K090240

Section 5: 510(k) Summary

AUG 0 6 2009

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:	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501 Tel: 510-337-0140 Fax: 510-337-0416
Device Common Name:	Frameless Stereotaxic Instrument Guide
Device Classification & Product Code:	Class II, HAW
Device Classification Name & Citation	Stereotaxic Instrument 21 CFR 882.4560
Device Proprietary Name:	Monteris Medical UFO™

Predicate Device Information:

Predicate Devices:	Navigus Trajectory Guide
Predicate Device Manufacturers:	Image Guided Neurologics
K#	992304
Predicate Device Common Name:	Frameless Stereotaxic Instrument Guide t
Predicate Device Classification Name & Citation:	Stereotaxic Instrument 21 CFR 882.4560
Predicate Device Classification & Product Code:	Class II, HAW

Predicate Devices:	Navigus II Trajectory Guide
Predicate Device Manufacturers:	Image Guided Neurologics
K#	012366
Predicate Device Common Name:	Frameless Stereotaxic Instrument Guide t
Predicate Device Classification Name & Citation:	Stereotaxic Instrument 21 CFR 882.4560
Predicate Device Classification & Product Code:	Class II, HAW

b. Date Summary Prepared
30 January 2009

K090240

c. Description of Device
The Monteris Medical UFO™ (Universal Frameless platform for neurO surgical applications) is designed to facilitate stereotactic targeting and positioning of various neurosurgical devices through a burr hole in the patient's skull. These devices could include laser probes, biopsy needles, electrodes and catheters.

The UFO is comprised of three telescoping legs connected to a center ball joint. Each of the legs can be attached to the patient's skull with two MRI-compatible titanium bone screws. By adjusting the height of each leg, and the axis of the rotatable center ball, various trajectories can be obtained for the guide tube that runs through the center ball. UFO is MRI compatible

Multiple center ball adapters are available to interface with the center ball guide tube. These adapters reduce the guide tube diameter down to an inner diameter that is compatible with the outer diameter of the tools that the user may want to place through the UFO. The adapter for a specific tool ensures the tool remains lined up along the intended axis of the UFO.

Several accessories are provided with the UFO to improve its utility during the preparation for stereotactic neurological procedures. They are all made of MRI compatible materials only.

All devices are single use only and ethylene oxide sterilized.

d. Intended Use

> The Monteris Medical UFO™ is intended to provide stereotactic guidance, placement and fixation for the operation of instruments or devices during the planning and operation of neurological procedures performed in conjunction with preoperative and(or) perioperative MR or CT imaging. These procedures include laser coagulation, biopsies, catheter placement and electrode procedures.

e. Comparison to Predicate Device
The Monteris Medical UFO™ is substantially equivalent in intended use, technology, design, materials, and physician use to the Navigus Trajectory Guides (K992304 & K012366).

The testing described below demonstrates that the differences in the devices do not raise any unresolved issues of safety or efficacy.

f. Summary of Supporting Data
Biocompatibility analysis demonstrates that the UFO is in compliance with ISO 10993.

Bench testing has demonstrated that the device is in compliance with the product specification, the expectations of the medical community and the product labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 6 2009

Monteris Medical, Inc.
c/o Craig Coombs
President
Coombs Medical Device Consultant, Inc.
1193 Sherman St.
Alameda, CA 94501

Re: K090240
Trade/Device Name: Monteris Medical UFO
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: II
Product Code: HAW
Dated: July 6, 2009
Received: July 8, 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.

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

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number (if known): K090240

Device Name: Monteris Medical UFO™

Indications For Use:

The Monteris Medical UFO™ is intended to provide stereotactic guidance, placement and fixation for the operation of instruments or devices during the planning and operation of neurological procedures performed in conjunction with preoperative and(or) perioperative MR or CT imaging. These procedures include laser coagulation, biopsies, catheter placement and electrode procedures.

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)

Page 1 of 1

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K090240