March 15, 2023

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

Re: K222983
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: February 10, 2023
Received: February 10, 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 (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/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 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 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: 2023.03.15 17:11:43 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
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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)*
K222983

Device Name
Monteris Medical NeuroBlate System,
NeuroBlate Fusion-S Software V3.17

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 3: 510(k) Summary - K222983

***5a. Device Information:***

| **Category** | **Comments** |
|---|---|
| Sponsor: | Monteris Medical<br>131 Cheshire Lane, suite 100<br>Minnetonka, MN 55305<br>866-799-7655<br>www.monteris.com |
| Correspondent Contact Information: | David H. Mueller<br>Senior Principal Regulatory Affairs Specialist<br>Monteris Medical,<br>TEL: 763-333-1614<br>Email: DMueller@Monteris.com |
| Device Common Name: | Magnetic Resonance Image Guided Laser Thermal Therapy System |
| Device Regulation and Name: | 21 CFR 878.4810<br>Laser surgical instrument for use in general and plastic surgery and in dermatology<br><br>21 CFR 882.4560<br>Stereotaxic instrument |
| Device Classification & Product Code: | Class II, GEX, ONO<br>Class II, HAW |
| 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 |
| Predicate Device Premarket Notification # | K193375, K201056 |
| Predicate Device Regulation: | 21 CFR 878.4810<br>Laser surgical instrument for use in general and plastic surgery and in dermatology<br><br>21 CFR 882.4560<br>Stereotaxic instrument |
| Predicate Device Classification & Product Code: | Class II, GEX<br>Class II, HAW |

***5b. Date Summary Prepared***

February 10, 2023

***5c. 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 K201056, the NeuroBlate System is typically used for the minimally invasive 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, cranial screws, fiducial markers, bone screws, 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 NeuroBlate Fusion-S™ Software Package (V3.17). While the modified software package includes several modifications which do not meet the FDA's "significant change" submission criteria, there is at least one intended change which modifies an existing risk control measure for a hazardous situation and thus, per FDA 510(k) guidance, requires a new 510(k) submission.

***5d. Indications for 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.*

*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.*

***5e. Comparison to Predicate Device***

There is no change to entire system, with the exception of an additional (alternative) NeuroBlate Fusion-S Software Package (V3.17). While the modified software package includes several modifications which do not meet the FDA's "significant change" submission criteria, there is at least one intended change which modifies an existing risk control measure for a hazardous situation and thus, per FDA 510(k) guidance, requires a new 510(k) submission

The substantial equivalency comparisons for the NeuroBlate System's Technical Characteristics are described in Table 1.

**Table 1: Substantial Equivalence: NeuroBlate System Comparison Table**

| Characteristic | Predicate: Monteris Medical NeuroBlate System (K193375, K201056) | Intended Alternative Modified Fusion-S Software (V3.17) |
|---|---|---|
| **Company** | Monteris Medical | Identical |
| **Regulation Number** | 21 CFR 878.4810<br>Laser surgical instrument for use in general and plastic surgery and in dermatology<br><br>21 CFR 882.4560<br>Stereotaxic instrument | Identical |
| **FDA Product Code** | GEX & HAW | Identical |
| **Indications for Use** | *The Monteris Medical NeuroBlate® System is a surgical tool for brain surgery (e.g., tumor and epilepsy surgery) and is indicated for use to ablate, necrotize, or coagulate intracranial soft tissue, including brain structures, through interstitial irradiation or thermal therapy in medicine and surgery in the discipline of neurosurgery with 1064 nm lasers.*<br><br>*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.*<br><br>*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 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.*<br>*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.*<br>*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.* |
| **Operating Principle (Technology)** | MRI-guided Laser Probe with near-real time thermographic monitoring of target tissue temperature | Identical |
| **Mode of Action** | Laser Interstitial Thermal Therapy (LITT) | Identical |

| Characteristic | Predicate: Monteris Medical NeuroBlate System (K193375, K201056) | Intended Alternative Modified Fusion-S Software (V3.17) |
|---|---|---|
| **Design** | • Families of gas-cooled Laser Delivery Probe (Probe) (SideFire & FullFire) to deliver controlled energy to a target zone.<br>• 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.<br>• 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, including the supporting cables and interconnections.<br>• A System Electronics Rack and Components, which includes necessary umbilicals, cables, penetration panels, and small hardware for system mechanical, electrical, and electronic operation, and<br>• A Control Workstation including the *M-Vision*™, *M-Vision Pro, Fusion-S* software, which includes a user interface for procedure planning, interactive monitoring of NeuroBlate procedures, and interfaces to the MRI and hardware subsystems.<br>• The Monteris Cranial Bolt and Mini-Bolt fixation components, and<br>• The AtamA Stabilization System, MRI head coils, as well as, other optional accessories, including: drill bits, bolts, thumbscrews, instrument adaptors, accessory host adaptors, MRI trajectory wands, cranial screws, bone screws, stereotactic manual driver with mandrel and T-handle, and other manual accessory instruments and tools. | Identical NeuroBlate System hardware<br>Software is changing as described along with the corresponding labelling updates, i.e., utilizing Fusion-S V3.17 Software |
| **NeuroBlate Software** | NeuroBlate M-Vision and Fusion-S Software Version V3.15 and V3.16 | NeuroBlate Fusion-S Software Version V3.17 |
| **Probe Distal diameter** | 2.2mm and 3.3 mm | Identical |

| Characteristic | Predicate: Monteris Medical NeuroBlate System (K193375, K201056) | Intended Alternative Modified Fusion-S Software (V3.17) |
|---|---|---|
| **3.3mm Probe Size as per Probe Body Length Range** | Size #000<br>Size #00<br>Size #1<br>Size #2<br>Size #3<br>Size #4<br>Size #5 | Identical |
| **2.2mm Probe Size as per Probe Body Length Range** | Size #000<br>Size #00<br>Size #1<br>Size #2<br>Size #3<br>Size #4<br>Size #5 | Identical |
| **Probe Diameters and Laser Output Direction** | • 2.2mm NeuroBlate FullFire (DTP) Probes<br>• 3.3mm NeuroBlate FullFire (DTP) Probes<br>• 3.3mm NeuroBlate SideFire (SFP) Probes | Identical |
| **Energy Source** | • Donier Medilase D Laser, or<br>• NeuroLase Laser | Identical |
| **Warnings and Cautions** | • Warnings and Cautions included in labeling and IFU content | Warnings and Caution statements updated |

### *5f. Summary of Supporting Data*

The updated Fusion-S (V3.17) 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 for the Fusion-S (V3.17) Software 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.

***5g. Discussion of Performance Testing***

The performance of the V3.17 software was tested utilizing automated and manual test methods and was found to be comparable to that of predicate V3.16 software. All tested metrics were measured to be within acceptable limits and improvements were noted in several metrics.

***5h. Conclusion***

Monteris concludes that the application for the Monteris Medical NeuroBlate System with the alternative V3.17 Software is substantially equivalent to the predicate Monteris NeuroBlate System (K193375, K201056) in intended use, technology, design and physician use.