K961969

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Attachment 1

510(k) Summary of Safety and Effectiveness

K961969

1.0 SUBMITTER INFORMATION:

1.1 Submitter: Hitachi Medical Systems America
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1.3 Date: May 15, 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: Version 6 Operating 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 revised to Version 6 to increase the clinical utility of the STRATIS / MRH-1500 in the stationary configuration.

Version 6 Operating System revisions include the addition of RF spoiling, SSP for enhanced 3D MRA, RF Fat Suppression, MTC for background suppression, 3D-FSE, 3D-FIR, rephase added to 2D-FSE and 2D-GFE, 2D-FIR Dual Contrast, RF coil uniformity image post-processing, and adaptive image post-processing.

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.