SECTION 5: 510(K) SUMMARY

APR - 8 2011 K110411

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
Establishment Registration Number	3005840757
Correspondent Contact Information:	K. Jeff Wilson, Ph.D. Monteris Medical, Inc. 100 - 78 Innovation Drive Winnipeg, MB R3T 6C2 CANADA Tel: 204-272-2220 Fax: 204-272-2219
Device Common Name:	Head Coil and Stabilization System
Device Classification & Product Code:	Class II, MOS
Device Classification Name & Citation	Magnetic resonance diagnostic device 21CFR892.1000
Device Proprietary Name:	Monteris Medical AtamA™ System

Predicate Devices Information:

Predicate Device:	Noras OR Head Coil 1.5 T
Manufacturer:	Siemens Medical Solutions USA, Inc. (Noras)
K#	K060758
Common Name:	Noras OR Head Coil 1.5 T
Device Classification Name & Citation:	Magnetic resonance diagnostic device 21CFR892.1000
Device Classification & Product Code:	Class II, MOS

Predicate Device:	Noras OR Head Holder
Manufacturer:	Siemens Medical Solutions USA, Inc. (Noras)
K#	K071179
Common Name:	OR Head Holder
Device Classification Name & Citation:	Neurosurgical head holder (skull clamp) 21CFR882.4460
Device Classification & Product Code:	Class II, HBL

Predicate Device:	Intra-operative Coil and Head Fixation Device (major component of Neuro II-SE Intra-operative Imaging System)
Manufacturer:	IMRIS
K#	Major Component of K071099
Common Name:	Head Coil Kit
Device Classification Name & Citation:	Magnetic resonance diagnostic device 21CFR892.1000
Device Classification & Product Code:	Class II, LNH

b. Date Summary Prepared

10.Feb.2011

c. Description of Device

The Monteris medical AtamA™ System is comprised of two major subsystems: (i) a MR head coil functionality, and (ii) a patient stabilization functionality. These two subsystems have been designed to work independently and in unison to meet the varied needs of neurosurgical procedures utilizing MRI.

The Head Coil Subsystem is comprised of a novel design of a standard split-array multichannel (8 channel) receive coil in the form of a common Lower Coil and two interchangeable Upper Coils (only one used at any time) and the appropriate coil configuration data, known as "coil files", for the selected MR system to be used.

The design of the two-part Head Coil system is such that, in conjunction with the rest of the AtamA System, openings in the two-part coil can be rotated around the patient's head to allow surgical access to essentially any supratentorial aspect of the patient's head, and still allow for the collection of MR data without repositioning the patient or moving the coils within the MR system. This will allow for more expedient collection of high quality MR data, minimize moving the patient, and maintenance of spatial registration (required for or supporting stereotactic procedures).

The Stabilization subsystem is comprised of three major components and their accessories. The major components are:

- A ***Head Fixation Ring*** (HFR) apparatus,
- A ***Cradle*** that fixates the HFR and the two-part Coil relative to each other and the MRI system bore, and
- A patient ***Board*** that allows for the effective transport of the patient to and from various procedures and procedure locations while maintaining the stability and spatial registration of the patient.

Intended Use

The intended use of the AtamA™ System (comprised of two major subsystems: a MR head coil apparatus and a patient stabilization apparatus), in conjunction with a magnetic resonance (MR) imaging system, is the collection of MR data and images of the human brain before, during, and at the end of brain surgery, in a standard operating room, diagnostic MR rooms, or in a MR intra-operative room, while stabilizing the patient's head during neurosurgical procedures and imaging.

The patient head-stabilizing apparatus can also be used for other neurosurgical procedures requiring the patient's head to be stabilized or fixed.

The head coil can also be used as a standard diagnostic head coil for diagnostic MR imaging.

When interpreted by a trained physician, these images provide information that can be useful in determining diagnosis.

The intended use of the AtamA System is essentially the same as the intended use of the predicate devices, as are the indications for use.

Technological Characteristics

The technical modes of action and technical principles are materially the same as the predicate devices, including: split array 8-channel MR head coil design and construction, materials being functionally similar in all cases (identical in several aspects), and relying upon the same principles of head stabilization/immobilization. The design differences are in how the AtamA System utilizes and integrates these technical characteristics in an expedient and convenient system.

Non-Clinical Performance Data

Performance testing was performed to recognized standards for the Coil functionality and to actual values of predicate devices measured in parallel of predicate devices (when available), or to values reported by the manufacturers of the predicates. NEMA Magnetic Resonance Imaging standards, where appropriate were followed. Biocompatibility, per ISO 10993, was demonstrated.

Clinical Performance Data

This application does not rely on any clinical investigations or clinical performance testing in support of substantial equivalence to the stated predicate devices.

Summary of Performance Data

Biocompatibility analysis demonstrates that the AtamA system 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
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

K. Jeff Wilson, Ph.D.
Vice President, Clinical and Regulatory Affairs
Monteris Medical
100-78 Innovation Drive
Winnipeg, MB R3T 6C2
CANADA

APR - 8 2011

Re: K110411
Trade/Device Name: Monteris Medical AtamA™ System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: February 10, 2011
Received: February 14, 2011

Dear Dr. Wilson:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K110411

Device Name: Monteris Medical AtamA™ System

Indications for Use:

The intended use of the AtamA™ System (comprised of two major subsystems: a MR head coil apparatus and a patient stabilization apparatus), in conjunction with a magnetic resonance (MR) imaging system, is the collection of MR data and images of the human brain before, during, and at the end of brain surgery, in a standard operating room, diagnostic MR rooms, or in a MR intra-operative room, while stabilizing the patient's head during neurosurgical procedures and imaging.

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Prescription Use X AND/OR Over-The-Counter Use ____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of ___

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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