K120561

APR 1 2013

Section 5: 510(k) Summary

a. Device Information:

Category	Comments
Sponsor:	Monteris Medical, Inc. 100 - 78 Innovation Drive Winnipeg, Manitoba CANADA R3T 6C2 Tel: 204-272-2220 Fax: 204-272-2219 www.monteris.com
Correspondent Contact Information:	John Schellhorn President & C.E.O. Monteris Medical Corp. 16305 36th Ave. North, Suite 200 Plymouth, MN 55446 763-253-4712 office 617-230-1252 mobile jschellhorn@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:	AutoLITT® System
Predicate Device Manufacturer:	Monteris Medical
Predicate Device Common Name:	Monteris AutoLITT® System
Predicate Device Premarket Notification #	K081509
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
28 March 2013

c. Description of Device
The Monteris NeuroBlate™ System is a unique collection of MRI-compatible laser devices and accessories that create an MRI guided delivery of precision thermal therapy. The NeuroBlate System components consist of:

- A gas-cooled Laser Delivery Probe (Probe) to deliver controlled energy to a target zone;
- A Probe Driver which allows the surgeon to precisely position, stabilize and manipulate a laser probe within the target zone;
- A System Electronics Rack and Components, which includes necessary umbilicals, cables, penetration panels, and small hardware for system mechanical, electrical, and electronic operation; and
- A Control Workstation including the M Vision™ Software, which includes a user interface for procedure planning, interactive monitoring of NeuroBlate™ procedures, and interfaces to the MRI and hardware subsystems.

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 Probe. 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 Monteris Medical NeuroBlate™ System is substantially equivalent to the predicate Monteris AutoLITT® device in intended use, technology, design and physician use.

All patient contacting materials are identical in composition, source, and use with respect to the predicate device.

The technical modes of action and technical principles are materially the same the predicate devices.

Bench testing has demonstrated that the System is in compliance with the medical community's expectations and the product labeling.

As the modifications presented in the current device do not change the intended use, operating principles, or raise any unaddressed safety concerns, with respect to the predicate device, it can be concluded the NeuroBlate™ System is substantially equivalent to the AutoLITT® System.

f. Summary of Supporting Data

Bench testing has demonstrated that the System is in compliance with the medical community's expectations and the product labeling.

In particular the following testing was conducted to demonstrate electromagnetic and MRI compatibility:

- EMC/EMI testing in accordance with IEC 60601-1-2.
- Verification of probe placement accuracy within MR environment.
- Testing for RF Induced heating during MR Imaging.
- MR compatibility for 1.5T and 3T per ASTM standards.

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

Monteris Medical, Incorporated
% Mr. John Schellhorn
Chief Executive Officer
16305 36th Ave. North, Suite 200
Plymouth, MN 55446

Letter dated: April 1, 2013

Re: K120561

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: February 22, 2012
Received: February 24, 2012

Dear Mr. Schellhorn:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting 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): K120561

Device Name: Monteris Medical NeuroBlate™ System

Indications for Use:

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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)

Neil R Ogden -S
2013.03.29 08:48:43 -04'00'

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K120561