

**SUMMARY OF SAFETY AND EFFECTIVENESS**

K970627

SEP - 4 1997

**General Information**

**Classification Name:** System, Tomography, Computed Emission  
**Product Code:** 90KPS  
**Device Trade Name:** E.CAM Coincidence Mode Option  
**Classification:** Class II Medical Device  
**Intended Uses:**      **Anatomical Region:** All  
                                 **Diagnostic Uses:** Imaging  
**Establishment Name and Address:** Siemens Medical Systems, Inc.  
Nuclear Medicine Group  
2501 N. Barrington Road  
Hoffman Estates, Illinois 60195-7372  
**Establishment Registration Number:** Owner/Operator No. 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**

The Siemens E.CAM Coincidence Mode Option is a product which is substantially equivalent to legally marketed devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP - 4 1997

Paul G. Oris  
Manager, Regulatory Affairs  
Siemens Medical Systems, Inc.  
Nuclear Medicine Group  
2501 North Barrington Road  
Hoffman Estates, IL 60195-5203

Re: K970627  
E.CAM™ Coincidence Mode Option (CM)  
Dated: June 5, 1997  
Received: June 6, 1997  
Regulatory class: II  
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Oris:

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 requirement, 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/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

510(k) Number (If Known): K970627

Device Name Siemens E.CAM Coincidence Mode Option

Nuclear Medicine Device

Indications For Use: To detect or image the distribution of radionuclides in the body or organ, using the following technique(s).

		YES	NO	Energy Range (keV)
A.	Planar Imaging		X	
B.	Whole Body Imaging		X	
C.	Tomographic Imaging (SPECT) for non Positron emitter		X	
D.	Positron imaging by coincidence	X		Camera range increases to 560 keV
E.	Positron imaging without coincidence		X	
F.	Positron Whole Body Imaging by coincidence.	X		Camera range increases to 560 keV

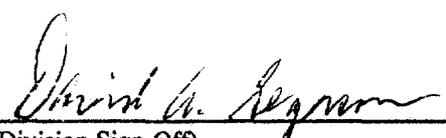
(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRE, Office of Device Evaluation (ODE)

Prescription Use  (Per 21 CFR 801.109)

OR

Over-the-Counter Use

  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K970627

(Optional Format 1-2-96)