DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 26, 2016

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

Re: K162762
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
Dated: September 29, 2016
Received: September 30, 2016

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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use

510(k) Number (if known): K162762

Device Name: Monteris Medical NeuroBlate™ System

Indications for Use:
The Monteris Medical NeuroBlate™ System is indicated for use to ablate, necrotize, or coagulate soft tissue 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.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5: 510(k) Summary

a. Device Information:

Category	Comments
Sponsor:	Monteris Medical Corp. 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, Inc 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:

Predicate Device:	NeuroBlate™ System
Predicate Device Manufacturer:	Monteris Medical
Predicate Device Common Name:	Monteris NeuroBlate™ System
Predicate Device Premarket Notification #	K120561, K141983, K14347
Predicate Device Regulation:	21 CFR 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology 21 CFR 882.4560 Stereotaxic instrument
Predicate Device Classification & Product Code:	Class II, GEX Class II, HAW

b. Date Summary Prepared

29 Sept 2016

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.

As previously described in K143457, 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 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.

d. Indications for Use
The Monteris Medical NeuroBlate™ System is indicated for use to ablate, necrotize, or coagulate soft tissue 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.

e. Comparison to Predicate Device

This submission proposes no physical changes to the NeuroBlate System hardware, software, or accessories. The indications for use within the NeuroBlate Systems' Instructions for Use (IFU) have not been changed, however, the product labeling has been modified and corrected as outcomes from the Class 1 Recall's corrective actions as well as from Monteris' response to FDA 483's observation. This submission also provides a listing of historical non-significant changes which have occurred.

The labeling changes include removing references to the discontinued (recalled) 2.2mm SideFire Probes (SFS) as well as providing clarified (or duplicate) warnings and precautions to more easily verify compliance to 21 CFR 1000 -1050 Radiological Health requirements as well as FDA Laser Notice #50 requirements.

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

The application for the Monteris Medical NeuroBlate™ System with the modified labeling is substantially equivalent to the predicate Monteris NeuroBlate™ System (K120561, K141983, K143457) in intended use, technology, design and physician use.

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 application NeuroBlate™ System with the modified labeling is substantially equivalent to the predicate NeuroBlate™ System.

f. Summary of Supporting Data

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

Reviewing the specific individual 21 CFR 1000 - 1050 requirements, demonstrates that the proposed labeling updates comply with these requirements and are substantially equivalent to the predicate devices.