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GE Medical Systems

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510(k) 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).

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Product Identification: GE Advantage Digitizer Workstation. This is a new product release.

Device Description: The GE Advantage Digitizer Workstation consists of a PC Pentium computer running Windows NT with a keyboard, mouse and SVGA color monitor, application software and a film digitizer.

Indications for Use: The GE Advantage Digitizer Workstation is a film digitizing and DICOM converting quality assurance (QA) workstation that permits viewing and annotation changes of digitized images prior to lossless storage to a hard drive or transmission to another DICOM device on a local or wide area network.

Comparison with Predicate Device: The GE Advantage Digitizer Workstation is comparable in key safety and effectiveness features, components and hardware requirements and has the same intended uses as the Dejarnette Imageshare Film Digitizer Acquisition Gateway, the Lumisys DICOM Toolkit, and the RadWorks Medical Imaging Software.

Summary of Studies: In addition to system design verification tests to assure conformance with the design specifications, the design has or will undergo further validation to assure overall user satisfaction.

Conclusion: Intended uses and basic system design, including the hardware, are similar to products manufactured by other companies. The features of this product are the same as those available on other legally marketed products. Therefore, it is the opinion of GE Medical Systems that the GE Advantage Digitizer Workstation is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.