OCT 25 1999 K992698

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 PageView software.

1.1 Company Identification

Stentor, Inc.
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South San Francisco, CA 94080
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
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Email: regman1@home.com

1.3 Date of Submission

August 10, 1999

1.4 Device Name

Classification Name:	PACS
Common/Usual Name:	Teleradiology System
Proprietary Name:	Stentor PageView

1.5 Substantial Equivalence

The PageView software is substantially equivalent to the Mitra, *Exhibit*

(K982769) and the Dome Imaging Systems, *PACScache* (K983815).

1.6 Device Description and Intended Use

Stentor PageView is a digital medical imaging distribution and display system to be used for both primary diagnosis and efficient distribution of medical images within the healthcare enterprise. It operates on the conventional TCP/IP internetworking infrastructure available in most healthcare organizations, and it uses commercially available computer platforms (Intel Pentium-based) and operating systems (Microsoft Windows NT, Windows 95, and Windows 98). The system does not permanently store or produce original medical images. For further information about the basic architecture of the system, please refer to the Stentor System Design Document Summary.

Intended Users: The PageView components are always integrated into client applications. These PageView client applications are designed to be used by people who are involved in healthcare delivery. This includes physicians, medical technologists, administrative staffs, hospital information technology staffs, and people who will support and service the PageView products.

1.7 Software Development

Stentor certifies that the PageView 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 used in this product is used to convert DICOM images to formats that can be displayed both within web browsers as well as stand-alone applications.

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:

The PageView software is a software package used to receive DICOM images, convert them to a web-browser compatible format, and to transfer those converted images to a viewing applet.

PageView is substantially equivalent to the Mitra Exhibit product, in that it receives DICOM images, converts them to wavelet format and displays them within a web browser. The intended use and technological characteristics of the system are virtually identical to Mitra Exhibit (K982769)or the Dome Imaging Systems PACScache (K983815). Any differences between the PageView 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 PageView product or hardware component which would be used in conjunction with the PageView 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 PageView product is "minor".

1.9 Substantial Equivalence Chart

Product Name	Mitra-Exhibit (K982769)	Dome Imaging Systems PACScache (K983815)	Stentor-PageView (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

OCT 25 1999

Stentor, Inc.
Gary Allesbrook
C/o Regulatory Management Services
16303 Panoramic Way
San Leandro, California 94578-1116

RE: K992698
Stentor PageView Teleradiology System
Dated: August 10, 1999
Received: August 11, 1999
Regulatory Class: I
21 CFR 892.2020/Procode: 90 LMD

Dear Mr. Allesbrook:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992698

Device Name: Stentor, ***PageView***

Indications For Use:

Stentor PageView is a digital medical imaging distribution and display system to be used for both primary diagnosis and efficient distribution of medical images within the healthcare enterprise. It operates on the conventional TCP/IP internetworking infrastructure available in most healthcare organizations, and it uses commercially available computer platforms (Intel Pentium-based) and operating systems (Microsoft Windows NT, Windows 95, and Windows 98). The system does not permanently store or produce original medical images.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992698