DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 25, 2017

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

Re: K171255
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: GEX, HAW
Dated: April 27, 2017
Received: April 28, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171255

Device Name
Monteris Medical NeuroBlate System

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K171255
Section 5: 510(k) Summary

a. Device Information:

Category	Comments
Sponsor:	Monteris Medical 14755 27th Avenue North Suite C Plymouth, MN 55446 763-253-4710 Fax: 763-746-0084 www.monteris.com
Correspondent Contact Information:	David H. Mueller Principal Regulatory Affairs Specialist Monteris Medical TEL: 763-253-2732 FAX: 763-746-0084 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 21 CFR 882.4560 Stereotaxic instrument
Device Classification & Product Code:	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 #	K162762, K170724
Regulation	21 CFR 878.4810 21 CFR 882.4560
Class/ Product Code	Class II GEX, HAW

b. Date Summary Prepared

July 21, 2017

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 that is currently indicated for the practice of neurosurgery.

As previously described in K162762, K170724, the NeuroBlate System is typically used for the minimally invasive ablation of neurosurgeon identified 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 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 AXiiiS stereotaxic mini-frame and 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.

<u>Change Description</u>

Monteris seeks clearance for minor modifications to the indications for use[1] statement to improve clarity and ease of understanding in alignment with the current intended use[13], the proposed changed text will read:

> The Monteris Medical NeuroBlate™ System is indicated for use to ablate, necrotize, or coagulate intracranial soft tissue, including brain structures, through interstitial irradiation

[13] United States Food and Drug Administration, the 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], Guidance for Industry and Food and Drug Administration Staff. Washington, D.C.: FDA, 2014. http://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf

or thermal therapy in medicine and surgery in the discipline of neurosurgery with 1064 nm lasers.

The clarified indications were determined to not create a new intended use or raise different questions of safety and effectiveness, and were also determined to not introduce any new or different technical characteristics which could raise different questions of safety and effectiveness, i.e., the clarified indications are more clearly consistent with the existing intended use as well as the exiting indications for use. This 510(k) submission meets the Traditional 510(k) criteria as the proposed changes involve a modification to the language of the indications for use to clarify the current indications.

Additionally, the proposed clarified indications were evaluated within the FDA General-Specific Guidance's[14] criteria which determined that the proposed labeling modifications are to provide clarification for the terminology utilized within the existing indications as the device is currently utilized and intended. The proposed changes are not intended to provide specific indications for use which are different than the current language.

The proposed clarified indications were also evaluated utilizing several other FDA Guidance Documents[15,16,17,18], which concluded that the modified Indications for Use clarify the terminology utilized within the existing indications as the device is currently used via its Intended use. The proposed changes are not intended to provide specific indications for use which are different than the current language.

The modified NeuroBlate has the same intended use and similar indications, and identical technological characteristics and principles of operation as the cleared NeuroBlate System. As explained in the attached 510(k) notice, the minor differences between the subject NeuroBlate and the predicate device do not raise any new questions of safety or effectiveness. Thus, we believe that the modified NeuroBlate System is substantially equivalent.

d. 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.

---

[14] United States Food and Drug Administration, Guidance for Industry and Food and Drug Administration Staff, General/Specific Intended Use. Washington, D.C.: FDA, 1998

[15] United States Food and Drug Administration, Deciding When to Submit a 510(k) for a Change to an Existing Device; Draft Guidance for Industry and Food and Drug Administration Staff. Washington, D.C.: FDA, 2016.

[16] United States Food and Drug Administration, The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], Guidance for Industry and Food and Drug Administration Staff. Washington, D.C.: FDA, 2014. http://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf

[17] United States Food and Drug Administration, Determination of Intended use for 510(k) Devices; Guidance for CDRH Staff (Update to K98-1). Washington, D.C.: FDA, 2002. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082166.pdf

[18] United States Food and Drug Administration, Device Labeling Guidance #G91-1. Washington, D.C.:FDA, 1991

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.

e. Comparison to Predicate Device

The application for the Monteris Medical NeuroBlate™ System with the modified labeling is substantially equivalent (and/ or identical) to the predicate Monteris NeuroBlate™ System (K162762, K170724) in intended use, indications for use, technology, design and physician use.

This submission proposes no physical changes to the NeuroBlate System hardware, software, accessories, manufacturing, design or the devices' specific step-by-step directions for use. This submission's intent is not to change the current indication or intended use, but to improve the indication's clarity, ease of understanding, and consistency with the intended use.

