

K963345

**Summary of Safety & Effectiveness**

**Product Identification:**

**Name:** Advantage Windows Tissue Volume Option

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**Manufacturer:** General Electric Medical Systems  
16800 W. Ryerson Road  
New Berlin, WI 53151

**Distributor:** Same as Manufacturer

**Indications for Use:**

Advantage Windows Tissue Volume Option is intended to calculate the volume of any three dimensional structure from a set of CT images. The images are displayed and measured on the CT/MR Advantage Windows Diagnostic Workstation (K913770). The Tissue Volume Option will automate manual measurements and estimates that are currently made regarding the measure of volume of anatomy and pathology imaged with computed tomography.

**Device Description:**

The device is a software package to be used on the Advantage Windows Workstation (K913770).

**Design:** The design is based on the same software platform as used for Advantage Windows 3D (VoxTool) and will operate on the Advantage Windows Operating System. The workstation hardware required for operation will be the Sun Sparc 20, Mod 40 or higher. The images used to measure volume can be captured by any CT scanner and transferred to Advantage Windows workstation by DICOM or Ethernet.

**Energy Source and Exposure Levels:** There is no energy source associated with this package in and of itself. However, the energy source used to make the image being analyzed is the same used to take standard CT diagnostic images.

**Principals of Operation:** The same as Advantage Windows 3D.

**Features:** To calculate the volume of areas of a CT image selected by the operator.

**Accessories:** None

**Marketing History:**

The Advantage Windows Tissue Volume Option is substantially equivalent to the currently marketed Advantage Windows 3D Option (K913770).

**Adverse Effects on Health:**

The package itself will not have any adverse affects on health. This tool measures and displays the volume of an outlined image. The outlining is in the hands of the operator who can choose to accept or reject the outlined region and then select to use that data to compare against earlier images or images from other patients.

**Conclusions:**

The Advantage Windows Tissue volume Option enhances the current Advantage Windows 3D package by automating volumetric measurements that are currently being made manually using the measure distance tools of the 3D package. It is substantially equivalent to the Advantage Windows 3D package in design, construction, principle of operation, and features.