

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:

Dicomit Imaging Systems Corp.  
75 East Beaver Creek Road, Unit 9  
Richmond Hill, Ontario  
Canada L4B 1K6

Contact Person: Terry Callahan  
Tel.: (905) 886-9496  
Fax: (905) 886-2109  
E-mail: tcallahan@dicomit.com

Date prepared: January 22, 1999

(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.

(5) A statement of the intended use of the device:

The DICOMIT Dicom Image Manager medical image management system is intended for acceptance, transfer, display, storage and digital processing of medical images. The software component provides functions for performing operations related to image manipulation.

The "3D ROI" software option enables the device to display and manipulate an adjunctive 3D volume image created with data from a diagnostic ultrasound scanning procedure.

(6) Predicate Device Comparison:

The DICOMIT Dicom Image Manager - with 3D Visualization Software Module is substantially equivalent to similar features in the predicate devices and has the same intended uses and technological characteristics as the predicate devices.

The DICOMIT system and the predicate devices all use standard ultrasound system probes. All systems acquire multiple sequential images scanned in a "freehand" manner by the user without special positioning devices or position sensors.

The resulting sequential images are stored in the ultrasound system memory commonly called "Cine" or "Cine Loop". On all three systems the 3D volume images are rendered using the individual B-mode scan images acquired from the "freehand" scan.

The DICOMIT Dicom Image Manager - with 3D Visualization Software Module creates a 3D volume image in the same manner as the predicate devices described in this submission.



APR 16 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Terry Callahan  
President  
Dicomit Imaging Systems Corp.  
75 East Beaver Creek Rd., Unit 9  
Richmond Hill, Ontario  
Canada L4B 1K6Re: K990248  
DICOM Image Manager, 3D Visualization Option  
"3D ROI"  
Dated: January 22, 1999  
Received: January 26, 1999  
Regulatory class: II  
21 CFR 892.1560/Procode: 90 IYO

Dear Mr. Callahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**510(k) Notification**  
**DICOM IMAGE MANAGER Addition of 3D Visualization Software Module**

510(k) Number (if Known): K990248

Device Name: DICOMIT Dicom Image Manager "3D ROI" Option

**Indications For Use:**

The DICOMIT Dicom Image Manager medical image management system is intended for acceptance, transfer, display, storage and digital processing of medical images. The software component provides functions for performing operations related to image manipulation.

The "3D ROI" software option enables the device to display and manipulate an adjunctive 3D volume image created with data from a diagnostic ultrasound scanning procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

*Donald J. ...*  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K990248