# Section 5: 510(k) Summary

**a. Device Information:**

| Category | Comments |
|---|---|
| Sponsor: | Monteris Medical, Inc.<br>100 – 78 Innovation Drive<br>Winnipeg, Manitoba<br>CANADA R3T 6C2<br>Tel: 204-272-2220<br>Fax: 204-272-2219<br>www.monteris.com |
| Correspondent Contact Information: | Craig Coombs<br>Coombs Medical Device Consulting<br>1193 Sherman Street<br>Alameda, CA 94501<br>Tel: 510-337-0140<br>Fax: 510-337-0416 |
| Device Common Name: | Magnetic Resonance Image Guided Laser Thermal Therapy System |
| Device Classification & Code: | Class II<br>GEX |
| Device Classification Name: | 21CFR878.4810<br>Laser surgical instrument for use in general and plastic surgery and in dermatology |
| Device Proprietary Name: | Monteris Medical AutoLITT™ System |

**Predicate Device Information:**

| **Predicate Devices:** | Visualase Thermal Therapy System | GreenLight HPS Series Surgical Laser System & Accessories | NaviVision |
|---|---|---|---|
| **Predicate Device Manufacturers:** | BioTex | LaserScope | BrainLab |
| **Predicate Device Common Name:** | Magnetic Resonance Image Guided Laser Thermal Therapy System | Laser Probe & Laser | Stereotaxic instrument |
| **Premarket Notification #** | K071328 | K062719 | K062086 |
| **Predicate Device Classification:** | 21CFR 878.4810 | 21CFR 878.4810 | 21 CFR 882.4560 |
| **Predicate Device Classification & Code:** | Class II, GEX | Class II, GEX | Class II, HAW |

**b. Date Summary Prepared**
28 April 2009

**c. Description of Device**

The Monteris AutoLITT™ System is a combination of three major components:

Monteris AutoLITT™ Laser Probe
Monteris AutoLITT™ Probe Driver
Monteris AutoLITT™ VizApp Software

**d. Intended Use**

*The Monteris Medical AutoLITT System is indicated for use to 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 AutoLITT 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) AutoLITT 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 AutoLITT analysis.*

**e. Comparison to Predicate Device**

The Monteris Medical AutoLITT™ System is substantially equivalent to the above described predicate devices in intended use, technology, design and physician use.

**f. Summary of Supporting Data**

Biocompatibility data demonstrates that the Laser Probe is in compliance with ISO 10993.

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

Animal testing demonstrated that the System, can be used to coagulate brain tissue under MRI guidance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2009

Monteris Medical
% Coombs Medical Device Consulting, Inc.
Mr. Craig Coombs
President
1193 Sherman Street
Alameda, California 94501

Re: K081509
Trade/Device Name: Monteris Medical AutoLITT™ System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 6, 2009
Received: March 9, 2009

Dear Mr. Coombs:

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K081509

Device Name: Monteris Medical AutoLITT™ 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081509