/Device Name: TRANBERG| Thermoguide Therapy System
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: December 30, 2021
Received: December 30, 2021

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K214125

Device Name

TRANBERG®\|Thermoguide Therapy System

Indications for Use *(Describe)*

The *TRANBERG®\|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 a wavelength of 1064nm.

When therapy is performed under MRI guidance, and when data from compatible MRI sequences is available, the *TRANBERG®\|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 TRANBERG®\|Thermoguide Therapy System is compatible with the following 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 *TRANBERG®\|Thermoguide Therapy System*.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) SUMMARY

Clinical Laserthermia Systems' TRANBERG®|Thermoguide Therapy System

Submitter

Clinical Laserthermia Systems, AB
Scheelevagen 2
223 81 Lund, Sweden

Phone: +46-(0)70-590 11 40

Contact Person: Dan Mogren, CEO

Date Prepared: September 22, 2022

Name of Device: TRANBERG®|Thermoguide Therapy System

Common or Usual Name: TRANBERG®|Thermoguide Therapy System

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulation: 21 CFR 878.4810

Product Code: ONO

Predicate Device

Medtronic Navigation Inc., Visualase Thermal Therapy System, K181859

Reference Device

Monteris Medical Inc., NeuroBlate System, K201056

Device Description

The TRANBERG®|Thermoguide Therapy System is indicated for use in an MRI suite to perform soft tissue ablations under MRI guidance, it consists of three parts*:*

1) TRANBERG®|Mobile Laser Unit, cleared by K142216.
2) TRANBERG®|Laser applicator and introducer, cleared by K201466.
3) TRANBERG®|Thermoguide Workstation, article no. 1100-01, **new in this submission**.

The TRANBERG®|Mobile Laser Unit includes a laser generator that operates at the wavelength of 1064nm, a continuous wave. The generated laser light is locally applied by means of a single use applicator kit (TRANBERG®|Laser applicator and introducer, cleared by K201466) through a minimally invasive surgical or percutaneous procedure. The energy from the laser generator is transmitted to tissue through the TRANBERG®|Laser applicator and absorbed by the tissue surrounding the laser applicator, resulting in increased tissue temperature that necrotizes or coagulates soft tissue. The TRANBERG®|Laser applicator is a 12m long optical fiber that allows the laser generator to be placed in the MRI control room. A workstation with software (TRANBERG®|Thermoguide Workstation) is used to extract temperature maps from magnetic resonance (MR) images and to calculate the thermal dose in treated tissue. Algorithms

used in the system to calculate temperature maps and thermal dose in tissue are well established and described in scientific literature.

The TRANBERG®|Mobile Laser Unit has safety systems to prevent the use of a malfunctioning unit, including self-testing at startup and continuous monitoring of software and components that are critical for the unit and laser emission to function optimally. All laser safety requirements are met according to IEC 60601-2-22:2019.

The TRANBERG®|Laser applicator utilizes an RFID tag which limits the maximum power and time (per applicator type) that can be used. It also ensures that an expired fiber, a reused fiber, or a fiber programmed for a different use cannot be used as a treatment fiber.

The TRANBERG®|Thermoguide Workstation has an interface for control of the TRANBERG®|Mobile Laser Unit output through the computer interface port of the laser unit (external laser control). It controls power and time settings on the laser unit, and it can start and stop the laser emission. Laser control and safety as per medical laser equipment requirements are managed by the TRANBERG®|Mobile Laser Unit.

Mandatory conditions must be satisfied to enable the laser unit and run a treatment. When one or more of these conditions are not met, the laser will not allow emitting laser radiation until all conditions are fulfilled:

- Real time images from the scanner are received at least every 5s. If Thermoguide Workstation detects update rates longer than 5s the laser emission is automatically interrupted.
- Laser unit enabled and the connection is verified, any loss of communication within 1.5s between the Laser unit and Thermoguide workstation or data incoherency automatically stops the laser emission.
- The use of the RFID tag is a mandatory condition to run a treatment and limits the maximum power and time (per applicator type).
- Laser Applicator type confirmed and received by TRANBERG®|Thermoguide Workstation, the information is read on the RFID tag belonging to the fiber.
- Minimum 1 ROI (monitoring or guard) has been set.
- Baseline temperature (e.g., core body temperature) is set and confirmed
- B0 drift compensation: Reference baseline ROI is set and confirmed
- Placement of the High temperature guard ROI.
- Test dose successful and confirmed

Safety guard functionality: TRANBERG®Thermoguide Workstation can be used to prescribe limits for the temperature at certain points (ROIs) in the image which can, in turn, be used to deactivate the laser if the limits are reached.

