K04 1935

AUG 16 2004

6 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h).

1. Identification of submitter:

Name:	Kimberly J. Meade
Title:	Manager, Quality Assurance
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Date Prepared:	July 16, 2004

2. **Identification of Product:**

Device name:	DR Systems PACS, Release 6.1
Classification:	21 CFR Section 892.2050
Manufacturer:	DR Systems 10140 Mesa Rim Road San Diego, CA 92121-2914

3. Marketed Devices

The DR Systems product is substantially equivalent to the devices listed below:

Model:	Seno Advantage Windows Review Workstation
Manufacturer:	General Electric Medical Systems
510 (k) Number:	K033400

Model:	Sectra IDS5 Radiology Workstation
Manufacturer:	Sectra Imtec AB
510 (k) Number:	K033712 as modified by K040376

4. Device Description:

The DR Systems Dominator Reading Station is a multi-modality PC-driven review workstation. It includes a color flat panel monitor and two or more high-resolution monitors, which may be high resolution CRT's or flat panel monitors. A standard keyboard is provided as well as a standard mouse. Optionally, a microphone may be attached.

DR Systems also provides components as described in the DR Systems User Guide, including:

- Ambassador Viewing Station Software typically used by referring doctors for viewing images, playing audio, or viewing reports, but not used for primary reading.
- Communicator Web Distribution Server.
- Guardian Archive System and optional DVD jukebox or EMC Centera archive.
- Catapult Technologist Workstation—for image and data input and editing as required.
- Universal Manager Workstations—primarily used by clerks for medical records and report management.

The DR Systems PACS, Release 6.1, provides the following features to the radiologist:

- DR Systems viewing software provides simple tools to enable display of any digital image at the same resolution as the initial acquired digital image, independent of the monitor matrix size.
- DR Systems provides several DICOM-compliant methods of lossless and lossy image compression (JPEG2000 and JPEG).
- The DR Systems PACS outputs DICOM medical image data to printers that adhere to appropriate regulatory standards.
- DR Systems archives medical imaging data in DICOM format on appropriate media (DVD, RAID servers, EMC Centera or other computer storage systems) that are designed to prevent data loss.
- DR Systems provides a software warning that identifies any image series where any image was not viewed prior to marking an examination as read, in order to prevent the reading physician from completing interpretation of an exam while inadvertently failing to view all images.
- DR Systems enables storage and reading of digitized images, including film-screen mammograms .

The DR Systems PACS is positioned to be the system of choice for all users of the following DICOM imaging modalities: CT, MR, XR, RF, XA, CR, DX, MG, NM, PET, US, SC.

5. **Indications for Use**

The DR Systems PACS is a medical image and information management system that allows viewing, selection, processing, printing, telecommunications, and media interchange of medical images from a variety of diagnostic imaging systems. The DR Systems PACS interfaces to various storage and printing devices using DICOM or similar interface standards.

The DR Systems PACS displays, stores, prints, and telecommunicates images from a number of medical modalities, including but not limited to MRI, CT, US, PET, DXA (bone densitometry), nuclear imaging, computed radiography, digital radiography, digitized films, digital photographs, mammographic images, and processed data from FDA-cleared third party image processing systems, including FDA-cleared systems for computer-aided detection and advanced image processing (e.g. 3-D processed images such as those produced by Voxar Corp.).

Lossy compressed mammographic images must not be used for primary diagnostic interpretation unless approved for use in digital mammography. Display monitors used for primary diagnostic interpretation of mammographic images must be approved for use in digital mammography.

6. Comparison with Predicate Devices

The DR Systems product is substantially equivalent to the following workstations used by radiologists:

Model:	Seno Advantage Windows Review Workstation
Manufacturer:	General Electric Medical Systems
510 (k) Number:	K033400

Model:	Sectra IDS5 Radiology Workstation
Manufacturer:	Sectra Imtec AB
510 (k) Number:	K033712 as modified by K040376

Each of these workstations allows easy selection, review, processing, archive, printing, and media interchange of multi-modality medical images from a variety of diagnostic imaging systems.

7. **Conclusions**

The DR Systems PACS and information management products provide specific features to integrate seamlessly into the radiology department workflow. The potential hazards have been studied and controlled as part of the product development process, including risk analysis, test and design considerations, and planned verification and validation testing processes. The DR Systems product provides images comparable to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2004

Ms. Kimberly J. Meade
Manager, Quality Assurance
DR Systems, Inc.
10140 Mesa Rim Road
SAN DIEGO CA 92121

Re: K041935
Trade/Device Name: DR Systems PACS, Release 6.1
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: July 16, 2004
Received: July 19, 2004

Dear Ms. Meade:

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

5 Indication(s) for Use Statement

510(k) Number: To be assigned by FDA K041935

Device Name: DR Systems PACS, Release 6.1

Indications for Use:

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The DR Systems PACS displays, stores, prints, and telecommunicates images from a number of medical modalities, including but not limited to MRI, CT, US, PET, DXA (bone densitometry), imaging, computed radiography, digital radiography, digitized films, digital photographs, mammographic images, and processed data from FDA-cleared third party image processing systems, including FDA-cleared systems for computer-aided detection and advanced image processing (e.g. 3-D processed images such as those produced by Voxar Corp.).

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) ~~AND~~/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)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041935