K073169
pg. 1 of 2

510(k) SUMMARY of Safety and Effectiveness

This following summary is provided as part of this Premarket Notification in compliance with and based on the format set forth in the Final Rule as published in the Federal Register, December 14, 1994. (See 21 CFR § 807.92)

(1) Submitters Name / Contact Information:

SciImage, Inc.
4916 El Camino Real
Suite 200
Los Altos, California 94022

JAN – 9 2008

Contact Person: Sai P. Raya, Founder & CEO
Tel.: (650) 694-4858
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E-mail: sai_raya@scimage.com

Official Correspondent:
Regulatory Management Services
Gary J. Allsebrook - Consultant
16303 Panoramic Way
San Leandro, CA 94578
Tel/Fax: (510) 276-2648
E-Mail: regman10@comcast.net

Date prepared: October 26, 2007

(2) Name of device:

Trade Name: PicomEnterprise

Common Name: Medical image workstation system, PACS.

Classification Name: §892.2050 Picture archiving and communications system.

(3) Identification of predicate device:

Manufacturer	Device	510(k) Number
SciImage, Inc.	Netra™ Workstation and NetraMD™ Software	K960911
SciImage, Inc.	Netra™ Workstation and NetraMD™ Software	K003484
AMICAS	AMICAS Vision Series PACS 4.3	K062477

(4) Description of the device:

The PicomEnterprise software is a multi-modality comprehensive two-, three- and four-dimensional image presentation software system intended for acceptance, transfer, display, storage and digital processing of medical images. The PicomEnterprise software combines reconstruction and display algorithms for medical image analysis in the familiar Microsoft Windows environment. PicomEnterprise offers full compliance with DICOM 3.0 standard that permit transfer of data from medical devices to storage server and then to other DICOM compliant devices.

(5) A statement of the intended use of the device:

The PicomEnterprise software is intended for acceptance, transfer, display, storage and digital processing of medical images.

Its hardware components may include digitizers, workstations, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices and hardcopy devices.

The software components provide functions for performing operations related to image manipulation, enhancement, compression or quantification.

To support the diagnostic interpretation of Mammography studies, PicomEnterprise will display the full fidelity DICOM image in a non-compressed format. Images will be rendered with patient and clinical information clearly displayed as part of the DICOM Overlay as required by MQSA, on monitors cleared by FDA for use in Digital Mammography. Lossy compressed mammography images and digitized film screen images should not be used for the purpose of primary diagnosis. Mammographic images may only be interpreted using an FDA approved monitor that offers at least five megapixel resolution and meets other technical specifications reviewed and accepted by FDA

(6) Predicate Device Comparison:

The PicomEnterprise software is substantially equivalent to similar features in the predicate devices and has the same intended uses and technological characteristics. The new features included in the modified software do not affect the safety or effectiveness of the device.

The modified device complies with the following voluntary standards as "Special Controls" to ensure safe and effective use:

- ACR/NEMA Digital Imaging and Communications in Medicine (DICOM) standard
- Joint Photographic Experts Group (JPEG) standard

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2008

ScImage, Inc.
% Mr. Gary J. Allsebrook
Consultant
Regulatory Management Services
16303 Panoramic Way
SAN LEANDRO CA 94578-1116

Re: K073169
Trade/Device Name: PicomEnterprise
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 23, 2007
Received: November 9, 2007

Dear Mr. Allsebrook:

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, 1796, 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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2.0 FDA Indication for use form.

510(k) Number (if Known): K073169

Device Name: PicomEnterprise

Indications For Use:

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(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 801.109)** OR **Over-The-Counter Use**

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073169