Intended Use / Indications for Use

The TRANBERG®|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 a wavelength of 1064nm.

When therapy is performed under MRI guidance, and when data from compatible MRI sequences is available, the TRANBERG®|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 TRANBERG®|Thermoguide Therapy System is compatible with 3.0T MR scanner systems. 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 TRANBERG®|Thermoguide Therapy *System*.

The Intended Use/Indications for Use has been limited as compared to the predicate device. Only a fixed wavelength of 1064nm (wavelength of the laser unit, part of TRANBERG®|Thermoguide Therapy System) and only neurosurgical interventions are part of the more limited Intended Use/Indications for Use. Also it is stated that only compatible scanners can be used with the system where the predicate names certain scanner types.

The differences are not critical to the intended therapeutic or surgical use of the device. 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.

Summary of Technological Characteristics

Soft tissue laser ablation and MRI thermometry is the technological principle for both the subject and predicate devices. The two systems are indicated for precise soft tissue laser ablation by medical professionals only and consist of a medical laser apparatus with single use sterile devices and software for extracting temperature maps from Magnetic Resonance (MR) images and calculation of thermal dose to the tissue. Generated laser light is locally applied within a tissue by means of a single use applicator. The energy within the laser light is absorbed by the tissue resulting in increased tissue temperature

At a high level, the subject and predicate devices are based on the following same technological elements:

- Mobile laser unit using the same energy source.
- Laser Applicator for transferring energy to tissue.
- MR thermometry workstation that can calculate and display temperature and thermal damage maps.
- Thresholds may be defined to deactivate laser power if the temperature in a target point is exceeded.
- Primary user interface for supporting the workflow and controlling the treatment is performed in the MR thermometry workstation

The following technological differences exist between the subject and predicate devices:

- The predicate operates in the optical wavelength range 980–1064 nm, whereas the subject device operates only at 1064 nm.
- The predicate devices use a cooled fiber whereas the subject device uses a non-cooled fiber. However, the subject device fiber is already cleared by K201466.
- The predicate device includes a cooling pump in its system, whereas no such pump is necessary for the subject device due to the use of a non-cooled fiber.
- Different operating systems are used: Thermoguide uses Windows 10, Visualase Linux. But the setup of hardware and supporting SOUPs (e.g. drivers) are similar. The combination of hardware and software is supplied pre-installed by each manufacturer.

- The predicate uses the Arrhenius model for calculation of thermal damage or thermal dose whereas the subject device uses the CEM43 algorithm. The CEM43 algorithm is used in the reference device, NeuroBlate System cleared under K201056.

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.

Labeling related to safety and mitigating actions of the TRANBERG Thermoguide System was compared to the predicate device, Visualase™ Thermal Therapy system and the reference device, NeuroBlate System. The minor differences in technical parameters between the subject device and predicate as well as reference device do not (1) raise different questions of safety and effectiveness; and (2) do not adversely affect the safety and effectiveness of the subject device compared to the predicate.

Performance Data

Bench Testing

The laser unit was designed and tested to comply with functional safety, basic safety, and essential performance as well as laser safety requirements of IEC60601-1, IEC60601-1-2, IEC60601-2-22. Since the original clearance in K142216, the testing has been repeated due to changes in the hardware as well as to show compliance to updated versions of the IEC standards.

Biocompatibility data for the invasive devices is not included in this submission as it was part of the recent clearance under K201466. Full software V&V data is provided for both the TRANBERG®|Mobile Laser Unit and the TRANBERG®|Thermoguide Workstation.

