

K 063267

510(k) SUMMARY

In accordance with the provisions of the Safe Medical Device Act of 1990, Stentor, Inc., a Philips Medical Systems Company is providing a summary of safety and effectiveness information regarding the iSite PACS software.

1.1 Company Identification

Stentor, Inc., a Philips Medical Systems Company  
5000 Marina Blvd, Suite 100  
Brisbane, CA 94005

NOV - 9 2006

**Registration Number:** 2954704

1.2 Contact Person

Deana Wiseman  
Sr. Manager of Quality and Regulatory  
Telephone: 650-228-5402  
Fax: 650-228-5566

1.3 Preparation Date

May 18, 2006

1.4 Identification of Product and Classification

**Device Trade Name:** iSite PACS v. 4. X  
**Classification Name:** Picture Archiving and Communications System  
**Classification Panel:** Radiology  
**CRF Section:** 892.2050  
**Device Class:** II  
**Product Code:** LLZ

1.5 Substantial Equivalence

**Manufacturer:** General Electric Medical Systems  
**Model:** GE Centricity PACS  
**510(k) Number:** K043415

**Manufacturer:** Eastman Kodak Company  
**Model:** Kodak PACS  
**510(k) Number:** K060055

**Manufacturer:** Stentor, Inc.  
**Model:** iSite PACS 3.3  
**510(k) Number:** K042292

RF II

## 1.6 Device Description and Intended Use

iSite PACS is an image management system intended to be used by trained professionals, including but not limited to physicians, nurses and medical technicians.

The system is a software package used with general purpose computing hardware to acquire, store, distribute, process and display images and associated data throughout a clinical environment. The software performs digital image processing, measurement, communication and storage.

iSite supports receiving, sending, printing, storing and displaying studies received from the following modality types via DICOM: CT, MR, NM, US, XA, PET, DX, DR, RF, RT, MG, SC, VL, as well as hospital/radiology information systems.

## 1.7 Software Development

Stentor certifies that the iSite software is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance. The software developed for this product is used to provide diagnostic-quality images and associated information to the intended users.

## 1.8 Safety and Effectiveness

### **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 the device. It is the user's responsibility to ensure that display quality, environmental lighting and other possible distractions are consistent with the clinical environment. The hardware components specified are all "off the shelf" computer components.

### **Conclusion:**

iSite is substantially equivalent in design and intended use to diagnostic radiological workstations, PACS and image management systems as substantiated in the feature comparison. Any differences between the iSite PACS software and the equivalent devices have no significant influence on safety or effectiveness. Therefore, iSite PACS raises no new issues of safety or effectiveness from its predicate devices.



Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

Stentor, Inc., A Phillips Medical System Company  
% Ms. Laura Danielson  
Program Manager  
TÜV Product Service  
1775 Old Highway 8  
NEW BRIGHTON MN 55112-1891

NOV - 9 2006

Re: K063267  
Trade/Device Name: iSite PACS v 4.x  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: October 25, 2006  
Received: October 30, 2006

Dear Ms. Danielson:

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.



*Protecting and Promoting Public Health*

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.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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: K063267

Device Name: iSite PACS v 4.x

Indications for Use:

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The system is a software package used with general purpose computing hardware to acquire, store, distribute, process and display images and associated data throughout a clinical environment. The software performs digital image processing, measurement, communication and storage.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.

Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

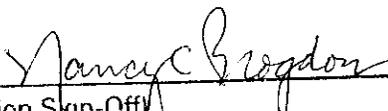
Prescription Use  (Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use \_\_\_\_\_ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K063267