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GE Medical Systems

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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, August 16, 1996
- Identification of the Product
SmartPrep IA

Manufactured by: GE Medical Systems
 3200 N. Grandview Blvd.
 Waukesha, WI 53188
- Marketed Device

The SmartPrep IA Option is a modification to the currently marketed Signa Horizon MR Systems.
- Device Description

The SmartPrep IA Option is an optional imaging technique that results in a scan acquisition being triggered off of the arrival of a user injected bolus of contrast agent at a prescribed volume of interest.
- Indications for Use

SmartPrep IA option enables breath hold studies and trigger acquisition based on timing related to the arrival of a user injected exogenous contrast agent bolus.
- Comparison with Predicate

The SmartPrep IA Option is substantially equivalent to the currently marketed Signa Horizon HiSpeed MR System. The Fast Gradient Echo pulse sequence is modified by the insertion of an Infusion Advisor scan.
- Summary of Studies

The SmartPrep IA Option was evaluated to the IEC 601-2-33 International medical equipment safety standard for Magnetic Resonance Systems. Evaluation testing confirmed the functionality of the software.
- Conclusions

It is the opinion of GE that the SmartPrep IA Option is substantially equivalent to the currently marketed Signa Horizon Fast Gradient Echo pulse sequence. The option does not result in any new potential hazards.