K042292

SEP - 8 2004

510(k) SUMMARY

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

1.1 Company Identification

Stentor, Inc.
5000 Marina Blvd
Brisbane, CA 94005

Registration Number: 2954704

1.2 Contact Person

Deana Wiseman
Director of Regulatory Affairs
Telephone: 650-228-5402
Fax: 650-228-5566

1.3 Preparation Date

April 29, 2004

1.4 Identification of Product and Classification

Device Trade Name:	iSite PACS
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: Centricity PACS Plus
510(k) Number: K023557

Manufacturer: Eastman Kodak Company
Model: Kodak DirectView PACS
510(k) Number: K030781

1.6 Device Description and Intended Use

iSite 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 that is 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.

Substantial Equivalence Summary:
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.

It is our conclusion that there is no software component in the iSite PACS product or hardware component which would be used in conjunction with the iSite PACS product that we know of whose failure or latent design flaw would be expected to result in death or injury to a patient. Thus the "Level of Concern" of the Stentor ISite PACS product is "minor".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

Stentor, Inc.
% Ms. Laura Danielson
Responsible Third Party Official
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K042292
Trade/Device Name: iSite™ PACS v3.3
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: August 23, 2004
Received: August 24, 2004

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 (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

K042292

Indications for Use

510(k) Number:

Device Name: iSite PACS v3.3

Indications for 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 used with general purpose computing hardware to acquire, transmit, process and store images and data throughout a clinical environment. Data and images are acquired through DICOM compliant imaging device or modalities.

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 ____X_____ 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 Device Evaluation (ODE)

David A. Lapsen

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042292