May 29, 2025

Medtronic Navigation
Sharon McDermott
Sr. Prinicipal Regulatory Affairs Specialist
200 Medtronic Drive
Lafayette, Colorado 80026

Re: K250307
Trade/Device Name: Visualase V2 MRI-guided Laser Ablation System (9736422)
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: May 1, 2025
Received: May 1, 2025

Dear Sharon McDermott:

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: 2025.05.29 11:15:08 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
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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)*
K250307

Device Name
Visualase V2 MRI-Guided Laser Ablation System

Indications for Use *(Describe)*
The Visualase V2 ™ MRI-Guided Laser Ablation System is a neurosurgical tool and is indicated for use to ablate, necrotize, or coagulate intracranial soft tissue including brain structures (for example, brain tumor, radiation necrosis, and epileptic foci as identified by non-invasive and invasive neurodiagnostic testing, including imaging) through interstitial irradiation or thermal therapy in pediatrics and adults with 980 nm lasers. The intended patients are adults and pediatric patients from the age of 2 years and older.

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

Submitter/Sponsor: Medtronic Navigation, Inc.
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Contact Person: Sharon McDermott (Primary)
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Rishi Sinha (Alternate)
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Date Summary Prepared: May 29, 2025

Device Trade Name: Visualase™ V2 MRI-Guided Laser Ablation System

Device Common Name: Neurological Laser with MR Thermometry

Device Classification: Class II

Product Code: ONO

Device Regulation: 21CFR 878.4810 – Laser surgical instrument for use in general and plastic surgery and in dermatology

Device Description: The Visualase MRI-Guided Laser Ablation System comprises hardware and software components used in combination with three MR-compatible (conditional), sterile, single-use, saline-cooled laser applicators with proprietary diffusing tips that deliver controlled energy to the tissue of interest. The system consists of:

- a diode laser (energy source)
- a coolant pump to circulate saline through the laser application
- Visualase workstation which interfaces with MRI scanner's host computer
- Visualase software which provides the system's ability to visualize and monitor relative changes in tissue temperature during ablation procedures, set temperature limits and control the laser output; one monitors to display all system imaging and laser ablation via a graphical user interface and peripherals for interconnections

Predicate Devices

General Information	**Primary Predicate** *Visualase MRI-Guided Laser Ablation System* (K211269)	**Secondary Predicate (for indications only)** *NeuroBlate System (K240877)*
FDA Regulation	21 CFR 878.4810	21 CFR 878.4810; 21 CFR 892.5050
FDA Product Code	ONO	ONO,GEX, HAW
Manufacturer	Medtronic Navigation, Inc	Monteris Medical

Indications for Use

The Visualase V2 ™ MRI-Guided Laser Ablation System is a neurosurgical tool and is indicated for use to ablate, necrotize, or coagulate intracranial soft tissue including brain structures (for example, brain tumor, radiation necrosis, and epileptic foci as identified by non-invasive and invasive neurodiagnostic testing, including imaging) through interstitial irradiation or thermal therapy in pediatrics and adults with 980 nm lasers. The intended patients are adults and pediatric patients from the age of 2 years and older.

Comparison of Device Indications for Use with Predicate Devices

Characteristic	**Subject Device** *VisualaseV2 MRI-guided Laser Ablation System*	**Primary Predicate** *Visualase Thermal Therapy System with 3.2 Software* (K1211269)	**Secondary Predicate (Indications ONLY)** *NeuroBlate System (K240877)*
Indications for Use	The Visualase V2 ™ MRI-Guided Laser Ablation System is a neurosurgical tool and is indicated for use to ablate, necrotize, or coagulate intracranial soft tissue including brain structures (for example, brain tumor, radiation necrosis, and epileptic foci as identified by non-invasive and invasive neurodiagnostic testing, including imaging) through interstitial irradiation or thermal therapy in pediatrics and adults with 980 nm lasers. The intended patients are adults and pediatric patients from the age of 2 years and older.	The Visualase™ MRI-Guided Laser Ablation System is a neurosurgical tool and is indicated for use to ablate, necrotize, or coagulate intracranial soft tissue including brain structures (for example, brain tumor, radiation necrosis, and epileptic 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 800nm through 1064nm lasers.	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 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.

