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GE Medical Systems

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P.O. Box 414, W-709
Milwaukee, WI 53201
USA

SUMMARY OF SAFETY AND EFFECTIVENESS

- This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).
- Identification of Submitter
Larry A. Kroger, Ph.D., 414-544-3894, May 24, 1996
- Identification of the Product
Signa Horizon Cx Magnetic Resonance System

Manufactured by: GE Medical Systems
3200 N. Grandview Blvd.
Waukesha, WI 53188
- Marketed Devices
The Signa Horizon Cx MR System with new 1.5T and 1.0T magnets is substantially equivalent to the currently marketed Signa Horizon System (software and electronics).
- Device Description

The Signa Horizon Cx System utilizes a superconducting magnet to acquire 2D single-slice and multi-slice, and 3D volume images. A wide variety of pulse sequences is provided to the operator, including inversion recovery, spin echo, gradient echo, gradient recalled, and steady state, free precession acquisitions. Imaging options such as cardiac gating, peripheral gating, flow compensation and fat/water suppression are provided to suppress artifacts due to physiological motion and improve image quality. The system can be used as a stationary or mobile system.
- Indications for Use

The Signa Horizon Cx System is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures of the head or body. The images produced by the Signa Horizon Cx 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 determining a diagnosis.



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- Comparison with Predicate

The magnets used with the Signa Horizon Cx System are 2 Tons lighter and have a lower cryogen boil off rate than the Signa Horizon magnets. The new magnets are also 68 cm shorter than the Horizon magnets.

- Summary of Studies

The Signa Horizon Cx System was evaluated to the appropriate NEMA performance standards as well as the IEC 601-1 International medical equipment safety standard. The Signa Horizon Cx System is comparable to the Signa Horizon MR Systems.

- Conclusions

It is the opinion of GE that the Signa Horizon Cx System is substantially equivalent to the Signa Horizon MR Systems. The Signa Horizon Cx does not include any new indications for use, nor does use of this device result in any new potential hazards.