K984274

JAN 25 1999

Attachment 1
510(k) Summary of Safety and Effectiveness

1.0 SUBMITTER INFORMATION:

1.1 Submitter: Hitachi Medical Systems America
1963 Case Parkway
Twinsburg, OH 44087
PH: **216** 425-1313
FX: **216** 425-1410

1.2 Contact: James Jochen Rogers

1.3 Date: November 26, 1998

2.0 DEVICE NAME:

2.1 Magnetic Resonance Diagnostic Device

2.2 Classification Name: System, Nuclear Magnetic Resonance Imaging

2.3 Classification Number: 90LNH

2.4 Trade/Proprietary Name: Version 5.0 Operating System Software

2.5 PREDICATE DEVICE(s):

Hitachi AIRIS with Version 4.0 Operating System Software
Hitachi MRP-7000 with Version 4.0 Operating System Software

3.0 DEVICE DESCRIPTION:

3.1 FUNCTION

Identical to the AIRIS and MRP-7000 with Version 4.0 Operating System software (*Cf.* K971279), and the AIRIS and MRP-7000 with Version 4.0D Operating System software as described in a memo-to-file document, dated September 22, 1997.

The AIRIS Operating System Software is revised to Version 5.0 to increase the clinical utility of the AIRIS in the stationary configuration. The MRP-7000 Operating System Software is revised to Version 5.0 to increase the clinical utility of the MRP-7000 in both stationary and mobile configurations.

Version 5.0 Operating System revisions include additional image acquisition sequences (3D SG TOF MRA, high SNR MR Fluoroscopy sequence, 3D FSE/FIR sequences, additional T1-weighted 2D FSE sequence, and addition of 2D RF-spoiled SARGE sequence). Image acquisition sequence enhancements include improvement in fat suppression for STIR and Fast STIR, addition of Dual Slice function to 2D GE/GR, addition of small FOV FSE sequence, addition of rephase to FIR sequence, addition of ECG-gating to 2D SG sequence (currently available only for 2D SE, GE and GR sequences), and addition of off-resonance MTC to 3D TOF, SE, GE and GR sequences (currently only on-resonance MTC available). A raw data filter is additionally available to reduce truncation artifacts.

3.2 SCIENTIFIC CONCEPTS

Magnetic Resonance (MR) is based on the fact that certain atomic nuclei have electromagnetic properties which cause them to act as small spinning bar magnets. The most ubiquitous of these nuclei is hydrogen, which makes it the primary nucleus used in current imaging experiments in magnetic resonance. When placed in a magnetic field, there is a slight net orientation or alignment of these atomic nuclei with the magnetic field. The introduction of a short burst of radiofrequency (RF) excitation of wavelength specific to the magnetic field strength and to the atomic nuclei under consideration can cause a reorientation of the proton's magnetization vector. When the RF excitation is removed, the proton relaxes and returns to its original orientation. The rate of relaxation is exponential, and varies with the character of the proton and its adjacent molecular environment. This reorientation process is characterized by two exponential relaxation times called T1 and T2 which can be measured.

These relaxation events are accompanied by an RF emission or echo which can be measured and used to develop a representation of these emissions on a three dimensional matrix. Spatial localization is encoded into the echo by varying the RF excitation and by appropriately applying magnetic field gradients in x, y, and z directions, and changing the direction and strength of these gradients. Images depicting the spatial distribution of NMR characteristics of the nuclei under consideration can be constructed by using image processing techniques similar to those used in CT.

For magnetic fields up to 1.5T, the RF frequencies commonly used range up to 65MHz. The RF fields have pulse powers from several watts to greater than 10 kilowatts, and repeat at rates from once every few seconds to greater than fifty per second. The time-varying magnetic gradient fields have a typical duration of sub-millisecond to several milliseconds.

3.3 PHYSICAL AND PERFORMANCE CHARACTERISTICS

MR is currently of great interest because it is capable of producing high quality anatomical images without the associated risks of ionizing radiation. In addition, the biological properties that contribute to MR image contrast are different from those responsible for x-ray image contrast. In x-ray imaging, differences in x-ray attenuation, largely based on differences in electro density are responsible for the contrast observed in x-ray images. In MR imaging, differences in proton density, blood flow, and relaxation times T1 and T2 all may contribute to image contrast. In addition, by varying the duration and spacing of the RF pulses, images may be produced in which the contrast is primarily dependent on T1 relaxation, T2 relaxation, proton density, or a combination of all three.

4.0 DEVICE INTENDED USE:

The MR system is an imaging device, and is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The MR system produces transverse, coronal, sagittal, oblique, and curved cross-sectional images that display the internal structure of the head, body, or extremities. The images produced by the MR system reflect the spatial

distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

- Anatomical Region: Head, Body, Spine, Extremities
- Nucleus excited: Proton
- Diagnostic uses: 2D T1- / T2-weighted imaging
  T1, T2, proton density measurements
  MR Angiography
  image processing
- Imaging capabilities: 2D, 3D Spin Echo (SE)
  2D, 3D Fast Spin Echo (FSE), Fast Inversion Recovery (FIR)
  2D,3D Gradient Field Echo (GE); also with rephasing (GR)
  2D Steady state acquisition with rewinded GE (SARGE)
  3D Steady state acquisition with rewinded GE (SARGE); also with rephasing
  2D Dual Slice acquisition (DS)
  MR Angiography (2D TOF, 3D TOF, half echo, high resolution/high definition, sloped slab profile, on- and off-resonance magnetization transfer contrast)
  RF Coil Uniformity
  Adaptive Image post-processing

5.0 DEVICE TECHNOLOGICAL CHARACTERISTICS:

Identical to the Predicate Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 1999

James Jochen Rogers
Manager, Regulatory Affairs
Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
Twinsburg, Ohio 44087-2371

Re: K984274
Version 5.0 Operating System Software for
Hitachi Airis and MRP-7000
Dated: November 26, 1998
Received: November 30, 1998
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Rogers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K984274

Device Name: Version 5.0 Operating System Software (AIRIS, MRP-7000)

Indications for Use:

The MR system is an imaging device, and is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The MR system produces transverse, coronal, sagittal, oblique, and curved cross-sectional images that display the internal structure of the head, body, or extremities. The images produced by the MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

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  RF Coil Uniformity
  Adaptive Image post-processing

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984274

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801-109

(Optional Format 1-2-96)