

4/16/99

DICOM IMAGE MANAGER - Addition of 3D Visualization Software Module

510 (k) SUMMARY

K990248

This following summary is provided as part of this Premarket Notification in compliance with and based on the format set forth in the Final Rule as published in the Federal Register, December 14, 1994. (See 21 CFR § 807.92)

(1) Submitters Name / Contact Person:

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(2) Name of device:

Trade Name: Dicom Image Manager™ "3D ROI™"

Common Name: 3D Visualization Module

Classification Name: Ultrasonic Pulsed Echo Imaging System

(3) Identification of predicate devices:

Manufacturer	Device	510(k) Number
Dicomit Imaging Systems Corp.	Dicom Image Manager	K951925
Advanced Technology Labs	ATL HDI 3000/5000 Ultrasound systems	K961459
General Electric Medical Systems	GE LOGIQ 700 Ultrasound system	K964617

(4) Description of the device:

The software changes described in this submission enable the DICOMIT Dicom Image Manager - with 3D-visualization software module to store in memory, multiple sequential ultrasound images when using a standard ultrasound transducer during any standard ultrasound scanning procedure. These images can then be rendered as a 3D image that can be displayed and manipulated in "windows" on the monitor.