K090080
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MAR 2 3 2009

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510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92(a)

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Date of Summary Preparation: December 17, 2008

Device Name:
CIRRUS OPEN
Magnetic Resonance Diagnostic Device, 21 CFR 892.1000, 90-LNH, Class II

Predicate Device(s):
Device Name: GE SIGNA PROFILE 0.2 T
(GE Signa Profile/i K992135)
Manufacturer/Submitter: GE MEDICAL SYSTEMS

Device Name: AIRIS MATE
(Airis II K974212)
Manufacturer/Submitter: HITACHI MEDICAL SYSTEMS

Device Description:
Cirrus Open is a Magnetic Resonance Imaging (MRI) System that utilizes a 0.2 Tesla permanent magnet to acquire 2D single and multi slice, and 3D volume images of a patient's head in the transverse, sagittal, coronal and oblique scan planes using pulse sequences such as spin echo, gradient echo, inversion recovery, driven equilibrium and free procession acquisitions. The open, four-post magnet system helps maintain a patient's connection to the external environment and offers MR personnel convenient access to the patient from all four directions. The patient bed system is manually operated by a push or pull from the hand of the MR personnel. The bed top has six, numbered discreet locating positions for placement of the radio frequency (RF) coil. By inserting the bed into the magnet to one of its six, numbered snap-in (detent) locations, that matches the numbered position of the RF coil placement, the patient region of interest is conveniently placed at magnet iso-centre. The MR console station allows the operator to enter patient registration information, and to select, edit and execute the required scan protocols. The MR console operator can also store, review and print image data.

Promotional Material
MR Imaging with Cirrus Open
Cirrus Open is a Magnetic Resonance Imaging System that offers patients and users simplicity, convenience and high image quality in an appealing, user-friendly operating environment.

The system utilizes a 0.2 Tesla permanent magnet in an open, four-post configuration that helps keep patients connected to their external environment and permits MR personnel quick and convenient four-way access to their patient. A patient's hand, arm or shoulder is readily accessible by a caregiver or family member should special comfort or support at any time be helpful for apprehensive or distressed patients.

The patient bed system offers appeal and simplistic function and style. The bed top is manually inserted or extracted with low force by the hand of the MR staff. The bed top in its fully extracted position has a snap-in detent to prevent bed movement during patient loading. For convenience, the bed top also has snap-in detent positions, numbered one through six, and six corresponding RF coil-locating features for quick and easy coil placement. The MR staff member simply places the coil at the desired position and sets up the patient onto the bed top and into the coil with the appropriate comfort padding and communication system services in place. The bed top is then pushed into the magnet to the detent that corresponds to the numbered location into which the coil has been placed. With the RF coil and patient precisely at the iso-centre of the magnet, all is ready for imaging. After imaging, all surfaces can be wiped down with ease, as all surfaces are smooth and rounded for fast effective cleaning in preparation for the next patient. In the infrequent case of liquid spills,

the bed top is designed to contain fluids for clean up and it can be removed for any thorough, occasional cleaning.

The MR console offers MR operators control of the system through a Windows style graphical user interface (GUI) to acquire a choice of 2D single and multi slice, and 3D volume images of the patient's head in the transverse, sagittal, coronal and oblique scan planes. The system displays a library of all potential choices of pulse sequences such as spin echo, gradient echo, inversion recovery, driven equilibrium and free procession acquisitions. Image display and processing, DVD data storage and DICOM printing are all standard user features.

Scientific Concepts:
To perform MRI, a patient is magnetized by being placed within a strong magnetic field ($\mathbf{B_0}$), which partially aligns the hydrogen nuclei (i.e. protons contained in body water and fat) and so creates a nuclear magnetization ($\mathbf{M_0}$). To excite the system away from this equilibrium a tuned radio coil energized with radiofrequency (RF) pulses is used to cause a realignment ('flip') of the **M** vector by 90°. This results in a detectable nuclear magnetic resonance (NMR) radio-frequency signal as **M** precesses about the $\mathbf{B_0}$ field direction at the Larmor resonant RF frequency. This frequency is proportional to both the proton gyromagnetic constant of the nuclei and to the magnetic field strength $\mathbf{B_0}$. For B0= 0.2 Tesla the RF frequency is around 8 MHz. In clinical imaging RF pulse lengths are of the order of 1ms long.