Comparison of Device Technical Characteristics with Predicate Device		
Characteristic	**Subject Device** *Visualase V2 MRI-guided Laser Ablation System*	**Predicate Device** *Visualase MRI-guided Laser Ablation System* (K211269)
Contraindications	The Visualase™ MRI-Guided Laser Ablation System is contraindicated for patients who have implanted medical devices that are contraindicated for MRI.	The Visualase™ MRI-Guided Laser Ablation System is contraindicated for the following patients: Patients who have medical conditions that are contraindicated for MRI. • Patients who have implanted medical devices that are contraindicated for MRI. • Patients whose physician determines that Laser-Induced Thermal Therapy (LITT) is not acceptable. • Patients for which invasive surgical procedures in the brain is not appropriate.
Software	• Interactive Graphical User Interface (GUI) • Interfaces with MRI to acquire images and thermometry data • Interactive selection of points-of-interest • Interactive monitoring of Visualase procedure; displays relative changes in tissue temperature, calculates estimate of thermal necrosis throughout procedure • Automated functionality	• Interactive Graphical User Interface (GUI) • Interfaces with MRI to acquire images and thermometry data • Interactive selection of points-of-interest • Interactive monitoring of Visualase procedure; displays relative changes in tissue temperature, calculates estimate of thermal necrosis throughout procedure
	Up to 15 temperature targets per MRI slice (up to 15)	Up to 6 temperature
	Monitor target type	None
	Surgeon placed low and high temperature markers to trigger laser off	Surgeon placed low and high temperature markers to trigger laser off
	High-temperature target default limit 85°C	High-temperature target default limit 85°C
	Low-temperature target default limit 43°C	Low-temperature target default limit 43°C

	Thermal Damage Estimate (TDE): representation of thermally damaged tissue in two zones: 1. Necrotic Zone (complete cellular death) 2. Transition Zone (mixture of lethally and non-lethally injured cells)	Thermal Damage Estimate (TDE): representation of thermally damaged tissue in two zones: 1. Necrotic Zone (complete cellular death) 2. Transition Zone (mixture of lethally and non-lethally injured cells)
Hardware	Single touchscreen	Dual screen
	Light mast with laser mode indicators	None
	980 nm laser (Software limits the 980-nm wavelength to max output power of 14.55 W)	980 nm wavelength (Software limited to max output power of 14.55 W)
	Peristaltic pump	Peristaltic pump
MRI Compatibility	1.5T and 3.0 T	1.5T and 3.0 T
	MRI parameters for thermometry listed in IFU	MRI parameters for thermometry listed in IFU

Testing Summary

Testing demonstrated the Visualase V2™ MRI-Guided Laser Ablation System meets all design requirements and user needs.

Test	Method
Software verification and validation	Per Medtronic 21 CFR 820.30 compliant Design Control procedure
System verification	Per Medtronic 21 CFR 820.30 compliant Design Control procedure
IEC electrical safety and applicable horizontal standards	UL certified

FDA guidances were employed in the development of the clinical evidence to support substantial equivalence for the modification of the indications for use. A clinical trial was not required to establish substantial equivalence. Clinical evidence provided in a literature summary format supports the safe use of the Visualase V2 System in the intended patient population.

Conclusion

The Visualase™ V2 MRI-Guided Laser Ablation System is substantially equivalent to the primary predicate Visualase MRI-Guided Laser Ablation System and the secondary predicate NeuroBlate System (indications only). The Visualase Indications for Use have been clarified to define the intended patient population, adults and pediatric patients 2 years and older The changes to the Contraindications removes redundant language and language aligned with medical judgement. The medication of the Indications for Use statement and the Contraindications does not change the intended use or risk profile of the device.

The Platform, software and corresponding labeling changes included in this submission have been verified and validated demonstrating the changes meet product requirements and user needs. None of the changes affect the intended use or fundamental technology of the Visualase System.