January 7, 2022

Medtronic Navigation, Inc.
Sharon Mcdermott
Principal Regulatory Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K211269
Trade/Device Name: Visualase MRI-Guided Laser Ablation System (SW 3.4)
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: April 26, 2021
Received: April 27, 2021

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 (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)*
K211269

Device Name
Visualase MRI-Guided Laser Ablation System (SW 3.4)

Indications for Use *(Describe)*
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.

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

Submitter/Sponsor: Medtronic Navigation, Inc.
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Date Summary Prepared: January 7, 2022

Device Trade Name: Visualase™ MRI-Guided Laser Ablation System (formerly Visualase Thermal Therapy 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; two monitors to display all system imaging and laser ablation via a graphical user interface and peripherals for interconnections
- Remote Presence software provides a non-clinical utility application for use by Medtronic only and is not accessible by the user

Predicate Devices

General Information	Primary Predicate *NeuroBlate System (K201056)*	Secondary Predicate *Visualase Thermal Therapy System with 3.2 Software* (K181859)
FDA Regulation	21 CFR 878.4810	21 CFR 878.4810; 21 CFR 892.5050
FDA Product Code	GEX, HAW	GEX, LLZ
Manufacturer	Monteris Medical	Medtronic Navigation, Inc

Indications for Use

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.

Comparison of Device Characteristics with Predicate Devices

Characteristic	Subject Device *Visualase MRI-guided Laser Ablation System* (v3.4) Software	Primary Predicate *NeuroBlate System (K201056)*	Secondary Predicate *Visualase Thermal Therapy System with 3.2 Software* (K181859)
Indications for Use	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 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 1064 nm lasers. The Monteris Medical NeuroBlate® System is intended for planning and monitoring thermal therapies under MRI	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

		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.	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 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.
Contraindications	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	• The following are contraindications that apply to the NeuroBlate System: • Patients who are contraindicated for MRI, including patients who may have contraindications due to implanted medical devices. • Patients who the physician determines are not appropriate candidates for laser interstitial thermal therapy (LITT). • Patients who are not candidates for invasive surgical	We strongly recommend physicians weigh advantages and disadvantages of using a diode laser. Other modalities or wavelengths may be more appropriate due to any of the following: • Depth of penetration • Volume of necrosis • Propensity for scarring This product should not be used if thermal therapy or interstitial laser therapy are contraindicated. Use the laser only for the specialties listed in the Indications for Use section.

	acceptable. • Patients for which invasive surgical procedures in the brain is not appropriate.	procedures in the brain	For those who whom the physician determines the laser is not the surgical tool of choice. Do not use the device endoscopically in any procedure where endoscopes are contraindicated. Patients who are unable to be treated by surgical means or who are intolerant to anesthesia.
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	*M-Vision, M-Vision Pro, M-Vision Fusion, and Fusion-S* software which includes: • user interface for procedure planning, • interactive monitoring of NeuroBlate procedures, • interfaces to the MRI and hardware subsystems.	• Interactive Graphical User Interface (GUI) • Interface 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
	Surgeon placed low temperature limit markers to protect critical structures	User selected pick points for temperature monitoring in regions of thermometry	Surgeon placed low temperature limit markers to protect critical structures
	High-temperature default limit 85°C	Temperature points for monitoring	High-temperature default limit 90°C
	Laser interlock to deactivate laser energy when low or high temperature limit targets reached	No laser interlock feature associated with pick points	Laser interlock to deactivate laser energy when low or high temperature limit targets reached
	Thermal Damage Estimate (TDE): representation of thermally damaged tissue in two zones: 1. Necrotic Zone (complete cellular death)	Thermal Dose Threshold (TDT) Lines: depicted as 3 contour boundary lines of thermal isodose region. Yellow: mixture of lethally and non-lethally injured cells	Treatment Estimate (TE): representation of thermally damaged tissue as one zone: 1. Necrotic Zone (complete cellular death) tissue

	2.Transition Zone (mixture of lethally and non-lethally injured cells)	Blue: area of complete cellular death White: All tissue experiences cell death within ≤48 hours The white TDT line resides inside the blue TDT line. The blue TDT line resides inside the yellow TDT line.	
MRI Compatibility	1.5T and 3.0 T	1.5T and 3.0 T	1.5T and 3.0 T

Testing Summary

Testing demonstrated the accuracy and precision of the Visualase MRI-Guided Ablation System's Thermal Damage Estimate and MR Thermometry for its intended use. Additionally, software and system verification and validation activities were successfully completed.

Test	Method
Accuracy and performance of MR Thermometry	In vivo testing conducted 1.5T and 3.0T (in accordance with 21 CFR 58)
Accuracy and performance of Thermal Damage Estimate	In vivo testing conducted in 1.5T and 3.0T (in accordance with 21 CFR 58)
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

Conclusion

The Visualase™ MRI-Guided Laser Ablation System is substantially equivalent to the primary predicate Monteris NeuroBlate System and the secondary predicate Visualase™ Thermal Therapy System. The Visualase Indications for Use have been narrowed and clarified 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) which aligns to the primary predicate's indications for use cleared in K201056. The changes to the Contraindications further align with the predicate NeuroBlate's labeling and removes redundant device description language. The language update in the Contraindications does not change the intended use or risk profile of the device.

The 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. Further, none of the changes, including the clarifications of the indications for use, create any new intended use and do not raise any new questions of safety and effectiveness of the Visualase MRI-Guided Laser Ablation System. Therefore, the subject device is substantially equivalent to the predicate device.