510(k) Summary

JAN 27 2014

Device Information

Category	Comments
Date Summary Prepared	22 January 2014
Sponsor	Monteris Medical Corporation 16305 36th Avenue North, Suite 200 Plymouth, Minnesota 55446 USA Tel: 763-253-4710 Fax: 763-746-0084 Contact: Brooke Ren, Ph.D. Sr. VP of Operations BRen@Monteris.com
Correspondent Contact Information	Craig J. Coombs President, Coombs Medical Device Consulting, Inc. 1193 Sherman St Alameda, CA 94501 Tel: 510-337-0140 Fax: 510-337-0416 CraigJCoombs@gmail.com
Device Trade Name	AtamA™ System
Device Common Name	Head Coil and Patient Stabilization System
Device Classification & Product Code	Class II, MOS
Device Classification Name & Citation	Magnetic Resonance Diagnostic Device 21CFR 892.1000
Device Proprietary Name	Monteris Medical AtamA™ System

Predicate Device Information

Predicate Device Trade Name	Monteris Medical AtamA™ Head Coil and Stabilization System
Manufacturer	Monteris Medical
510(k) Number	K110411
Device Common Name	Head Coil and Patient Stabilization System
Device Classification Name & Citation	Magnetic Resonance Diagnostic Device 21CFR 892.1000
Device Classification & Product Code	Class II, MOS

Description of Device

The AtamA™ System is comprised of two subsystems:

(i) MR Head Coil
(ii) Patient Stabilization System

These two subsystems have been designed to work independently and in unison to meet the varied needs of neurosurgical procedures utilizing MRI. In addition, the patient head fixation ring subsystem and patient board can also be used for other neurosurgical procedures requiring the patient's head to be stabilized or fixed. Also, the head coil can also be used as a standard diagnostic head coil for diagnostic MR imaging.

Specifically, the AtamA System allows a streamlined workflow for procedures requiring the patient to undergo MRI examination before, during, or after neurosurgical procedures. The AtamA System maintains patient head fixation while providing a patient board for convenient, safe and effective method of moving the patient from an OR table to transport gurney to MRI couch without the need to unpin and re-pin the patient.

This submission clears the use of the additional 3.0 Telsa AtamA Head Coil for use with specific Siemens and Imris 3.0 Telsa MRI Systems, and the expanded labeling of the components of the Patient Stabilization System for their compatibility with both 1.5 Tesla and 3.0 Telsa systems.

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.

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.

Comparison to Predicate Device

The proposed Monteris Medical AtamA System is substantially equivalent in intended use, technology, design, materials, and physician use to the current Monteris Medical AtamA Head Coil and Patient Stabilization System, cleared under 510(k) Number K110411 for use in 1.5 Tesla MR Systems.

The testing described below demonstrates that the proposed addition of a 3.0 Tesla MR head coil and associated labeling changes on the AtamA System for 3.0 Tesla MR conditional compatibility do not raise any issues of safety or efficacy.

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 device.

Comparison of Subject Device to Predicate Devices

Parameter or Characteristic	Predicate AtamA™ System	New AtamA™ System
510(k) Number	**K110411**	**K132444**
FDA Product Classification / Code	21 CFR 892.1000 / MOS	**Same**
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. 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.	**Same**
Operating Principle / Technology	Receive-only, 8-channel split array head coil accompanied by head fixation apparatus that interfaces with MRI systems.	**Same**
Design	The AtamA System is comprised of two subsystems: • MR Head Coil • Patient Stabilization system	**Same**
Materials	Thermoplastics / Titanium / Brass	**Same**
Use Location	Operating Room / MRI Diagnostic Suite	**Same**
MRI Compatibility of Head Coil	1.5T Conditional	**1.5T / 3.0T Conditional**
MRI Compatibility of Stabilization Subsystem	1.5T Conditional	**1.5T / 3.0T Conditional**

Summary of Supporting Data

The proposed AtamA 3.0 Tesla MR Head Coil is made by the same manufacturer, and is of the same basic design. as the currently marketed AtamA 1.5 Telsa MR Head Coil. Bench testing in accordance with NEMA Standards has demonstrated that the 3.0 Tesla MR Head Coil is compatible with 3.0 Telsa MRI systems.

An analysis of materials has shown that the AtamA Patient Stabilization Subsystem is also compatible with 3.0 Tesla MR environments and can be labeled with 1.5T and 3.0 T MR Conditional Compatibility.

Conclusions

It can be concluded from the results that the Monteris Medical AtamA System is safe and effective for use in both the 1.5 and 3.0 Tesla MRI environments and can be labeled with both 1.5 T and 3.0 T MR Conditional Compatibility.

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
BROOKE REN
1193 SHERMAN STREET
ALAMEDA CA 94501

January 27, 2014

Re: K132444
Trade/Device Name: AtamA™ System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: December 9, 2013
Received: December 11, 2013

Dear Dr. Ren:

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 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/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara For

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132444

Device Name
Monteris Medical AtamA™ System

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."