K053309

JAN 2 4 2006

510(k) SUMMARY

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
Twinsburg, Ohio 44087-2371
Phone: (330) 425-1313
Fax: (330) 425-1410

Contact Person: Doug Thistlethwaite
Manager, Regulatory Affairs
Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
Twinsburg, Ohio 44087-2371
Phone: (330) 425-1313
Fax: (330) 425-1410

Date Prepared:November 15, 2005

Name of Device

Altaire MR Interventional Package

Common or Usual Name

MRI System

Classification Name

Magnetic Resonance Diagnostic Device

Predicate Device

Hitachi AIRIS II Magnetic Resonance Diagnostic Device Interventional MR Package (K984280)

Intended Use

The Hitachi Model Altaire MR Interventional Package aids in the performance of minimally invasive, diagnostic, therapeutic, interventional and intra-operative surgical procedures for the head, body, and extremities that may be facilitated by real-time MR guidance. Such procedures must be performed with MRI-compatible instrumentation as selected and evaluated by the clinical user.

Device Description

The Hitachi Model Altaire Interventional MR Package is an optional enhancement designed for use with the Hitachi Model Altaire Magnetic Resonance Diagnostic Device (K050620). It's intended function and use is to aid to aid in the performance of minimally invasive, diagnostic, therapeutic, interventional and intra-operative surgical procedures for the head, body, and extremities that may be facilitated by real-time MR guidance. (Such procedures must be performed with MRI-compatible instrumentation as selected and evaluated by the clinical user).

The package consists of an open head coil, an open body coil and an MR compatible in room color monitor. The head and body coils are used for obtaining diagnostic images of the head and body regions, while the display monitor is used for in room review of the images during the interventional procedure(s). The head and body coils are compatible with existing Altaire hardware and software. Therefore no hardware or software modifications are needed to use these coils.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2006

Mr. Doug Thistlewaite
Manager, Regulatory Affairs
Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
TWINSBURG OH 44087-2371

Re: K053309
Trade/Device Name: Hitachi Model Altaire MR Interventional Package
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: November 23, 2005
Received: November 28, 2005

Dear Mr. Thistlewaite:

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 (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~TBD~~ K053309

Device Name: Hitachi Model Altaire MR Interventional Package

Indications for Use:

The Hitachi Model Altaire MR Interventional Package aids in the performance of minimally invasive, diagnostic, therapeutic, interventional and intra-operative surgical procedures for the head, body, and extremities that may be facilitated by real-time MR guidance. Such procedures must be performed with MRI-compatible instrumentation as selected and evaluated by the clinical user.

Prescription Use X
(Part 21 CFR 801 Subpart D)

~~AND~~/OR

Over-The-Counter Use _____
(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)

David A. Lagom

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053309