TRANBERG®|Thermoguide Workstation used together with TRANBERG®|Thermal Therapy System when used for treatments in MR was tested addressing:

- Intraoperability between the different devices of the TRANBERG®|Thermoguide Therapy System, i.e., Mobile laser unit, Thermoguide Workstation, Laser applicator, and MRI scanners.
- Correct operation of the thermometry algorithm used in the Thermoguide Workstation 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.
- Verify that the products fulfil product requirement specifications.

Pre-clinical Animal Study

The accuracy and performance of MR Thermometry and Thermal Damage Estimate were evaluated for the TRANBERG®Thermoguide Therapy System in a prospective preclinical animal study under GLP conditions.

No clinical data was provided in support of this submission.

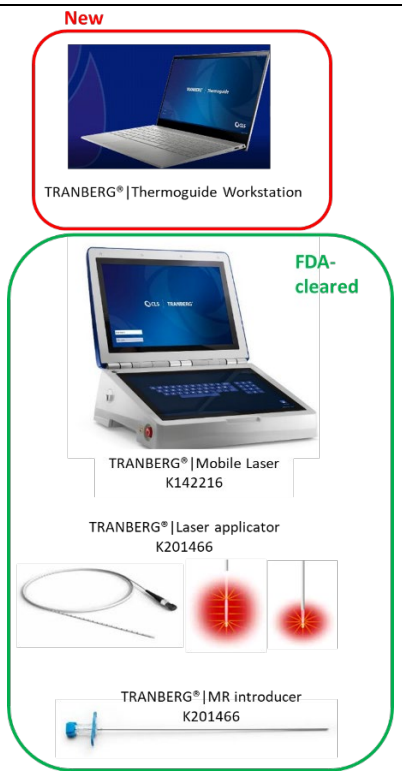
In all instances, the TRANBERG® Thermoguide Therapy System functioned as intended and the performance observed was as expected.

Conclusions

The TRANBERG®|Thermoguide Therapy System is as safe and effective as the Visualase Thermal Therapy System (K181859). The TRANBERG®|Thermoguide Therapy System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended therapeutic or surgical use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor

technological differences between the TRANBERG®|Thermoguide Therapy System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the TRANBERG®|Thermoguide Therapy System is as safe and effective as the Visualase Thermal Therapy System (K181859). Thus, the TRANBERG®|Thermoguide Therapy System is substantially equivalent.

Table 1. Substantial equivalence of the TRANBERG®|Thermoguide Therapy System is claimed to the predicate device Visualase® Thermal Therapy system, cleared under K181859.

Parameter		
Product name	**TRANBERG®|Thermoguide Therapy System**	**Visualase™ Thermal Therapy system**
Manufacturer	**Clinical Laserthermia Systems CLS, Sweden**	**Medtronic Navigation, Inc.**
Intended use / Indications for use	The TRANBERG®|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 a wavelength of 1064nm. When therapy is performed under MRI guidance, and when data from compatible MRI sequences is available, the TRANBERG®|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 TRANBERG®|Thermoguide Therapy System is compatible with the following 3.0T MR scanner systems: Siemens MRI Magnetom and GE MRI Signa. When interpreted by a trained physician, this	"The Visualase® Thermal 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 cardiovascular thoracic surgery (excluding the heart and the vessels in the pericardial sac), dermatology, ear-nose-throat surgery, gastroenterology, general surgery, gynecology, head and neck surgery, neurosurgery, plastic surgery, orthopedics, pulmonology, radiology, and urology, for wavelengths 800nm through 1064nm. When therapy is performed under MRI guidance, and when data from compatible MRI sequences is available, the Visualase® 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

