510(K) SUMMARY

AUG 14 1996

K962048

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: May 24, 1996

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: 1W/kg SAR (Part of Version 6-05 Operatin System Software

2.5 PREDICATE DEVICE(s):

Hitachi STRATIS with Version 3 Operating System Software
Hitachi MRH-1500 with Version 3 Operating System Software

3.0 DEVICE DESCRIPTION:

3.1 FUNCTION

The STRATIS / MRH-1500 Operating System Software is 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 MRH-1500 and STRATIS MR Devices were originally cleared for marketing with an SAR limit of 0.4 W/kg (K943798, K922846B, and K945386), 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 MRH-1500 and STRATIS 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 MRH-1500 and STRATIS 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 MRH-1500 or STRATIS 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 Short Spin Echo (SES)
  2D, 3D Fast Spin Echo (FSE)
  2D Inversion Recovery (IR)
  2D, 3D Fast Inversion Recovery (FIR)
  2D,3D Gradient Field Echo (GFE); also with rephasing
  2D, 3D Rapid Scan (RS)
  MTC, RF Spoiling
  MR Angiography, (2D INFA, 3D INFA, 2D GFEA, 3D GFEA, Sloped Slab Profile (SSP))
  RF Coil Uniformity
  Adaptive Image post-processing

5.0 DEVICE TECHNOLOGICAL CHARACTERISTICS:

Identical to the Predicate Device.