

NOV 10 1999

K992731

Summary Of Safety and Effectiveness

I. General Information

Classification Name: Emission Computed Tomography System
Classification Number: 21 CFR 892.1200
Class of Device: II
Common/Usual Name: Emission tomography system (Computer)
Device Trade Name: E.CAM Computer

Intended Use: To detect or image the distribution of radionuclides in the body or organ, using the following techniques:

- Planar Imaging
- Whole body imaging
- Tomographic imaging (SPECT) for non positron emitter
- Positron imaging by coincidence
- Positron imaging without coincidence up to 588 keV

Establishment Name and Address:

Siemens Medical Systems, Inc.
Nuclear Medicine Group
2501 North Barrington Road
Hoffman Estates, IL 60195-5203

Establishment Registration Number:

1423253 (Owner/Operator 9010023)

Performance Standard:

None established under Section 514 of The Food, Drug and Cosmetic Act

II Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

General Safety and Effectiveness Concerns:

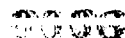
The device labeling contains instructions for use. It includes indications for use and cautions. This information assures safe and effective use of the device.

Substantial Equivalence:

Siemens Medical Systems, Inc., Nuclear Medicine Group, believes that within the meaning of the Safe Medical Device Act of 1990 and the Medical Device Amendments of 1992 the E.CAM Computer, Emission Tomography System (Computer) is substantially equivalent to the currently marketed by Siemens Medical Systems, Inc., Nuclear Medicine Group, E.CAM (IP-500, K952109) and ICON (K903315B) and ADAC Pegasys (K892358).

Contact:

Robert W. Callahan
Manager of Regulatory Affairs
Siemens Medical Systems, Inc.
Nuclear Medicine Group
2501 North Barrington Road
Hoffman Estates, IL 60195-5203
Phone: (847) 304-7516
Fax: (847) 304-7516
robert.callahan@nmg.sms.siemens.com





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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Robert W. Callahan
Manager of Regulatory Affairs
Siemens Medical Systems, Inc.
2501 North Barrington Road
Hoffman Estates, IL 60195-5203

Re: K992731
E.CAM Computer
Dated: August 12, 1999
Received: August 13, 1999
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Callahan:

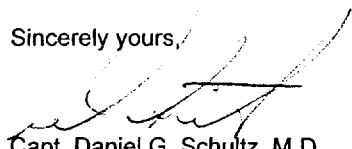
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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

Indications for Use Form

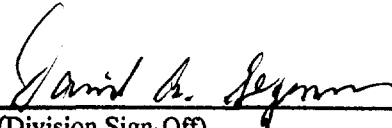
510(k) Number (if known) K992731

Device Name: E.CAM Computer, Emission Tomography System (Computer)

Indication for Use: To detect or image the distribution of radionuclides in the body or organ, using the following techniques:

- Planar Imaging
- Whole body imaging
- Tomographic imaging (SPECT) for non positron emitter
- Positron imaging by coincidence
- Positron imaging without coincidence up to 588 keV

PLEASE DO NOT WRITE BELOW THIS LINE
Concurrence of the CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K992731

Prescription Use
(Per 21 CFR 801.109)

Or

Over-The-Counter Use