

K964778

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Attachment K

510 (k) Summary / Safety and Effectiveness

1. 510 (k) Summary, Safety and Effectiveness

The following information is in accordance with 21 CFR 807.92

**Submitter's Name, Address, Telephone Number , Contact Person,
Preparation Date**

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Name of the Device and Classification Name/Number

HI STAR, Magnetic Resonance Imager.
The FDA has reclassified these devices, 90LNH, to Class II.

Predicate Devices

<u>Manufacturer</u>	<u>Commercial Name</u>	<u>Description</u>
Health Images	HI-Standard	0.6T whole body MRI imager, superconducting magnet
Health Images	HI-Standard/Calibre IRIS sequence	0.6T whole body MRI imager, superconducting magnet, IRIS Silicone Specific Sequence
Health Images	HI STAR	0.6T whole boy MRI imager, superconducting magnet
Elscint	Gyrex 2T Prestige	Spectral Fat Suppression, FSE
Philips	Gyroscan NT, 1T	Spectral Fat Suppression

Description of the Device

The Health Images HI STAR is a proton (H-1) Magnetic Resonance Imaging device. The HI STAR has been designed to produce transverse, sagittal, coronal, and oblique section images of the head, body and extremities of the human body. Contrast in these images is produced primarily by T1, T2, and proton density tissue characteristics. This imager employs conventional MRI imaging techniques in which the application of a combination of pulsed radio frequency energy and magnetic gradient fields is applied to the body to generate MR proton echo signals. These multidimensionally coded signals are converted by Fourier transform into 2D and 3D image sets.

Device Characteristics

<u>Parameter</u>	<u>Example</u>
Type of magnet	Superconducting, passive/active shim
Static field strength	0.6T
Type of RF coils	Transmit/Receive - quadrature Body Receive - quadrature Head, MRA, Neck, Spine, Wrist Receive - linear Bilateral TMJ, Volume Extremity, Bilateral Breast, Shoulder General Purpose Surface (body & extremity) 29.2 cm x 15.2 cm (11.5 x 6.0 inch) 19.0 cm x 19.0 cm (7.5 x 7.5 inch) 12.7 cm x 12.7 cm (5.0 x 5.0 inch) 6.4 cm x 6.4 cm (2.5 x 2.5 inch)
Data acquisition modes	Single slice, Multi-slice, Multi- angle oblique, 3D Volume, Physiologic Gating
Pulse Sequences	Spin Echo, Field Echo, Turbo Field Echo, Multi-spin Echo, Inversion Recovery, MRA, FSE
Additional Contrast Techniques	IRIS (Silicone Specific), FatSat, Magnetization Transfer
Reconstruction Technique	Fourier transform
Type of installation:	Mobile, Fixed
Slice selection method:	Selective Gradient, 3D phase encode
Display Matrix	Variable up to 1024 x 1024

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Acquisition Matrix	In plane 64 - 512, increment of 8
Number of slices, Range and Increment	2D, 1 - 256 slices, increment of 1 3D, 12 - 256 increment of 2
Post processing	Window and level Rotate image Mirror image Zoom image Pan image Add and Subtract images HI-Q image processing noise reduction function
Slice orientation	Transverse, Sagittal, Coronal, Single and multiple oblique
Interslice spacing, minimum, maximum,	From Contiguous up to 320 mm, increment of 0.5 mm

Intended Uses

The HI STAR system is indicated for use a general purpose MR imager that produces transverse, sagittal, coronal, and oblique cross-sectional images of internal structures of the human body, head, and extremities. Contrast in these images reflect the intrinsic properties of the hydrogen proton, proton density, T1, and T2, and the extrinsic parameters of the applied imaging sequences. The indications for the HI STAR do not differ significantly from the predicate, or legally marketed devices.

Safety Parameters

<u>Parameter</u>	<u>FDA Limit</u>	<u>HI STAR</u>	<u>Test Standard</u>
Maximum Static Magnetic Field	≤ 2 tesla	0.6T	Manufacturer
Rate of Magnetic Field Strength change	≤ 20 T/second	< 20 T/s	IEC 601-2-33
SAR	< 1.5 W/kg, averaged over whole body (First Controlled Operating Level)	< 1.5 W/kg	IEC 601-2-33
	1.5 ≤ SAR < 4.0 W/kg, averaged over whole body (Second Controlled Operating Level)	1.5 ≤ SAR < 4.0 W/kg	IEC 601-2-33
Acoustic Noise Levels	< 105 dB (A weighted average over 1 hour)	< 92 dBA	NEMA MS-4

Imaging Performance Parameters

<u>Parameter</u>	<u>Data</u>	<u>Standard</u>
Specification Volume	Head 25.6 cm DSV Body 48 cm DSV	Manufacturer
Signal-to-noise Ratio		
Body Coil	103	NEMA MS-1
Head Coil	62	NEMA MS-1
MRA Coil	50	NEMA MS-6
Wrist Coil	117	NEMA MS-6
Neck Coil	108	NEMA MS-6
Spine Coil	62	NEMA MS-6
Breast Coil	100	NEMA MS-6
Bilateral TMJ Coil	133	NEMA MS-6
Extremity Coil	49	NEMA MS-6
Shoulder Coil	108	NEMA MS-6

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<u>Parameter</u>	<u>Data</u>	<u>Standard</u>
General Purpose Surface Coils		NEMA MS-6
29.2 cm x 15.2 cm (11.5 x 6.0 inch)	95	
19.0 cm x 19.0 cm (7.5 x 7.5 inch)	98	
12.7 cm x 12.7 cm (5.0 x 5.0 inch)	80	
6.4 cm x 6.4 cm (2.5 x 2.5 inch)	133	
Image Uniformity Body Coil	12%, Specification Volume	48 cm NEMA MS-2
Head Coil	6%, Specification Volume	25.6 cm NEMA MS-2
Slice Thickness, Separation	10% of specified	AAPM-28
Resolution	Body Head 1.5 mm 1 mm	AAPM-28
Geometric Distortion	Body Head < 5% < 5% @ 31 cm @ 15.5 cm	NEMA #2

Sample images included with this submission were obtained on R & D systems at Health Images, Inc. using employee volunteers. Each volunteer signed a consent form. There were no adverse reactions noted on any of the participants.