K050943

MAY 2 3 2005

Attachment B:

Summary of Safety and Effectiveness

Prepared in accordance with 21 CFR Part 807.92(c).

GE Healthcare

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

Section a):

1. Submitter: GE Medical Systems, Ultrasound and Primary Care Diagnostics
PO Box 414
Milwaukee, WI 53201

Contact Person: Allen Schuh,
Manager, Safety and Regulatory Engineering
Telephone: 414-647-4385; Fax: 414-647-4090

Date Prepared: April 12, 2005

2. Device Name: ViewPoint V5 Ultrasound Image Management and Reporting System
System, Image Processing, Radiological , 21 CFR 892.2050, 90-LLZ

3. Marketed Device: KinetDx® Diagnostic Workstation for Radiology - K041029, 6/8/2004, 90-LLZ
Currently placed in commercial distribution by Siemens Medical Solutions.

4. Device Description: GE ViewPoint is a software based medical image management system providing ability to schedule patient exams, review exam images and data, prepare and printing reports and communicate with ultrasound scanners and other PACS devices via DICOM or other network protocol. It is sold with or without the designated computer hardware.

5. Indications for Use: The GE ViewPoint is intended to accept, transfer, display, store and process medical images and data, including the ability to measure, calculate, annotate and prepare and print patient examination reports primarily for diagnostic ultrasound.

6. Comparison with Predicate Device: The GE ViewPoint is of a comparable type and substantially equivalent to the KinetDx® Diagnostic Workstation. It has equivalent technological characteristics, key safety and effectiveness features, physical design, construction, and materials, and has essentially the same intended uses as the predicate device.

Section b):

1. Non-clinical Tests: The device has been evaluated for conformance to its design specifications and applicable industry standards for software development. It is further verified for system compatibility with the devices with which it communicates. Computer hardware is certified to applicable safety standards.

2. Clinical Tests: None required to confirm safety and effectiveness. However, evaluation in a clinical setting is performed to help assure reliability and compatibility within the intended network environment.

3. Conclusion: Intended uses and other key features of the device are consistent with traditional clinical practice, FDA guidelines and established methods of handling patient examination images and data. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001:2000 and ISO 13485:2000 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through internal and independent quality system audit. PACS devices and medical information management systems in general have accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Healthcare that GE ViewPoint is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Allen Schuh
Manager, GE Ultrasound Safety and
Regulatory Engineering
General Electric Company
GE Healthcare
P.O. Box 414
MILWAUKEE WI 53201

MAY 2 3 2005

Re: K050943
Trade/Device Name: GE ViewPoint
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 12, 2005
Received: April 14, 2005

Dear Mr. Schuh:

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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 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

Attachment E

Indications for Use

510(k) Number (if known): K050943

Device Name: GE ViewPoint

Indications For Use: The GE ViewPoint is intended to accept, transfer, display, store and process medical images and data, including the ability to measure, calculate, annotate and prepare and print patient examination reports primarily for diagnostic ultrasound.

Prescription Use XXX
(Part 21 CFR 801 Subpart D)

~~AND~~/OR

~~Over-The-Counter Use~~ _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050943