October 15, 2018

Monteris Medical
David Mueller
Senior Principal Regulatory Affairs Specialist
14755 27th Avenue North
Suite C
Plymouth, Minnesota 55447

Re: K182036
    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
    Dated: July 27, 2018
    Received: July 30, 2018

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/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
Monteris Medical NeuroBlate™ System

Indications for Use
The Monteris Medical NeuroBlate™ System 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.

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.

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510(k) Summary

**Device Information:**

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<tr>
<th>Category</th>
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<tr>
<td>Sponsor:</td>
<td>Monteris Medical Corp.</td>
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<tr>
<td></td>
<td>14755 27th Avenue North</td>
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<tr>
<td></td>
<td>Suite C</td>
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<td></td>
<td>Plymouth, MN 5546</td>
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<tr>
<td></td>
<td>763-253-4710</td>
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<tr>
<td></td>
<td>Fax: 763-746-0084</td>
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<td></td>
<td><a href="http://www.monteris.com">www.monteris.com</a></td>
</tr>
<tr>
<td>Correspondent Contact</td>
<td>David H. Mueller</td>
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<tr>
<td>Information:</td>
<td>Senior Principal Regulatory Affairs Specialist</td>
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<tr>
<td></td>
<td>Monteris Medical, TEL: 763-253-4710 x2732</td>
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<tr>
<td></td>
<td>FAX: 763-746-0084</td>
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<tr>
<td></td>
<td>Email: <a href="mailto:DMueller@Monteris.com">DMueller@Monteris.com</a></td>
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<td>Device Common Name:</td>
<td>Magnetic Resonance Image Guided Laser Thermal Therapy System</td>
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<tr>
<td>Device Classification Number:</td>
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**Predicate Device Information:**

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<td>Laser Interstitial Thermal Therapy (LITT)</td>
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<td><strong>Class/ Product Code</strong></td>
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Date Summary Prepared
27 July 2018

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 K170724, K171255, K172881, and K173305, the NeuroBlate™
System is typically used for the minimally invasive ablation of target tissue (tumors, 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™ and M-Vision Pro™ FUSION™
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 Axiiis stereotaxic mini-frame and the Monteris Cranial Bolt and Mini-Bolt fixation
components, and
• The AtamA Stabilization System, as well as, 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).

Monteris’ existing NeuroBlate System Laser Delivery Probes (“Probe”) include the 3.3mm
FullFire and SideFire Probes and the 2.2mm FullFire Probe. In order to ensure that the Probe tip
maintains an appropriate temperature while the laser is on, all Monteris Probes incorporate an
internal temperature sensor which measures the probe tip’s internal temperature. The sensor
transmits the temperature reading to the NeuroBlate System and associated M-Vision Software
which regulates the cooling system for the laser probe, e.g., ensures sufficient gas coolant is sent to the Probe tip to maintain an appropriate temperature.

Note: The only function for the Probe’s temperature sensor is to measure the Probe tip’s internal temperature, i.e., the sensor is not utilized for determining the patient’s brain tissue temperature and is not utilized for the software’s thermography visualization.

To perform a NeuroBlate procedure, a NeuroBlate Laser Probe is connected to a Portable Connector Module (PCM). The PCM integrates with the Interface Platform(IP). The IP attaches to the MRI system’s patient table or the ATAMA board, and provides supporting electronics for the Probe Drivers and interconnections (including the Portable Connector Module) for the Laser Delivery Probes.

This submission’s proposed change simply replaces the Probe’s existing internal metallic (wire) thermocouple with a non-metallic fiber optic, temperature sensor. The optical fiber temperature sensor has the identical function as the existing metallic (wire) thermocouple, i.e., to measure the probe tip’s internal temperature and to transmit the temperature measurement to the NeuroBlate System and associated M-Vision Software.

Corresponding hardware and software changes are proposed in order to incorporate the new optical fiber component, e.g., (hardware) modified Connector Module, a Signal Conditioner (converts optical fiber signal to electrical temperature signal), and (software) M-Vision Pro Software Package (V3.14), along with associated labeling updates. Additionally, existing Contraindications, Warnings and Cautions are duplicated within the IFU and clarified for ease of reader understanding.

