510(k) summary

(in accordance to 21 C.F.R. § 807.92)

OCT 5 2010

K101768

Submitter Identification

Holder / Headquarters:	MiE GmbH Hauptstrasse 112 23845 Seth, Schleswig-Holstein Germany
Telephone Number:	+49 4194 9977 0
Fax Number:	+49 4194 9977 55
Contact Person:	Thomas Kuehl th.kuehl@miegermany.de

Date summary prepared: 07 / 26 / 2010

Product Identifaction

Name:	ECAM SCINTRON
Common Name:	Gamma Camera System
Classification Name:	Emission Computed Tomography System 21 C.F.R. § 892.1200
Classification:	Class II

Identification of Legally Market and Equivalent Devices

510(k) #	Device	Manufacturer
K101013	SCINTRON	MiE GmbH / MiE America Inc.
K963983	e.cam	Siemens Medical Solutions USA, Inc.

Device Description

The ECAM SCINTRON Gamma Camera System is a remanufactured Siemens Gamma Camera with MiE Workstation. It is designed for diagnostic nuclear medicine used to perform static, dynamic and gated studies (non positron emitting tomography), as well as SPECT or planar procedure on standing, seated or recumbent patients.

The ECAM SCINTRON Gamma Camera System is substantially equivalent to the legally market device e.cam, K963983, from Siemens and our device SCINTRON, K101013.

The changes incorporated into the remanufactured ECAM Gamma Camera include economical and ecological issues. This closes the gap between more durable electronics and mechanics lifetimes and shortened development cycles.

Intended Use

The Intended Use of the ECAM SCINTRON Gamma Camera System is similar to the legally market devices. The ECAM SCINTRON System is designed for data acquisition, reviewing and processing of nuclear medicine data, expected positron emitting tomography. It is intended to detect the location and distribution of gamma ray radionnuclides in the body or organ. Following types of acquisition are provided:

- planar
- dynamic
- whole body
- SPECT (non positron emitting tomography)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Thomas Kuehl
Official Correspondent
MiE GmbH
Hauptstrasse 112, 23845 Seth, Schleswig-Holstein
GERMANY

OCT 5 2010

Re: K101768
Trade/Device Name: ECAM SCINTRON
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: August 9, 2010
Received: August 9, 2010

Dear Mr. Kuehl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K101768

Device Name: ECAM SCINTRON

Indications for Use:

The ECAM SCINTRON Gamma Camera System for diagnostic nuclear medicine is used to perform static, dynamic and gated studies (non positron emitting tomography), as well as SPECT or planar procedure on standing, seated or recumbent patients.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

for David G Brooks

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101768