

MAY 11 1999

K990A42

**Section 510(k) Premarket Notification Summary**  
(as required by 807.92 (j))

**Submitter:** Vital Images, Inc.  
3100 West Lake Street  
Minneapolis, MN 55416-4510  
Phone # (612) 915-8001  
Fax # (612) 915-8030

**Date Prepared:** February 8, 1999.

**Contact Person:** Robert C. Samec

**Device Trade Name:** Vitrea 1.3 Image Processing Software

**Device Common Name:** Image Processing Software for CT/MRI Scanners

**Classification Name:** 90LLZ – System, Image Processing

**Substantially Equivalent to:** Cardiac Scoring Option (K970980)  
Elscint, Inc.

**Indications for Use:** Cardiac scoring from whole body computed tomography derived measurements. For non-invasive detection and quantification of atherosclerotic plaque.

**Device Description:** The Vitrea 1.3 Coronary Artery Calcification Scoring (CACS) module is an additional software feature/option to K963697, Advanced Diagnostic Viewer (ADV). ADV was subsequently marketed as Vitrea - Image Processing Software by Vital Images, Inc. This feature provides visualization, quantification and reporting of the amount of calcium detected in the coronary arteries by processing data from Electron Beam or spiral/helical scanning image data.

**Software Development:** The software utilized was designed, developed, tested and validated according to written procedures. These procedures specify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation and maintenance.

**Performance Testing:** All software testing specified in the Software Development and Test Plan will be successfully completed prior to market release.

**Clinical Evaluation:** Software Beta testing will be successfully completed validating feature/performance prior to market release.

## Substantial Equivalence Comparison Chart

**Item**

**Vitrea 1.3**

**Elscint (K970980)**

**Intended Use:** Cardiac Scoring from whole body computed tomography derived measurements.

**Data Source:** CT Scanner

**Computing Method:** Agatston method for quantification of high density structures

## Substantial Equivalence Comparison Chart

<b>System:</b>	<b><u>Elscent, Inc.</u></b> Cardiac scoring Option (K970980)	<b><u>Vital Images, Inc.</u></b> Cardiac Scoring Option
<b>Intended Use:</b>	Cardiac scoring from whole body computed tomography derived measurements.	Cardiac scoring from whole body computed tomography derived measurements.
<b>Data Source:</b>	CT Scanner	CT Scanner
<b>Physical Characteristics</b> (workstation)	DICOM 3.0 compatible Archive capability Manual segmentation/ contour	DICOM 3.0 compatible Archive capability Manual segmentation/ contour
<b>Performance Measurement Testing</b>	See Attached Clinical Comparison Summary/Data	
<b>Safety:</b>	Physician review of data/ scoring integral to use of feature.	Physician review of data/ scoring integral to use of feature.



MAY 11 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Robert C. Samec  
Vice President, QA/RA  
Vital Images, Inc.  
3100 West Lake Street  
Suite 100  
Minneapolis, Minnesota 55416-4510

Re: K990442  
Advanced Diagnostic Viewer (ADV),  
Model Vitrea-1.3 CT/MRI Workstation  
Dated: February 8, 1999  
Received: February 10, 1999  
Regulatory Class: II  
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Samec:

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) Number (if known): K 990442

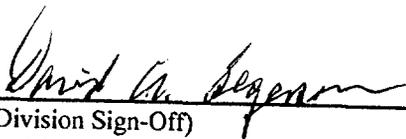
Device Name: Cardiac Scoring (Option)

INDICATIONS FOR USE:

Intended Use:

*Indications for Use:* Cardiac Scoring from whole body computed tomography derived measurements. For non-invasive detection and quantification of atherosclerotic plaque.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)  
Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K990442

Prescription Use X  
Per 21 CFR 801.109

OR

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

(Optional Format 1-2-96)