JUL - 3 1997

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
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1.2 Contact: James Jochen Rogers

1.3 Date: April 4, 1997

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 4 Operating System Software

2.5 PREDICATE DEVICE(s):

Hitachi AIRIS with Version 3.7 Operating System Software
Hitachi MRP-7000 with Version 3.7 Operating System Software

3.0 DEVICE DESCRIPTION:

3.1 FUNCTION

The AIRIS Operating System Software is revised to Version 4 to increase the clinical utility of the AIRIS in the stationary configuration. The MRP-7000 Operating System Software is revised to Version 4 to increase the clinical utility of the MRP-7000 in both stationary and mobile configurations.

Version 4 Operating System revisions include automatic per patient RF Gain calibration for improved fat suppression, daily- or per-patient x- y- and z-axis gradient offsets for regional shimming, MR cholangiography sequences (MRCP) for improved imaging of the biliary tract, Fluoroscopic MR imaging sequences for 'near-real-time' imaging, FLAIR (fast low-angle inversion recovery) sequence for suppression of CSF signal, segmented K-space SARGE sequence for time-improved cardiac imaging, addition of rephasing to several FSE sequences, addition of RS (RF Spoiled) SARGE sequence, improved method for body return artifact rejection, sub-millimeter slice thickness for 3DTOFMRA sequences, reduced slice interval for 3D TOF/GE/SARGE/SE acquisitions, high-definition imaging by 512 matrix reconstruction, short TE SE sequences (TE=9, 10ms), addition of rephasing to 3D SARGE sequence, 'whole echo' 3DTOFMRA, non-linear window for MRA, brightness normalization for selected images with the same acquisition parameters within a patient study, and ACR/NEMA/DICOM 3 support.

In addition, the MRP-7000 and AIRIS Operating System Software are modified to change the maximum SAR limit from 0.4 W/kg to 1.0 W/kg as permitted under the International Electrotechnical Commission (IEC) standard Part 2: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis.

Because of the recent approval of the IEC-601-2-33 standard on MR safety, Hitachi seeks to take advantage of the acceptance of the higher SAR level permitted under that standard for the *general patient population*. We believe that the FDA has accepted the provisions of the IEC standard with respect to its SAR requirements, in compliance, we interpret the FDA's position with regard to the IEC standard for SAR as superceding its previous limit for SAR (up to 0.4 W/kg whole body is of no concern), and no further evidence is necessary beyond that given in the IEC standard and its rationale.

The Hitachi MRP-7000 and AIRIS MR Devices were originally cleared for marketing with an SAR limit of 0.4 W/kg (K9903318 [MRP-7000], and K945155 [AIRIS]), in compliance with the FDA's August 2, 1988 "Guidance for the Content and Review of a Magnetic Resonance Diagnostic Device 510(k) Application". In the FDA guidance, Safety Parameter Action Levels limit SAR to $\leq$ 3.2 W/kg averaged over the head, to $\leq$ 0.4 W/kg whole body, or to demonstrate that exposure to RF fields is insufficient to produce a core temperature increase in excess of 1°C and localized heating greater than 38°C in the head, 39°C in the trunk, and 40°C in the extremities.

The IEC standard, in defining the NORMAL OPERATING MODE, allows SAR values up to 1.5 W/kg under conditions of favorable environmental conditions (a scan room temperature $\leq$ 24°C, scan room relative humidity $\leq$ 60%). However, the IEC standard dictates that maximum SAR values be derated up to a floor value of 1.0 W/kg for scan room temperature and humidity above these baseline environmental conditions, provided these ambient conditions are consistent with the overall device operating specifications. Since the MRP-7000 and AIRIS do not presently have bore temperature or humidity sensors, maximum SAR is derated to a maximum of 1.0 W/kg. In order to comply with the NORMAL OPERATING MODE defined in the IEC standard, we at Hitachi propose that SAR control for the MRP-7000 and AIRIS MRI systems be limited to a maximum of 1.0 W/kg, from the current limit of 0.4 W/kg

No marketing claims will be made for the MRP-7000 and AIRIS stating compliance with the IEC standard. A separate future 510(k) premarket notification will describe full implementation of the IEC standard with respect to control of SAR, including, 1) the three operating modes (normal, first-level, and second-level, operating modes) as defined in the IEC standard, 2) modified clinical user interface through visual screens, and 3) control of access to the upper operating modes. However, the IEC standard permits operation of an MR device entirely within the NORMAL OPERATING MODE without any of these features.

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 Fast Spin Echo (FSE); also with rephasing
  3D Fast Spin Echo (FSE)
  2D, 3D 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, 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

James Jochen Rogers
Manager, Regulatory Affairs
Hitachi Medical Systems America, Inc.
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JUL - 3 1997

Re: K971279
Version 4 Software for AIRIS/MRP-7000 (MRI)
Dated: April 4, 1997
Received: April 7, 1997
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 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 requirement, 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/dsmamain.html".

Sincerely yours,

Lillian Yin

Lillian Yin, Ph.D.
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): K97 1279

Device Name: Version 4.0 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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  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, magnetization transfer contrast)
  RF Coil Uniformity
  Adaptive Image post-processing

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971279

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

(Optional Format 1-2-96)