K990426

MAY 12 1999

Attachment 11

510(k) Summary

Siemens Calcium Scoring Software Package

April 30, 1999

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. General Information.

Establishment

- **Address:** Siemens Medical Systems, Inc.
  186 Wood Avenue South
  Iselin, NJ 08830

- **Contact Person:** Kathleen M. Rutherford
  Manager, Regulatory Submissions
  (908) 321-4779 phone
  (908) 321-4841 fax

Device Name

- **Trade Name:** Calcium Scoring
- **Common Name:**
- **Classification Name:** Picture Archiving and Communication System (PACS)
- **Classification:** Class II
- **Performance Standards:** None established under Section 514 of the Food, Drug, and Cosmetic Act.

II. Information Supporting Substantial Equivalence Determination.

• Device Description:
Calcium Scoring is a software package running on the 3Dvirtuoso workstation that allows the user to mark regions of detected calcification in CT cardiac images, to assign each region to a coronary artery, and to calculate the Agatston score and other information from the identified pixels. Film and paper reports of the results can also be prepared. Calcium Scoring is also a cost –effective alternative to Electron Beam CT (EBCT), since it produces calcium scores that correlates to the EBCT's gold standard, but at a much lower cost.

• Intended Use:
The calcium-scoring package is a non-invasive diagnostic tool that can be used to evaluate the calcified plaques in the coronary arteries, which is a risk factor for coronary artery disease. Calcium scoring may be used to monitor the progression or regression overtime of the amount or volume of calcium in the coronary arteries, which may be related to the prognosis of a cardiac attack.

- **Technological Characteristics as compared to the Predicate Device:**

  As in the predicate devices UltraAccess and NetraMD, the Calcium Scoring software evaluates standard CT images for pixels above a given CT number threshold. These data are evaluated to calculate the Agatston score and other information. The results may be printed out to a paper report or to film.

- **Substantial Equivalence:**
  Siemens Calcium Scoring is substantially equivalent to the following devices:
  1. - Imatron Ultra Access Device (K972903) cleared by FDA on 11/04/97
  2. - SCImage NetraMD Device (K960911) cleared by FDA on 05/29/96

Kathleen Rutherford
Manager, Regulatory Submissions
Imaging Systems Group, Siemens Medical Systems

4/28/99
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 1999

Alicia Juergensen
Technical Specialist, Regulatory Affairs
Siemens Medical Systems, Inc.
186 Wood Avenue
Iselin, New Jersey 08830

Re: K990426
Calcium Scoring Software Package
Dated: April 30, 1999
Received: April 30, 1999
Regulatory Class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Ms. Juergensen:

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

Attachment 1

Indications for Use

510(k) Number (if known) _____
Device Name: Calcium Scoring Software Package

Indications For Use:

From user specified sets of CT cardiac images, Calcium Scoring can be used to: -

- Allow the user to interactively indicate regions of detected calcification
- To allow the user to allocate each detected region to one of several coronary arteries
- To estimate algorithmically a score for the amount of detected calcification in each allocated artery
- To prepare reports including calcium score data, imagery, ECG traces, Comparison of score to cited literature and additional relevant information

The calcium-scoring package is a diagnostic tool that can be used to evaluate the calcified plaques in the coronary arteries, which is a risk factor for coronary artery disease. Calcium scoring may be used to monitor the progression or regression overtime of the amount or volume of calcium in the coronary arteries, which may be related to the prognosis of a cardiac attack.

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Concurrence of the CDRH, Office of Device Evaluation (ODE)

David G. Hanson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990426

Prescription Use ✓
(Per 21 CFR 801.109)