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IMIG-MRI 510(k) Summary

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Device Name: Magnetic Resonance Diagnostic Device.

Classification Number: 90LNH

Device Class: Class II, under 21 CFR 892.1000

Device Trade Name: IMIG-MRI™

Intended Uses: Anatomy: head, limbs, spine, torso; Nuclei: H-1; Diagnostic uses: Imaging

Predicate Device: Siemens Magnetom P8

Safety parameter data summary:

Maximum static magnetic field: 0.15 Tesla
Maximum rate of magnetic field change: 18.4 Tesla/sec
Maximum RF power deposition: .05 W/kg
Acoustic noise levels: 114 dB peak; 95 dB A-weighted RMS

Performance test data summary:

(Receive coil:)	(head)	(body)
Specification volume:	15 cm dsv	30 cm dsv
S/N:	> 32	> 31
Uniformity:	< 15 %	< 40 %
Geometric distortion:	< 2.5 %	< 3.5 %

Slice thickness : within 10% of nominally designated value
Slice position (gap): within 10% of nominally designated value
Spatial resolution: nominally equivalent to pixel size

General safety and effectiveness concerns: Safe and effective use of the machine is assured by associated labeling. This labeling includes:advertising brochures, Site Planning Guide, and Instructions for Use (comprised of Clinical Users Guide, User Safety Guide, User Training Guide, User Applications Guide, and User QA & Maintenance Guide)

Substantial equivalence: This device has the same intended use and basic technological characteristics as the Siemens Magnetom P8.