DEC 0 5 2001

K013630

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 Radiology software.

1.1 Company Identification

Stentor, Inc.
385 Oyster Point Blvd. Suite 8B
South San Francisco, CA 94080
Establishment Registration #2954704
Contact: Deanna Wiseman, Operations Manager
Tel: (650) 866-4100
Fax: (650) 866-4197

1.2 Official Correspondent

Gary J. Allsebrook
Regulatory Management Services
16303 Panoramic Way
San Leandro CA USA 94578-1116
Tel: (510) 276-2648
Fax: (510) 276-3559
Email: regman1@home.com

1.3 Date of Submission
August 27, 2001

1.4 Device Name

Classification Name:	PACS
Common/Usual Name:	Soft-copy reading system
Proprietary Name:	iSite Radiology

1.5 Substantial Equivalence

The iSite Radiology software is substantially equivalent to the Kodak, AutoRad (K955092) and the GE Advantage Windows Diagnostic X-RAY workstation (K942120) product.

1.6 Device Description and Intended Use

iSite Radiology is designed as a Diagnostic reading workstation software package, which may be marketed as software only, as well as packaged with standard PC hardware.

iSite Radiology is capable of receiving and displaying DICOM images.

Images sent to ISite Radiology are converted into formats suitable for viewing in its framework, and temporary stored in a local cache (memory. The algorithms used by ISite Radiology to view JPEG and wavelet images follow known and accepted protocols.

Images sent to ISite Radiology can be viewed using an executable program that is installed on a Personal Computer equipped with the appropriate hardware.

ISite Radiology uses standard "off-the-shelf" PC hardware and communicates using the standard TCP/IP stack. The network hardware used to support the TCP/IP stack is superfluous to ISite Radiology.

1.7 Software Development

Stentor certifies that the ISite Radiology 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 indented users.

1.8 Safety and Effectiveness

General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and indications for use.

The hardware components specified (but not supplied) are all "off the shelf" computer components.

Validation and Effectiveness:

Extensive testing of the software package has been performed by programmers, by non-programmers, quality control staff, and by potential customers.

Substantial Equivalence:

iSite Radiology software is a software package used to receive images from the Stentor iSite Server. It provides the user diagnostic quality images and the tools to make a diagnosis.

ISite Radiology is substantially equivalent to the Cemax-Icon AutoRAd product, in that it receives DICOM images, displays them on Diagnostic Quality Monitors and provides the tools and associated information required for diagnosis. The intended use and technological characteristics of the system are virtually identical to Cemax-Icon AutoRAd (K955092) or GE Advantage Windows Diagnostic X-RAY workstation (K942120). Any differences between the ISite Radiology software and the equivalent devices have no significant influence on safety or effectiveness.

It is our conclusion that there is no software component in the ISite Radiology product or hardware component which would be used in conjunction with the ISite Radiology 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 Radiology product is "minor".

1.9 Substantial Equivalence Chart

Product Name	GE Advantage Windows (K942120)	(Kodak) Cemax-Icon AutoRad (K955092)	Stentor-ISite Radiology (this submission)
Print to Paper Capability	Yes	Yes	Yes
Graphical UI	Yes	Yes	Yes
Windows O.S. - Client	Yes	Yes	Yes
Uses Standard. Monitor	Yes	Yes	Yes
Scales Image to Display.	Yes	Yes	Yes
Image Input	DICOM 3.0	DICOM 3.0	DICOM 3.0
Images stored on remote NT server	Yes	Yes	Yes
Network Protocol	TCP-IP	TCP-IP	TCP-IP
Compression	Wavelet	J-Peg	Wavelet
Annotation	Yes	Yes	Yes
Image Measurement	Yes	No	Yes
Cine tool	Yes	Yes	Yes
Comparison Mode	Yes	Yes	Yes
Review Report from RIS	Yes	Yes	Yes
Designed for Use Inside & Outside of Radiology	Yes	Yes	Yes
Flip / Rotate of Images	Yes	Yes	Yes
User Log In	Yes	Yes	Yes
Multiple Layout Options	Yes	Yes	Yes
WW/WL control & Pre-sets	Yes	Yes	Yes
Patient & Study Browser	Yes	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 5 2001

Stentor, Inc.
% Mr. Mark Job
Program Manager
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K013630
Trade/Device Name: iSite Radiology
Soft-Copy reading system
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving
and Communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: November 19, 2001
Received: November 20, 2001

Dear Mr. Job:

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 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 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:

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" (21 CFR Part 807.97). 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

510(k) Number (if known): K013630

Device Name: Stentor, ***iSite Radiology***

Indications For Use:

Stentors' iSite Radiology is a medical image softcopy reading software package to be used for display of digital radiology images.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 901.109) OR Over-the-Counter Use____

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013630