



K96-0613

GE Medical Systems

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APR 30 1996

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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Date Prepared: February 12, 1996

Product Identification: GE Advantage Windows Review Workstation. This is a device modification.

Marketed Devices: Legally marketed devices include the Advantage CT/MR Radiology Diagnostic Workstation (K913770) manufactured by GE Medical Systems and the Advantage Windows Diagnostic X-Ray Workstation (K942120) also manufactured by GE Medical Systems.

Device Description: The GE Advantage Windows Review Workstation consists of a Sun Microsystems Sparc 4, 5, 20 or UltraSparc Unix workstation or equivalent with 32 to 128 MBytes of RAM, 1 to 4 GBytes of mass storage memory, an Ethernet or ATM networking interface and 1 to 4 color landscape or high resolution monochrome monitors. The GE Advantage Review Windows software application is designed and produced by GE Medical Systems. Earlier versions of this software were included in previous 510(k) Premarket Notification submissions (K913770, K942120).

Indications for Use: The GE Advantage Windows Review Workstation is a two dimensional review station which allows selection and review of DICOM images from Computed Tomography (CT), Magnetic Resonance (MR), X-Ray (XR), Computed Radiography (CR) and Secondary Capture (SC) modalities.

Comparison with Predicate Device: The GE Advantage Windows Review Workstation is comparable in key safety and effectiveness features, uses similar design, construction, and materials, and has the same intended uses as the GE Medical Systems Advantage CT/MR Radiology Diagnostic Workstation (K913770) and the GE Medical Systems Advantage Windows Diagnostic X-Ray Workstation (K942120).

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: The design and development of the modification conforms with relevant FDA Standards. Therefore, it is the opinion of GE Medical Systems that the GE Advantage Windows Review Workstation modification is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.