March 13, 2026

Medtronic Navigation, Inc.
Sharon McDermott
Sr. Principal Regulatory Specialist
200 Medtronic Dr.
Lafayette, Colorado 80026

Re: K253391
Trade/Device Name: Visualase Cooled Laser Applicator System (9735559); Visualase Cooled Laser Applicator System (9735560); Visualase Cooled Laser Applicator System (9735561)
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: February 18, 2026
Received: February 18, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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,

JULIA E. SLOCOMB -S

Digitally signed by JULIA E. SLOCOMB -S
Date: 2026.03.13 16:17:37 -04'00'

for Jaime Raben, Ph.D.,
Division 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)*
K253391

Device Name
Visualase Cooled Laser Applicator System (9735559); Visualase Cooled Laser Applicator System (9735560); Visualase Cooled Laser Applicator System (9735561)

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter/Sponsor: Medtronic Navigation, Inc.
200 Medtronic Drive
Lafayette, CO 80026

Contact Person: Sharon McDermott (Primary)
Phone:(720) 890-3461 Fax: (720) 890-3500
E-mail : sharon.mcdermott@medtronic.com

Rishi Sinha (Alternate)
Phone: (720) 890-2485 Fax: (720) 890-3500
E-mail: rishi.k.sinha@medtronic.

Date Summary Prepared: October 31, 2025

Device Trade Name: Visualase Cooled Laser Applicator System (9735559);
Visualase Cooled Laser Applicator System (9735560);
Visualase Cooled Laser Applicator System (9735561)

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 Cooled Laser Applicator System (VCLAS) is an MR-compatible (conditional), sterile, single-use, saline-cooled laser applicator with proprietary diffusing tips that deliver controlled energy to targeted tissue when connected to the Visualase Systems.

The VCLAS is an accessory to both cleared versions of the Visualase Cooled Laser Ablation Systems - Visualase MRI-guided Laser Ablation System (V1 System, K211269) and Visualase V2 MRI-guided Laser Ablation System (V2 System, K250307). The V1 and V2 systems are not subjects of this submission.

This change encompasses changes to the Visualase Cooled Laser Applicator System (VCLAS) pump tubing set, extension tubing and inlet/outlet ports to ensure compatibility with both cleared Visualase Systems (K211269 and K250307) and accompanying information to inform safe and effective use. The device modifications include material changes a nd there are no changes to Visualase Systems (V1 and V2 system)' hardware or software.

Predicate Devices

General Information	**Predicate** *Visualase V2 MRI-Guided Laser Ablation System* (K250307)	**Predicate (**Visualase MRI-Guided Laser Ablation System (K211269)
FDA Regulation	21 CFR 878.4810	21 CFR 878.4810
FDA Product Code	ONO	ONO
Manufacturer	Medtronic Navigation, Inc	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 1064 nm.

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 980 nm lasers. The intended patients are adults and pediatric patients from the age of 2 years and older.

Comparison of Indications for Use

Subject Device Visualase Cooled Laser Applicator System	**Predicate Visualase V2 MRI-guided Laser Ablation System (K250307)**	**Predicate Visualase MRI-guided Laser Ablation System (K211269)**	**Comments**
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 1064 nm. 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 980 nm lasers. The intended patients are adults and pediatric patients from the age of 2 years and older.	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 1064 nm	The VCLAS is a component of the Visualase System; the indications for use are the same as that of the systems. The VCLAS IFU points to the Visualase System Manual for comprehensive Indications. A secondary and primary predicate are provided since the VCLAS devices are compatible with both the V1 and V2 Systems.

Comparison of Technological Characteristics

Technical Characteristic	Subject Device Visualase Cooled Laser Applicator System	Predicate Device Visualase V2 MRI- guided Laser Ablation System (K250307) and Visualase MRI-guided Laser Ablation System (K211269)	Comments
Laser Diffusing Fiber:			
Fiber core diameter	200 – 1000 µm	200 – 1000 µm	Same (no changes)
Numerical aperture	0.37	0.37	Same (no changes)
Proximal connector	SMA 905 connector	SMA 905 connector	Same (no changes)
Wavelength range	800nm – 1064 nm	800nm – 1064 nm	Same (no changes)
Laser operation mode	Continuous wave	Continuous wave	Same (no changes)
Diffusing region length	7.5 – 30 mm	7.5 – 30 mm	Same (no changes)
Diffusing tip assembly diameter	0.6 – 1.4 mm	0.6 – 1.4 mm	Same (no changes)
Tip shape	Blunt	Blunt	Same (no changes)
Lesion Shape	Ellipsoidal	Ellipsoidal	Same (no changes)
Cooling Catheter:			
Material	Makrolon (polycarbonate)	Makrolon (polycarbonate)	Same (no changes)
Coolant	Sterile Saline	Sterile Saline	Same (no changes)
Size	1.5 – 3.2mm	1.5 – 3.2mm	Same (no changes)
Inlet and Outlet Port – Contains DEHP	No	Yes	Removal of DEHP to meet global materials of concerns requirements – no impact on safety or effectiveness
Tissue Effect	Ellipsoidal	Ellipsoidal	Same (no changes)
Pump Tubing and Extension Set			
Patient contacting	No	No	Same (no changes)
Contains DEHP	No	Yes	Removal of DEHP to meet global materials of concerns requirements – no impact on safety or effectiveness
Compatible with either Visualase V1and V2 systems	Yes	No	2nd pump tubing section added for dual compatibility
Sterilization			
Method	EtO	EtO	Same (no changes)
Sterilization Assurance Level	10^{-6}	10^{-6}	Same (no changes)

MR Compatibility	1.5T and 3T	1.5T and 3T	Same (no changes)
Biocompatibility	Per ISO 10993	Per ISO 10993	Same (no changes)

Testing Summary

Verification testing demonstrated the subject Visualase Cooled Laser Applicator System (VCLAS) meets all design requirements and user needs.

Test	Method
Design Verification	Per Medtronic 21 CFR 820.30 compliant Design Control procedure
System verification	Per Medtronic 21 CFR 820.30 compliant Design Control procedure
Biocompatibility	ISO 10993-1 and applicable horizontal standards

Conclusion

The subject Visualase Cooled Laser Applicator System (VCLAS) is substantially equivalent to the predicate devices. The changes to the pump tubing/extension tubing sets and CCS inlet and outlet ports and updates to labeling do not affect the intended use or fundamental technology of the devices. These changes do not impact risks. Testing confirms that the subject VCLAS device performs as intended. None of the changes raise new questions of safety or effectiveness.