December 8, 2023

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

Re: K231061
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: GEX, HAW, ONO
Dated: November 8, 2023
Received: November 8, 2023

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 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: 2023.12.08 15:27:42 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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and Neurodiagnostic Devices
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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)*
K231061

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.

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.

Section 5: 510(k) Summary

5.1. Device Information:

Category	Comments
Sponsor:	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 Number:	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, GEX Class II, HAW Class II, ONO
Device Proprietary Name:	Monteris Medical NeuroBlate® System

Predicate Device Information:

Predicate Device:	NeuroBlate System
Predicate Device Manufacturer:	Monteris Medical
Predicate Device Common Name:	Monteris NeuroBlate System
Primary Predicate Device	K222983
Additional Predicate *Monteris*	K182036
Additional Predicate *Non-Monteris*	
• Clinical Laserthermia Systems AB	K214125
• Medtronic	K211269
Predicate Device Regulations:	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
Predicate Device Classifications & Product Codes:	Class II, GEX Class II, HAW Class II, ONO

5.2. Date Summary Prepared
December 8, 2023

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

As previously described in K182036 and K222983, the NeuroBlate System is typically used for the ablation of target tissue (tumors, radiation necrosis, epileptic foci) in the brain.

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 Probe Drivers and interconnections for the Laser Delivery Probes (e.g., Connector Module).
- A System Electronics Rack and Components, which includes the laser and 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*™ , or *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, MRI head coils, and other optional accessories, including: drill bits, bolts, thumbscrews, instrument adaptors, accessory host adaptors, MRI trajectory wands, fiducial markers, stereotactic manual driver with mandrel and T-handle, and other manual accessory instruments and tools.

There is no change to entire system, with the exception of an additional NB3 (1.6mm) Laser Probe and the corresponding labeling updates.

5.4. Indications for Use
There is no change to the indications for use, i.e., they remain:

> *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.*

5.5. Comparison to Predicate Device
The NB3 probe does not include changes to the entire existing NeuroBlate System, Software, and Indications for Use (as described in K222983). The NB3 is simply the addition of a smaller diameter probe (1.6mm) to the existing probe family, i.e., the NeuroBlate 2.2mm and 3.3mm laser probes (as described in K182036). The NB3 probe has the same function and Indications for Use as existing laser probes. The smaller diameter NB3 probe uses the same probe cooling range, and delivers the same maximum power as the NeuroBlate FullFire probe types currently used in clinical practice.

Monteris' NB3 probe is substantially equivalent to Monteris' 2.2mm and 3.3mm diameter NeuroBlate Optic Laser Probe (Secondary Predicate K182036) in design, technology, and function. Use of the NB3 probe requires no changes to the overall NeuroBlate System and Software (Primary Predicate K222983). Additionally, the NB3 1.6 diameter probe is substantially equivalent to Medtronic Visualase probes (K211269) and CLS Tranberg and Prism laser probes (K214125).. Reference **Table 1: Substantial Equivalence; Technical Comparison**.

As the modifications presented in the current device do not change the intended use, operating principles, or raise any unaddressed safety concerns, it can be concluded the NeuroBlate System with the alternative NB3 Probe is substantially equivalent to the predicate NeuroBlate System with existing NeuroBlate probes and to probes used with competitive systems.

Table 1: Substantial Equivalence; Technical Comparison

Characteristic	NB3 Probe K231061	PRIMARY PREDICATE: K222983 Monteris NeuroBlate System Laser Probes SECONDARY PREDICATE: K182036 NeuroBlate System DTP Fiber Design Laser Probes
Fiber		
Fiber Core Material	**No change from current NBS probes**	Fused Silica
Fiber Size	**400um core,** **440um clad, 470um hard clad, 600um jacket ([5])**	**600um core,** **660um clad, 710um jacket**
Emitting Length	**4mm([6])**	**6mm**
Connector	**No change from current NBS probes**	E2000
Lens		
Lens material	**Borosilicate Glass**	**Sapphire-synthetic**
Wavelength		
Probe's Laser wavelength capability	**No change from current NBS probes**	Fiber optic can transmit visible and invisible laser wavelengths
Power		
Maximum Power	**No change from current NBS probes**	Diffuse Tip Probe 12W max power settings
Energy Delivery	**No change from current NBS probes**	600 J/min
Probe Cooling Control	**No change from current NBS probes**	Closed Loop control using fiber optic temp sensor
Coolant	**No change from current NBS probes**	Carbon dioxide
Operating Time of Laser for Clinical Use	**No change from current NBS probes**	No limits
ISO 60825-1 compliant	**No change from current NBS probes**	ISO 60825-1 compliant
Probe Characteristics		
Probe Outer Diameter (OD) ([7])	**1.6 mm([7])**	**2.2 mm and 3.3mm**
Probe Fiber Insertable Length	**275mm([8])**	**135-280 mm**
Diffuse Tip	**Diffuse Tip**	Diffuse Tip (2.2mm and 3.3mm)
Overall Probe + Umbilical length	**1380mm([9])**	**Multiple lengths: 1190mm – 1320mm**
MRI Compatible	**No change from current NBS probes**	MRI Conditional
Incorporated ruler(s)	**Probe Holder Ruler (No Change);** **Visible gradations on inner Probe shaft** **Flexible plastic ruler([10])**	**Probe Holder Ruler incorporated**
Depth Stop	**Modified design that locks onto Probe Shaft**	**Depth Stop incorporated**
Sterilization	**No change from current NBS probes**	Ethylene oxide
Single Use	**No change from current NBS probes**	Yes
Shelf-Life	**No change from current NBS probes**	2 year

Table 1 footnotes

(1) Pharmaceutical packaging glass as an outer cladding, which includes glass filaments as scattering elements made of a Pb-containing white glass.
(3) Plastic tube filled with transparent matrix with light dispersing particles
(4) Distal end sealed with higher concentration of scattering particles in a conical structure to prevent forward energy transmission

(5) Substantially Equivalent to PREDICATE Medtronic K211269: Fiber size; 400, 600, 800, 1000 um.
(6) Substantially Equivalent to PREDICATE CLS K214125: Fiber emitting length is within this probes 1mm to 25 mm range
(7) Substantially Equivalent to PREDICATE CLS K214125; Probe 1.55mm diameter; NB3 is within the range of 1.55mm to 2.2mm.
(8) Substantially Equivalent to PREDICATE Medtronic K211269; Probe length 355 mm; NB3 is within the range of 135mm to 355mm.
(9) Substantially Equivalent to PREDICATE CLS K214125; Overall Probe + Umbilical length maximum is 12,000mm; NB3 is within the range of 1190mm and 12,000mm
(10) Substantially Equivalent to PREDICATE Medtronic K211269; which also includes plastic ruler for initial depth setting.

5.6. Summary of Supporting Data

The updated NeuroBlate NB3 Probe 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 for the NB3 Probe when used within the NeuroBlate System.

The Design Verification process utilized protocols to detail the associated tests. Each verification test protocol incorporated clearly defined acceptance criteria. The corresponding test reports confirmed (and documented) the design output met the design input for the requirements.

The Design Validation process utilized protocols to detail the associated tests. Each validation protocol described the objective, test method and acceptance criteria. The corresponding test reports confirmed (and documented) the modified NeuroBlate System met the user needs and intended use.

The application for the Monteris Medical NeuroBlate System with the NB3 Laser Probe is substantially equivalent to the predicate Monteris NeuroBlate System 2.2mm and 3.3mm laser probes (K182036, K222983) and to the non-Monteris laser probe devices (K214125, K211269) in intended use, technology, design and physician use.