**Indications for Use**

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

*The Monteris Medical NeuroBlate™ System 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.*

*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.*
**Comparison to Predicate Device**

In order to ensure that the Probe tip does not over-heat during laser ablation, all Monteris Probes incorporate an internal temperature sensor which measures the probe tip’s internal temperature. The sensor transmits the temperature reading to the NeuroBlate System and associated M-Vision Software which regulates the cooling system for the laser probe ensuring sufficient gas coolant is sent to the Probe tip to maintain an appropriate temperature.

This submission’s proposed fiber optic temperature sensor (FOTS) has the identical function as the existing (predicate) NeuroBlate Probe’s metallic (wire) thermocouple, i.e., to measure the probe tip’s internal temperature and to transmit the temperature measurement to the NeuroBlate System and associated M-Vision Software.

These proposed changes are in response to a recall (Z-0194-2018) regarding MRI induced unintentional Probe heating. Replacing the metallic thermocouple with a FOTS prevents the MR energy from coupling to the probe umbilical and thus eliminates the root cause of unintended Probe heating.

In order to incorporate the FOTS component, the current NeuroBlate hardware, software and labeling are also modified.

- **Hardware: Portable Connector Module (PCM)**
  The proposed PCM modifies the existing PCM to incorporate a new optical fiber connector port (and a pre-attached fiber optic cable). The modified and existing PCM remain Substantially Equivalent.

- **Hardware: Signal Conditioner**
  The current NeuroBlate Probe’s Thermocouple (TC) provides its temperature signal via electrical current while the modified Probe with FOTS utilizes light signals. The provided FOTS signal is “converted” to a temperature signal at the new Optical Signal Conditioner. The Optical Signal Conditioner and the existing Signal Conditioner (WIKA Transmitter Puck) remain Substantially Equivalent.

- **Hardware: Associated Fiber Optic Cabling and Accessories**
  The current Thermocouple (TC) transmits its electrical temperature signal via electrical cabling and connectors. A fiber optic electrical signal must be transmitted via fiber optic cabling and connectors. These cables and accessories remain Substantially Equivalent.

- **Software: M-Vision V3.14 Software**
  The existing M-Vision V3.13 Software is slightly modified to form V3.14 such that the system reads probe tip temperature via an optic signal conditioner. Several minor
software updates were also completed to incorporate FOTS. M-Vision V3.13 and V3.14 remain Substantially Equivalent.

- Labeling: Fiber Optic Labeling Updates and Additional Labeling Clarifications
  Labeling updates include product label branding (i.e., Optic™), corresponding Probe and system component drawings, photographs and instructions related to FOTS incorporation. Additionally, existing Contraindications, Warnings, Cautions, and Instructions are duplicated within the IFU and clarified for ease of reader understanding.

The 510(k) application for the Monteris Medical NeuroBlate™ System with the fiber optic temperature measurement system demonstrates it to be substantially equivalent to the predicate 510(k) submissions for the Monteris NeuroBlate™ System [K173305, K17288, K171255, K170724, K162762, K143457, K141983, K131955, K131278, K120561, and K081509 in intended use, technology, design and physician use.

As the modifications presented do not change the intended use, operating principles, or raise any unaddressed safety concerns, it can be concluded the application NeuroBlate™ System with the fiber optic temperature (measurement) sensor is substantially equivalent to the predicate NeuroBlate™ System.

**Summary of Supporting Data**

The development process for the NeuroBlate™ System Probe with the fiber optic temperature sensor 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 modified Probe when used within the NeuroBlate System.

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

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

As the proposed modifications do not change the intended use, operating principles or raise any unaddressed safety concerns, the application for the Monteris Medical NeuroBlate™ System Probe with the fiber optic temperature sensor is substantially equivalent to the predicate Monteris NeuroBlate™ System (K173305, K17288, K171255, K170724, K162762, K143457, K141983, K131955, K131278, K120561, and K081509) in intended use, technology, design and physician use.