	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 TRANBERG®|Thermoguide Therapy System.	certain selected points may be monitored and/or displayed over time. The Visualase® Thermal Therapy System is compatible with General Electric Medical Systems Signa model MR scanners and with Siemens Medical Solutions Magnetom Espree systems. 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 Visualase® analysis."
Device Regulatory Classification	21 CFR 878.4810 (ONO)	CFR892.2050 (LLZ) CFR878.4810 (GEX) CFR880.5725 (FRN)
Product code	ONO (Neurosurgical Laser With MR Thermography)	LLZ (Image Processing System) GEX (Surgical Laser, Laser Applicator) FRN (Infusion Pump)
Device class	2	2
510(k) No	K214125	K181859
Diode laser generator	Cleared under K142216	Cleared under K092197 Biotex, Inc.PHOTEX30 DIODE LASER
Laser wavelength	1064 nm	800 – 1064nm
Laser applicator / handpiece	Cleared under K201466	Cleared under K053087
Thermometry software system	New TRANBERG®|Thermoguide Workstation software	Cleared under K063505 Visualase ENVISION Software system
Workstation OS	Windows	Linux
Software access	Installation of TRANBERG®|Thermoguide Workstation can only be performed by qualified personnel authorized by CLS. Installation controlled by License code. Log into the system with login prompt and password.	The Visualase® Thermal Therapy System should only be assembled and installed by a Medtronic Service Representative. Log into the system with login prompt and password.
GUI	Temperature and damage information is displayed in near real-time during the treatment GUI with running Thermoguide software is the primary user interface and control tool for the entire TRANBERG®|Thermoguide Therapy System and provides a Workflow guidance for the user.	Temperature and damage information is displayed in near real-time during the treatment Visualase *Console window* is the primary user interface and control tool for the entire Visualase system.
Imaging modality	MR Types are defined in the IFU	MR Types are defined in the IFU

Connectivity	DICOM Import	DICOM Import
Image import	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.
Thermometry processing	Relative changes in temperature calculated from complex phase angle.	Relative changes in temperature calculated from complex phase angle.
Laser control	Using external communication input of laser generator.	Using external modulation input of laser generator.
Temperature monitoring	2D color-coded temperature map. Additionally, up to 6 Region of interest (ROIs as point, line or area) user definable. A single point ROI is corresponding to a target point. Temperature values are displayed.	2D color-coded temperature map. Additionally, up to 6 target points. In defined target points temperature values are displayed
Temperature threshold	Thresholds may be defined to de-active laser power if temperature in ROI is exceeded	Thresholds may be defined to de-active laser power if the temperature in target point is exceeded
Thermal dose	Thermal Dose, expressed as equivalent minutes of exposure at 43 °C (CEM43)[1]	Arrhenius model for calculation of thermal damage or thermal dose
Maximum treatment time	Laser will automatically revert to STANDBY mode whenever it is idle for five minutes	Laser will automatically revert to STANDBY mode whenever it is idle for five minutes
High temperature limit	High temperature default limit 85°C	High temperature default limit 85°C
Safety features	As safety guard functionality Thermoguide may be used to prescribe limits for the temperature at certain points (ROIs) in the image which can, in turn, be used to deactivate the laser if the limits are reached. Additional safety features are provided. Mandatory conditions to enable the laser unit and run a treatment: – Real time images from scanner are received at least every 5s. – Real time images from the scanner are received at least every 5s. If Thermoguide Workstation detects update rates longer than 5s the laser emission is automatically interrupted. – Laser unit enabled and the connection is verified, any loss of communication within 1.5s between the Laser unit and Thermoguide workstation or data incoherency automatically stops the laser emission. – The use of the RFID tag is a mandatory condition to run a treatment and limits the maximum power and time (per applicator type). – Laser Applicator type confirmed and received by TRANBERG®|Thermoguide	Real-time thermal analysis of specified targets can be used as an optional safety interlock feature to deactivate the laser – At least one target point has to be selected. – Set the *Tbody* value to the patient's core temperature value.

	Workstation, the information is read on the RFID tag belonging to the fiber. – Minimum 1 ROI (monitoring or guard) has been set. – Baseline temperature (e.g., core body temperature) is set and confirmed – B0 drift compensation: Reference baseline ROI is set and confirmed – Placement of the High temperature guard ROI. – Test dose successful and confirmed Laser safety is handled entirely by the laser unit that has been tested according to IEC60601-2-22:2019 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	
Maintenance	requires authorized personal for maintenance	requires authorized personal for maintenance
Biocompatibility	See Laser applicator / handpiece	See Laser applicator / handpiece
Sterilization	See Laser applicator / handpiece	See Laser applicator / handpiece
User Population	trained medical professionals	trained medical professionals

[1]: A reference device, NeuroBlate System cleared under K201056, was used for equivalence to thermal dose. The reference device utilized the same CEM43 algorithm for calculation of the thermal does as the TRANBERG®|Thermoguide Therapy System.