The indications for use are being clarified to ensure alignment and conformance with the currently cleared NeuroBlate System's intended use. This proposed change clarifies that the existing NeuroBlate (K162762) indications for use are in reference to the ablation of soft "brain" tissue, i.e.,

- Current K162762, K170724 Indication (excerpt) states. . . to ablate "soft tissue" in "in the discipline of neurosurgery" while utilizing "stereotaxic placement of MRI compatible (conditional) NeuroBlate™ Laser Delivery Probes". . .

- Based on the K162762, K170724 provided Directions for Use, both textual statements and graphics demonstrate that the existing NeuroBlate System's intended use is to ablate *brain* tissue, i.e., brain tissue ablation refers to the ablation of "intracranial soft tissue," including "brain structures".

This clarification is based on the considerations that:

- Previous FDA cleared NeuroBlate System 510(k) submissions (e.g., K162762, K170724) demonstrate the device's intended use, based upon the submission contents and the associated proposed labeling and directions for use[10] is the ablation of brain tissue.

- The K162762, K170724 submitted NeuroBlate System content, labeling and directions for use included both textual and graphic brain tissue and skull specific

directions for use[10] demonstrating the device's intended use[19,20] is brain tissue ablation.

- As "brain soft tissue" is really the "matter" or "tissue" inside the patient's skull (or cranium), the term "intracranial" is the appropriate medical terminology to describe the "soft tissue" to be ablated, i.e., "intracranial soft tissue".

- When physicians desire to identify specific "intracranial soft tissue" anatomical regions or areas within the brain, medical naming conventions divide the entire human brain into various areas or regions. While all these identified regions are "intracranial soft tissue", the generalized naming terminology for these intracranial soft tissue regions is "brain structures". Thus, as the NeuroBlate System is intended and indicated to ablate soft brain tissue, utilizing both "intracranial soft tissue" and "brain structure" naming conventions is appropriate in order to provide clarity and consistency between the Indications for Use and the Intended use.

The proposed labeling modifications:

- Do not change the intended use, i.e., they only clarify the indications for use within the existing intended use,
- Do not raise new or different questions of safety and effectiveness,
- Do not introduce any new or different technical characteristics that raise different questions of safety and effectiveness,
- Present no change to the NeuroBlate System's operating principles, design, manufacturing, function or specific directions for use.

It can be concluded this NeuroBlate™ System application with the modified labeling would meet FDA's "non-significant change" criteria for which "changes to the device name *or description* that are *consistent with the cleared indications for use* and *changes to improve* readability or *clarity that do not affect the substance* of the indications for use"([21]), i.e., a new 510(k) would not be necessary. However, having previously observed inconsistency in interpreting this guidance in coordination with general to specific use questions, a conservative approach was utilized and a new 510k submission was submitted to demonstrate that the clarified indications are substantially equivalent to the described predicate devices.

The proposed clarified indications were also assessed utilizing the FDA General-to-Specific Guidance[22] with the resulting conclusion being that the proposed Indications for use

---

[19] United States Food and Drug Administration, the 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], Guidance for Industry and Food and Drug Administration Staff. Washington, D.C.: FDA, 2014. http://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf

[20] United States Food and Drug Administration, Determination of Intended use for 510(k) Devices; Guidance for CDRH Staff (Update to K98-1). Washington, D.C.: FDA, 2002. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082166.pdf

[21] United States Food and Drug Administration. K97-1 Deciding When to Submit a 510(k) for a Change to an Existing Device. Washington, D.C.: FDA, 1997.

[22] United States Food and Drug Administration, Guidance for Industry and Food and Drug Administration Staff, General/Specific Intended use. Washington, D.C.: FDA, 1998

modifications 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.

The application for the NeuroBlate™ System with the modified labeling is substantially equivalent, and/ or identical, to the predicate Monteris NeuroBlate™ System (K162762, K170724) in intended use, technology, design and physician use

Thus, the predicate terminology describing brain tissue and brain structure ablation are all synonymous (identical) or equivalent, in intended use, technology, design and physician use.

Additionally, this submission proposes no manufacturing changes, process changes, materials changes, or technology proposed changes to the NeuroBlate System. The technical modes of action and technical principles remain the same as the predicate devices.

The fundamental functionality and technical characteristics of the proposed modified device is identical and substantially equivalent to the existing NeuroBlate System (K162762, K170724). The conclusion is that the difference in technological characteristics between proposed modified device and the current NeuroBlate System (K162762, K170724) 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

Considering the proposed changes are labeling clarifications, the previously provided in-vitro (bench), and in-vivo (animal) data remains applicable, and are incorporated by reference.

Given that the modifications to the indications for use do not create a new intended use or raise new or different questions of safety or efficacy, clinical data are not necessary to demonstrate substantial equivalence.