



AUG 18 1998

K982004

GE Medical Systems

Summary of Safety & Effectiveness
General Electric Company
P.O. Box 474, Milwaukee, WI 53201

This 510(k) summary of safety and effectiveness is submitted in accordance with the requirements of: 21 CFR Part 807.87(h).

Identification of submitter: Larry A. Kroger, Ph.D.
(414) 544-3894
Summary prepared 29 May 1998

Product Identification:

Name: CT Coronary Artery Calcification Scoring Option for Advantage Windows

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

Marketed Devices: The CT Coronary Artery Calcification Scoring (CACS) option for Advantage Windows is substantially equivalent to the currently marketed Elscint Cardiac Scoring Option (K970980).

Indications for Use: CT Coronary Artery Calcification Scoring Option for Advantage Windows is intended to be used by a trained physician for the review and analysis of CT images as an aid in cardiac analysis. It runs on Advantage Windows independent workstations (K913770)

Device Description: A software productivity package that semi-automatically quantifies manually identified cardiac calcifications by a weighted number instead of manually calculating area of Regions of Interest (ROIs) and the density within each ROI.

Principles of Operation: The same as Advantage Windows 3D.

Features:

- Tools for selecting Regions of Interest;
- Image Selection: manually and/or semi-automatically using EKG data;
- Automatic computation of calcium score for individually selected ROI or group of ROIs;
- Creation of a report with calcium score
- Pre-formatted film output of selected images and patient information; and
- Collection of EKG data and statistics with output of selected images with corresponding EKG.

Accessories: A recording EKG machine is an optional accessory that aids in the review and selection of images for scoring. (i.e. Invivo Research EKG, Millennium Model 3500 Series, K950688.) The EKG device is used to record the patient's EKG during scanning. A time stamp is placed on the EKG data to show when the imaging started. This allows the operator to select images with reduced motion artifacts. Images may also be selected without the use of an EKG.

Adverse Effects on Health: The package itself will not have any adverse effects on health. This tool displays reconstructed CT images and allows the user to perform post-processing image analysis.

Conclusions: The CT Coronary Artery Calcification Scoring (CACS) option for Advantage Windows enhances the current Advantage Windows package by providing the physician a tool for analyzing cardiac images. It is substantially equivalent to analysis packages currently in the marketplace.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Larry A. Kroger, Ph.D.
Senior, Regulatory Program Manager
GE Medical Systems
P.O. Box 414
Milwaukee, WI 53201Re: K982004
CT Coronary Artery Calcification Scoring (CACS)
for Advantage Windows
Dated: June 1, 1998
Received: June 8, 1998
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Dr. Kroger:

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 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



K982004

Indications for Use Statement

510(k) Number (if known):

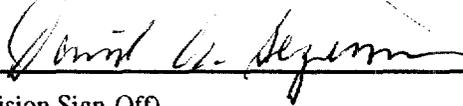
Device Name: CT Coronary Artery Calcification Scoring Option for Advantage Windows

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
DRAERD

510(k) Number: K982004

Prescription Use _____
(Per 21CFR801.109)

or

Over-The-Counter Use _____
(Optional Format 1-2-96)