April 23, 2026

Monteris Medical
David Mueller
Senior Principal Regulatory Affairs Specialist
131 Cheshire Ln.
Suite 100
Minnetonka, Minnesota 55305

Re: K260976
Trade/Device Name: NeuroBlate 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, HAW, GEX
Dated: March 24, 2026
Received: March 24, 2026

Dear David Mueller:

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), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

JAIME RABEN -S

for Julia Slocomb, PhD
Acting 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260976

Device Name
NeuroBlate System

Indications for Use *(Describe)*
The Monteris Medical NeuroBlate(R) 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.

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.

510(k) Summary: K260976

a. Device Information:

Category	Comments
Sponsor / Submitter:	Monteris Medical 131 Cheshire Lane, suite 100 Minnetonka, MN 55305 866-799-7655 www.monteris.com
Correspondent Contact Information:	David H. Mueller Senior Principal Regulatory Affairs Specialist Monteris Medical TEL: 763-333-1614 Email: DMueller@Monteris.com
Device Common Name:	Magnetic Resonance Image Guided Laser Thermal Therapy System
Device Classification Regulation & Name:	21 CFR 878.4810 • Laser surgical instrument for use in general and plastic surgery and in dermatology • Neurosurgical Laser With MR Thermography 21 CFR 882.4560 Stereotaxic instrument
Device Classification & Product Code:	Class II, ONO Class II, GEX Class II, HAW
Device Proprietary Name:	Monteris Medical NeuroBlate® System

Predicate Device Information:

Manufacturer	**Monteris Medical**
Commercial Name	NeuroBlate System
Common Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology; Stereotaxic instrument
Premarket Notification #	K240877
Regulation	21 CFR 878.4810 21 CFR 882.4560
Class/ Product Code	Class II; ONO, GEX, HAW

b. Date Summary Prepared

March 24, 2025

c. Description of Device

The Monteris NeuroBlate® System is a collection of MRI-compatible laser devices and accessories that create an MRI guided delivery of precision thermal therapy in the practice of neurosurgery.

The NeuroBlate System components consist of:

- Families of gas-cooled Laser Delivery Probe (Probe) (SideFire & FullFire) to deliver controlled energy to a target zone.
- Probe Drivers which allow the surgeon to precisely position, stabilize and manipulate a probe, endoscope or other device within the target zone.
- An Interface Platform, which attaches to the MRI system patient table and provides supporting electronics for the Probe Drivers and interconnections for the Laser Delivery Probes;
- A System Electronics Rack and Components, which includes necessary umbilicals, cables, penetration panels, and small hardware for system mechanical, electrical, and electronic operation,
- A Control Workstation including the M-Vision™, M-Vision Pro™, M-Vision Fusion, and Fusion-S software , which includes a user interface for procedure planning, interactive monitoring of NeuroBlate procedures, and interfaces to the MRI and hardware subsystems.

The NeuroBlate System is utilized with stereotaxic frames and patient stabilization systems, such as:

- The Monteris Cranial Bolt and Mini-Bolt fixation components, and
- The AtamA Stabilization System and MRI receive-only head coil, as well as, other optional accessories, including: drill bits, bolts, thumbscrews, instrument adaptors, accessory host adaptors, MRI trajectory wands, cranial screws, bone screws, fiducial markers, stereotactic manual driver with mandrel and T-handle, and other manual accessory instruments and tools.

d. Indications for Use/ Intended Use

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.

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e. Comparison to Predicate Device

This 510(k) submission is specific to adding the Fast Scan capability to the GE 1.5T MRI parameters. Adding the GE 1.5T Fast Scan parameter also results in minor Instructions for Use (IFU) update specifically for the GE 1.5T MRI. While the overall validation data for GE 1.5T

Fast Scan meets the same applicable requirements as the previously described Siemens (1.5T and 3.0T) and GE 3.0T MRIs, there were differences between the data sets when they were compared to each other. Noting these differences, Monteris further investigated the data differences and concluded that the observed differences were not practically different and do not result in device safety or performance differences.

The modified device presents no additional or different risks or technological characteristics when compared to the predicate devices, there are no manufacturing, process, material, or technology proposed changes to the NeuroBlate System. The technical modes of action and technical principles remain the same as the predicate NeuroBlate devices. The fundamental functionality and technical characteristics of the proposed modified device are identical to the existing NeuroBlate System (K240877).

The conclusion is that the modified device does not raise new or different questions of safety and effectiveness, i.e., the proposed modified device is as safe as the described predicate device.

f. Summary of Supporting Data

The updated GE 1.5 Fast Scan Software development process followed Monteris' documented Quality System and incorporated a design verification and design validation process. This process included an overarching Design Verification and Design Validation Master Plan. This plan describes the design verification and the design validation of the user needs.

As part of Monteris' further data investigation, Monteris utilized various test methods, including human volunteers, to collect data for the evaluation of Fast Scan parameters. Human volunteer MRI scans were used to collect baseline (non-heated) tissue temperatures for data comparison purposes([1],[2]).

Given that the GE 1.5 related Fast Scan test data demonstrated conformance to all existing design and performance requirements, adding the Fast Scan capability to the GE 1.5 MRI meets the non-significant change definition([3]). However, Monteris is using a conservative regulatory submission approach prior to implementing Fast Scan Parameters on GE 1.5T to ensure FDA has the opportunity to review the overall data collection process, analysis and corresponding conclusions via the formal 510(k) submission and clearance process.

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[1] Human volunteers were used to obtain MRI sample images for baseline comparisons for Temperature Precision, TDT Line evaluation and Pixel Drop analysis. A routine set of diagnostic MRI scans were utilized, a documented protocol was followed, volunteers were not subjected to any surgical procedure and were provided informed consent. Additional details are provided in the reports.

[2] The use of human volunteers in this MRI testing qualifies as the testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk, and thus is exempt from Regulatory agency clinical trial status, e.g., 21 CFR 812.2(c)(4) clinical exempt status. All human volunteers signed the corresponding facilities' standard MRI procedure forms.

[3] 21 CFR 807.81(a)(3): (i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process, (ii) A major change or modification in the intended use of the device.

g. Risk Analysis Summary

Monteris Medical's Quality Systems utilize various Risk Assessment and Risk Mitigation methodologies. As there are no physical changes, manufacturing changes, process changes, materials changes, or technology changes to the NeuroBlate System, and the technical modes of action and technical principles remain the same as the predicate devices, and the proposed changes are labeling related, the previously provided (K240877) Risk Assessment and Risk Mitigation documentation remains applicable.

This supporting information demonstrates that the subject NeuroBlate System is as safe and effective as the predicate device.