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GE Medical Systems

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USA

SUMMARY OF INFORMATION RESPECTING SAFETY AND EFFECTIVENESS

January 12, 1996

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

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Product: Advantage Windows with FuncTool Option
CT/MR Accessory
Manufactured by GE Medical Systems - Europe, Buc, France
Distributed by GE Medical Systems, Milwaukee, WI

1) Indications for Use

The FuncTool option to the Advantages Windows workstation is a software module that provides supplemental information to those images extracted from CT and MR temporal datasets.

2) Device Description

FuncTool is a functional Imaging software package which allows to display the temporal variation in dynamic CT and MR datasets. Single or multi-slice datasets, with equally spaced time intervals are used for input. The purpose is to provide Time Intensity Curves and parametric images that provide clinical information for diagnosis purposes. This software is used during post-processing of MR and CT images on GE's CT and MR Systems.

3) Marketing History

This software is presently being marketed as the Multiple Region of Interest (MIROI) function in the Signa MR Systems 510(k) K913475. FuncTool automates what is presently done manually.

4) Comparison with Predicate

The use of the FuncTool Option does not result in any additional potential hazards when compared to previously marketed devices.

5) Conclusions

It is the opinion of GE that the FuncTool Option is substantially equivalent to the Advantage Windows Diagnostic Workstation (K913770) and Signa Advantage (K913475). The FuncTool Option does not include any new indications for use, nor does use of this device result in any new potential hazards.