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Attachment 1

510(k) Summary of Safety and Effectiveness

1.0 SUBMITTER INFORMATION:

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2.0 DEVICE NAME

2.1 Classification Panel: Radiology

2.2 Classification Number: 892.1000 Magnetic Resonance Diagnostic Device

2.3 Product Number: 90LNH

2.4 Product Nomenclature: System, Nuclear Magnetic Resonance Imaging

2.5 Trade/Proprietary Name: Revised RF Transmit Coil

2.6 Predicate Device: AIRIS

3.0 DEVICE DESCRIPTION:

3.1 FUNCTION

The AIRIS RF Transmit Coil offers improved RF Field Uniformity at the edge of the Imaging Volume to accommodate larger patients.

3.2 SCIENTIFIC CONCEPTS

MR images are obtained by placing the patient or area of interest within a powerful, highly uniform, static magnetic field. A portion of the protons (hydrogen nuclei) within the patient align with this main magnetic field, similar to small bar magnets. These protons precess, or rotate about the axis of the main magnetic field, much like a spinning child's top. The frequency of rotation is directly proportional to the strength of the main magnetic field, and is given by the Larmor equation, $\omega = 2\pi \gamma B_0$, where ω is the frequency of rotation, γ is the gyromagnetic ratio, and B_0 is the strength of the main magnetic field. In the case of Hydrogen protons, the precessional frequency is 4.26MHz for a magnetic field strength of 0.1Tesla. This precessional frequency of rotation is the resonant frequency of the protons. A resistive, permanent, or cryostat magnet provides the strong, homogeneous static magnetic field.

The Hydrogen nucleus aligns itself in one of two ways, such that it precesses either parallel or anti-parallel to the applied magnetic field. These two alignments have slightly different energy levels, and nuclei are said to be in one of two discrete energy states. The parallel energy state possesses slightly lower energy than the anti-parallel state. Correspondingly, there will be a greater number of nuclei in the lower-energy state than in the higher-energy state.

Energy may be added to the system in the form of radio frequency (RF) waves at the resonant frequency of the precessing nuclei. Some of the nuclei will absorb sufficient energy to flip over from the lower-energy parallel level to the higher-energy anti-parallel level. The more energy added to the system, the greater number of nuclei that will flip over to the higher energy state. If the RF energy source is switched off, the nuclei will gradually lose energy to the surrounding environment, by radiating the energy in the form of RF waves, and flip back to the lower-energy level. A powerful (>5kW) RF Amplifier and RF transmit coils are utilized to introduce RF energy to the system.

The RF signal received immediately after the RF pulse is switched off is proportional to the number of protons resonating in the sample, and is referred to as proton density. The decay of RF signal as the protons return to equilibrium is exponential in nature, and is known as spin-lattice relaxation; its time constant of decay is designated T1. During the RF pulse, the protons precess in synchronization (in phase) with each other. After the pulse is switched off, the protons' magnetic moments interact with each other, and with local variations in the magnetic field. These interactions lead to a gradual, exponential dephasing. This dephasing is known as spin-spin relaxation, with a time constant designated T2. These three quantities, proton density, T1, and T2, vary with tissue, and may be used to form a diagnostic image, provided that they may be spatially, and if necessary, temporally, located.

A variety of sensitive antennae are available to detect this radiated RF energy, however, the 'raw' signal emitted from the patient in response to an RF pulse gives no indication of the position within the patient of the excited nuclei. In order to produce an image, it is necessary to encode positional information into the returned RF signal. This is done by utilizing small magnetic field gradients which alter the local magnetic fields, which, in turn, alter the precessional frequency of the emitting nuclei. Three orthogonal gradients are utilized for slice selection, frequency encoding, and phase encoding (x, y, z). 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.

If a magnetic field gradient is applied from head to foot of a patient, (HF), then protons in different transverse planes of the patient will experience different local magnetic fields, and will precess at different frequencies. If an RF pulse

of a single frequency is utilized to excite nuclei, only those nuclei in the plane corresponding to the RF pulse's frequency will be excited. Therefore, the return signal will come only from that transverse plane or slice. The signal is thus localized to a single plane. This process is slice selection, and utilizes the slice gradient.

A second magnetic gradient may be applied across the patient, from left to right, (LR), during signal acquisition, so that different sections of the selected plane emit signals of differing frequencies. This process is frequency encoding, and utilizes the read gradient. The read gradient localizes signals in one dimension across the selected plane.

Finally, a third gradient may be applied from anterior to posterior across the patient, (AP), just before the read gradient is applied. This has the effect of altering the phase of precession of the nuclei in the selected slice, by an amount dependent upon their position along the AP axis. This process is phase encoding, and utilizes the phase gradient. The phase gradient localizes signals in the second dimension across the selected plane.

This excitation and follow-up read must be repeated several times, each time with a different phase encode gradient, such that the phase of any point along the AP axis varies with a frequency dependence upon its position. The returned signal is now a complex waveform containing many frequencies and phases. The signal amplitude at each frequency can be calculated using a Fourier transform. A second Fourier transform extracts signal amplitude at each phase. Amplitudes can be assigned to gray scale levels, resulting in the construction of an image. In its simplest form, this amplitude plot shows the proton density in a single plane through the patient.

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. A computer is responsible for the generation and timing of the RF and gradient waveforms. High-current analog amplifiers and gradient coils convert the gradient waveforms to slice, frequency and phase gradients across the patient. The computer also the 2D Fourier transforms required for image reconstruction, and provides the operator with a variety of image manipulation and processing techniques.

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, 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, surgery planning, or therapy monitoring.

In order to ensure the availability for evaluating the accuracy of MRI results, intended patients are those subjects for whom it is anticipated that adequate, independent confirmation of any lesion apparently detected with the MR system can be obtained. With the exception of normal volunteers, eligible patients must have suspected or documented neoplastic, degenerative, infectious, or developmental disease process strongly suspected or established by physical exam, history, or conventional histologic, biochemical, bacteriological, or imaging techniques, or have surgical or aspiration biopsy pending that will be used to establish a diagnosis. The intended patients are primarily drawn from a pool of those subjects undergoing diagnostic evaluation by physicians who are skilled in diagnosis and treatment of the disease process(es) under consideration.

- 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)
  2D Inversion Recovery (IR)
  2D Fast Inversion Recovery (FIR)
  2D, 3D Gradient Echo (GE)
  2D, 3D Gradient Echo with Rephasing (GR)
  2D, 3D Steady state acquisition with rewinded GE (SARGE)
  2D Dual Slice acquisition (DS)
  MR Angiography (2D TOF, 3D TOF, MTC, SSP, half echo,
  high resolution/high definition)

5.0 DEVICE TECHNOLOGICAL CHARACTERISTICS:

Identical to the Predicate Device.