510(k) Summary

JUL - 8 2004

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.

8.2 GENERAL INFORMATION

Establishment:

- Address: Siemens Medical Solutions, Inc
  400 W Morgan Road
  Ann Arbor, MI 48108
- Registration Number: 1836549
- Contact Person: Ana Ladino
  Technical Specialist Regulatory Submissions
  Telephone: (610) 448-1785
  Telefax: (610) 448-1787

Device Name:

- Trade Name: KinetDx
- Classification: Picture Archiving and Communications System (PACS)
- Classification Panel: Radiology
- CFR Section: 21 CFR §892.2050
- Device Class: Class II
- Product Code: LLZ

Date of Preparation of Summary: April 16th, 2004

8.3 SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

- **Intended Use**
  The intended use of the KinetDx system is for the acceptance, transfer, display, storage, and post-processing of digital medical images, including manipulation and quantification.

- **Device Description**
  The KinetDx system is a digital image management system that includes a server. This system receives, stores, distributes, and archives images from digital image acquisition devices such as ultrasound and x-ray angiography machines. The system has workstations that can be used to review, edit, and manipulate image data; as well as review, generate quantitative data, qualitative data, and diagnostic reports.

This premarket notification addresses an upgrade and modification of the KinetDx Picture Archival and Communications System as described in K023772 (cleared on 11/22/02). KinetDx in addition provides advanced reporting features, cardiology features for review and analysis of x-ray angiographic images, a new archiving option of standalone DVD and capability to host additional 3rd party software applications

- **Technological Characteristics**
  Similar to the predicate devices, the computer hardware components used for the KinetDx server and workstations are standard computer hardware procured from qualified vendors. The KinetDx server and workstations use proprietary software to accomplish their functions. KinetDx Servers use the Windows 2000 operating system and KinetDx Workstations use the Windows XP operating system

- **General Safety and Effectiveness Concerns:**
  The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of this device.

  Risk management is ensured via a risk analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical and radiation hazards, Siemens Medical Solutions adheres to recognized and established industry practices and standards.

- **Substantial Equivalence**
  The KinetDx system described in this premarket notification has the same intended use and similar technical characteristics as the device listed below

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
KinetDx Picture Archiving Communication System	K023772	11/22/02
Camtronics Echocardiography System Series 95000	K992259	09/08/99

In summary, Siemens is of the opinion that KinetDx does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 8 2004

Ms. Ana Ladino
Technical Specialist,
Regulatory Submissions
Siemens Medical Solutions, Inc.
400 W. Morgan Road
ANN ARBOR MI 48108

Re: K041029
Trade/Device Name: KinetDx
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: April 16, 2004
Received: April 21, 2004

Dear Ms. Ladino:

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 either class II (Special Controls) or class III (PMA), 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 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041029
Device Name: KinetDx

Indications for Use

The intended use of the KinetDx system is for the acceptance, transfer, display, storage, and post-processing of digital medical images, including manipulation and quantification.

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

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

Prescription Use √ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041029