The RF signal decays with an approximately exponential time-constant T2, and recovers to the equilibrium condition with an exponential time-constant T1. T2* is related to T2 and represents signal decay including reversible signal loss. MRI relies on the introduction of a spatial dependence (i.e. field gradients) into this basic nuclear magnetic resonance (NMR) procedure. For this purpose a field gradient system is used which produces three fields Gx, Gy, Gz which can be pulsed to produce 2D and 3D imaging. This system includes powerful amplifiers and large coils that surround the patient. The pulsing of the gradient system produces acoustic noise and eddy currents (including within the patient). Measurable signals can be produced using spin-echoes (using a refocusing RF pulse) or gradient echoes (by gradient reversal). Echo data is collected using an RF receiver system and is reconstructed into images using the Fast Fourier Transform (FFT). Different types of image contrasts are available by use of the appropriate MRI pulse sequence. Some common choices are proton density, T1-weighted, T2-weighted and T2*-weighted images. Different tissues have different relaxation times, and moreover pathology can alter relaxation times, making MRI a powerful diagnostic tool. In some cases a contrast agent is injected to enhance contrast.

Indications for Use:
Cirrus Open is an open, 0.2 Tesla MR imaging device intended to provide a physician with physiological and clinical information obtained non-invasively using magnetic resonance imaging (MRI) without the use of ionizing radiation. Cirrus Open is indicated for use as a diagnostic imaging device to produce images in the transverse, sagittal, coronal and oblique scan planes of a patient's head. The images produced by Cirrus Open reflect the spatial distribution of protons (hydrogen nuclei). The magnetic properties that determine the appearance of images are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and T2* relaxation time. Additional contrasts that can be used include magnetization transfer and diffusion. When interpreted by a trained physician, these images provide information that can be useful in diagnosis.

Differences with Predicate Device Indications for Use
The indications for use for the Cirrus Open system are the same as those given for the predicated devices, the exception being that the Cirrus Open system is limited to imaging of the head. Information on the predicate devices can be found in the Appendix "Predicate Devices Information".

Technological Characteristics
The Cirrus Open is an MRI system comprising the following:

1. 0.2 T four poster permanent magnet – the predicate devices are two pillar designs. This presents the Cirrus system with different access to the patient then the predicate devices. This different access does not have an effect on patient safety, and may actually enhance safety by giving patient handlers more areas for access to the patient.
2. Gradient coils and gradient amplifiers – the maximum gradient strength is the same as the predicate devices, but the gradient slew rate is higher in the Cirrus. Despite this, dB/dt testing in accordance with IEC 60601-2-33 showed that the patient will not be subject to time varying magnetic fields beyond the limit defined for normal operation.
3. RF coil and RF amplifier – the predicate devices have transmit coils built into their structure, with receive only coils positioned around the patient's anatomy of interest. The Cirrus Open does not have a built-in transmit coil; instead it uses a transmit/receive duplex coil positioned around the patient's anatomy of interest. Testing showed that this arrangement does not exceed the SAR limit. Another difference is that the predicate devices include coils to image different anatomy whereas the Cirrus Open uses a head coil only.
4. Signal generation and processing system (console) – The predicate devices use different computers, operating systems and software then the Cirrus Open. Despite this, the tasks that this difference equipment performs (generating signals to excite the NMR effect in a predictable way, and receiving and processing the resulting NMR signal to create an image of anatomical structure) are the same. Furthermore, the Cirrus Open console incorporates features, such as SAR and dB/dt magnitude

computations and SAR monitoring, that is similar to the predicate devices (see footnote 16 in the Substantial Equivalence Comparison Table).

Summary of Studies / System Performance Testing
The Cirrus Open MR System was evaluated to the appropriate NEMA MRI performance test standards as well as IEC 60601-2-33 *Particular requirements for the safety of magnetic resonance equipment for medical diagnosis.* Safety testing results demonstrate that SAR, dB/dt and acoustic noise levels are below the limits for normal MRI operation. NEMA performance test results are similar to those for the predicate devices and therefore support the claim of substantial equivalence.

Conclusion(s):
Based upon the safety and performance testing carried out in accordance with NEMA and IEC standards the Cirrus Open MR System operates within safety limits and meets the performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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% Ms. Anita Chan, CEO
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CANADA

Re: K090080
Trade/Device Name: Cirrus Open
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: December 24, 2008
Received: January 12, 2009

Dear Ms. Chan:

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, 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.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K090080

Device Name: Cirrus Open

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090080