March 6, 2019

Medtronic Navigation Inc.
c/o Sharon McDermott
Principal Regulatory Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K181859
   Trade/Device Name: Visualase Thermal 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: GEX
   Dated: July 11, 2018
   Received: July 12, 2018

Dear Ms. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Matthew C. Krueger -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Device Name
Visualase Thermal Therapy System

Indications for Use (Describe)

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 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.

CONTINUE ON A SEPARATE PAGE IF NEEDED.
5  510(k) Summary

Submitter/Sponsor: Medtronic Navigation, Inc.
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This 510(k) submission notifies FDA of labeling changes to the Visualase Thermal Therapy System Manual to add new warnings and information. No design changes are the subject of this submission.

Date Summary Prepared: March 5, 2019

Device Trade Name: Visualase™ Thermal Therapy System

Device Common Name: Magnetic Resonance Image-guided Laser Thermal Therapy System

Device Classification: Class II

Product Code: GEX (Surgical Laser, Laser Applicator)
LLZ (Image Processing System)
FRN (Infusion Pump)

Device Regulation:
21CFR 878.4810 – Surgical Laser Instrument/Applicator
21CFR 892.2050 – Picture Archiving and Communications System
21CFR 880.5725 – Infusion Pump

Predicate Device: Visualase™ Thermal Therapy System

Predicate Manufacturer: Medtronic Navigation, Inc.

Predicate 510(k): K081656 (Biotex, Inc)

Predicate Product Code: GEX (Surgical Laser, Laser Applicator)
LLZ (Image Processing System)
FRN (Infusion Pump)

Predicate Regulation:
21CFR 878.4810 – Surgical Laser Instrument/Applicator
21CFR 892.2050 – Picture Archiving & Communications System
21CFR 880.5725 – Infusion Pump
**Indications for Use:** 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 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 Description:** The Visualase Thermal Therapy System comprises of 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.

**Comparison of Technological Characteristics with Predicate Device**

The changes that are the subject of this 510(k) submission are labeling updates that do not change the indications for use or impact the device’s technology. Along with grammatical corrections, the labeling changes encompass the addition of warnings and notes that were provided via a Field Corrective Action distributed to current users on June 1, 2018 and August 21, 2018.

**Performance Characteristics**

No new performance testing was required for this change as there are no changes to the design of the Visualase™ Thermal Therapy System as a result of this labeling change.
Conclusion

The Visualase™ Thermal Therapy System is substantially equivalent to the predicate Visualase™ Thermal Therapy System. The labeling changes do not affect the intended use or fundamental technology. Further, the labeling modifications do not raise any new questions of safety and effectiveness of the Visualase Thermal Therapy System.