June 4, 2024

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

Re: K240877
Trade/Device Name: Monteris Medical 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, GEX, HAW
Dated: March 29, 2024
Received: March 29, 2024

Dear David H. 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 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.

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: 2024.06.04 12:34:20 -04'00'

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)*
K240877

Device Name
Monteris Medical NeuroBlate System

Indications for Use *(Describe)*

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.

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

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, HAW Class II, ONO Class II, GEX
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 #	K231061
Regulation	21 CFR 878.4810 21 CFR 882.4560
Class/ Product Code	Class II; ONO, GEX, HAW

b. Date Summary Prepared

21May2024

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 (Advanced Probe Driver, Robotic Probe Driver) 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 Advanced and Robotic 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*™ and *M-Vision Pro*™ 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 indicated for use to ablate, necrotize, or coagulate soft intracranial 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 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.

e. Comparison to Predicate Device

The application for the Monteris Medical NeuroBlate System with the modified labeling is substantially equivalent to the predicate Monteris NeuroBlate System (K231061) in intended use, technology, design and physician use. Reference **Table 1**.

This submission proposes no physical changes to the NeuroBlate System hardware, software, accessories, operating principles or functionality.

The proposed change defines the existing "adult and pediatric" intended patient population to include both adults and pediatric patients from the age of 2 years and older.

The proposed indication presents no (zero) physical or technological changes to the predicate device, and no changes to the Indications for Use (except for adding "The intended patients are adults and pediatric from the age of 2 years and older" to the Indications for Use) in the Instructions for Use/ Directions for Use.

As the modified device presents no additional or different risks or technological characteristics when compared to the predicate devices, no labelling modifications are necessary, e.g., there are no (zero) labelling changes to the Device Description, Contraindications, Warnings, and Precautions, potential Adverse Events sections.

Additionally, 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 device. Considering the proposed changes are labeling related, the previously provided in-vitro (bench) data remains applicable and no additional bench testing was required.

The fundamental functionality and technical characteristics of the proposed modified device is identical to the existing NeuroBlate System (K231061). The conclusion is that the difference in technological characteristics between proposed modified device and the described predicate devices do not raise new or different questions of safety and effectiveness, i.e., the proposed modified device is as safe as the described predicate devices.

f. Summary of Supporting Data

This submission proposes no physical changes, manufacturing changes, process changes, materials changes, or technology changes to the NeuroBlate System. Considering the proposed changes are labeling, the previously provided in-vitro (bench), in-vivo (animal) data remains applicable and no additional testing was required.

Multiple FDA Guidance documents were utilized to ensure substantial equivalency, e.g.:

- United States Food and Drug Administration. Deciding When to Submit a 510(k) for a Change to an Existing Device. Washington, D.C.: FDA, 2017.
- United States Food and Drug Administration, Guidance for Industry and Food and Drug Administration Staff, General/Specific Intended Use. Washington, D.C.: FDA, 1998

- United States Food and Drug Administration. Premarket Assessment of Pediatric Medical Devices Guidance, Guidance for Industry and Food and Drug Administration Staff. March 24th edition. Washington, D.C. 2014

The proposed modifications to the NeuroBlate System's Indications For Use (IFU) are to provide clarification for the existing terminology utilized within the existing indications as the device is currently utilized. The proposed changes are not intended to provide specific indications for use which are different than the current language.

In this submission, Monteris monitors LITT related clinical literature, as well as our own NeuroBlate System commercial clinical experience, to ensure our current instructions and device remain appropriate for their use. Additionally, adult and pediatric data from Monteris' prospective LAANTERN Registry was also reviewed. Monteris has concluded from these reviews that the NeuroBlate LITT system has been, and remains, an effective and safe tool for use in pediatric patients.

g. Conclusion

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 that the technical modes of action and technical principles remain the same as the predicate devices, and that the proposed changes are labeling related, the previously provided (K231061) 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.

Table 1: Substantial Equivalence Comparison

Characteristic	UNDER REVIEW	PRIMARY PREDICATES: K231061 Current Monteris NeuroBlate System Laser Probes
Indications For Use	No change from Monteris predicate.	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.
	(ADDED) The intended patients are adults and pediatric from the age of 2 years and older.	Not Applicable
IFU Stated Patient Population	Stated in Indications for Use	Not stated
Clinical Evidence Provided in Submission	**Yes**	**Yes**