K980243

APR 3 1998

510(k) Summary

1. Company Identification

Parameter Developments, Inc.
15711 Highway 101 South
Harbor, Oregon 97415
Tel. (541) 412-0321
Fax (541) 412-0277

2. Official Correspondent

Gary J. Allsebrook
Regulatory Affairs

3. Date of Submission

January 21, 1998

4. Device Name

Classification Name:	Digital Image Storage System/ Teleradiology System
Common/Usual Name:	Picture Archiving and Communications System
Proprietary Name:	Parameter Developments, DICOM Archival Server (DAS)/DICOM IntraNET Service (DIS)

5. Substantial Equivalence

Fuji, *FCR DMS Optical Disk Image Filing System, OD-F614, K960326*
Lockheed, *ECHONET*, K960946
Kodak, *Kodak Digital Science (KDS) Medical Image and Info, K960981*
Base Ten Systems, *UPACS Version 1.7, K961160*
Autocyt Group, Inc, AMICAS Web/Intranet Server, K970064

6. Device Description and Intended Use

The ***DICOM Archival Server*** (DAS) software product provides for the centralized management and storage of radiographic studies, replacing or augmenting the historical film-based processes.

The operating system utilizes Microsoft © Windows NT © Release 4.0 and later. This environment provides for all communication (i.e. TCP/IP), file storage (e.g. NTFS), security management, and display management processes. It also insulates the DAS from detail hardware management processes, allowing customers to make whatever choices in these areas best serve them.

This environment supports a variety of back-up/restore processes which may be used at the customer's discretion.

The Microsoft© SQL Server product is used as the primary management component for the archive contents and for responding to requests, whether they be in the form of SQL Server direct requests or via the DICOM Query/Retrieve process.

This software-only product is fully DICOM-3.0 compliant for the following DICOM *Service Classes*:

Service Class	Service Type
Verification	SCP
Storage	SCP and SCU
Query/Retrieve	SCP
Print	SCU
Patient Management	SCU
Study Management	SCU
Results Management	SCU

This product consists only of software and executes in a Windows© NT© environment on Intel© platforms. This product, when combined with appropriate server platform hardware and operating system, falls into the FDA proposed designation of a PACS system as Class II (Special Controls). The following attributes are noted:

- this product accepts, stores and transfers images;
- no image processing is done by this product;
- no compressed images are accepted for storage by this product;
- this product will supply compressed images as requested by client products, at the level of compression requested by those clients;
- no image viewing is provided by this product;
- the *reliability* of the product is dependent upon the hardware on which the software is installed, and is determined by the installation;
- *disaster recovery* attributes of an installation are dependent upon installation-determined policies, and are totally under the control of the installation.

The DAS product contains the following advanced features to facilitate rapid movement of images to desired targets within a PACS system:

- automatic image forwarding
- automatic image printing

Automatic image forwarding enables a policy-managed forwarding process wherein each image received by the DAS will automatically be forwarded to one or more target workstations based upon the following image contents:

- modality station name,
- body part,
- referring physician, and
- modality type.

Automatic image printing is an extension of the automatic forwarding process wherein the forwarding target is a DICOM Print Service Class Provider.

The ***DICOM IntraNET Service*** (DIS) software product provides for centralized distribution of stored radiographic studies. DIS is an integrated client-server software system designed to allow secured access to radiographic images by licensed medical professionals. The software's server and client ends rely on off-the-shelf Windows NT software with compatible

Intel hardware. The client end accesses images through a WEB Browser similar to Microsoft's Internet Explorer through a Query/Retrieve process.

The DIS system becomes an extended Viewer attached to a secured internal network or an extended secured Intranet using TCP/IP communications protocol. Full resolution, lossless images are always available to the Client Browser. If lossy compression where used, similar to our equivalent products listed in item 10; Kodak, Base-Ten, or Autocyt, we would recommend that they be used for secondary viewing only and not for diagnostic interpretation.

This DIS software is intended to provide the means for medical professionals to display data generated by medical scanning devices on a personal computer or workstation. Competent healthcare professionals would reasonably be expected to exercise judgment in use of this information.

7. Hazard Analysis

Hazard analysis on this product has been performed throughout the definition, design, coding and testing phases of product development and implementation. This process has emphasized:

- identification of potential hazards, their causes, and their effects;
- development of methodologies to control the occurrence of hazards and to constrain their effects; and
- determine any effect on patient safety and system effectiveness.

The potential hazards associated with this software product are no different than those of other PACS storage facilities. These are primarily related to failure of computer system components, and may be variously obviated by decisions taken by the customers of this product. None of these failures are expected to materially contribute to patient death or injury.

It is our conclusion that there is no hardware or software component, operating in a properly configured environment, whose failure or latent design defect would be expected to result in death or injury of a patient. Thus the "Level of Concern" is "Minor".

Additional discussion is available in the following sections.

8. Safety Concerns

All hardware associated with a PACS system based upon this product is standard, off-the-shelf hardware used for server applications. This hardware has been approved by UL and CSA. The hardware will comply with part 15 of the FCC rules, as well as the DHHS Radiation Performance Standards (21 CFR Subchapter J) as appropriate.

It is important to note that the installing institution has the option of installing redundancy in its networks to obviate failure problems and increase reliability. Such redundant components are managed by the hardware *and* software environment, not by the DAS/DIS.

9. Data Compression

Only uncompressed images are accepted for storage in the DAS. Once received, the image files are stored via the standard disk processes supplied by Windows NT, which can include a lossless compression. Lossy compression techniques are never used in storing images in the DAS. Once an image file has been stored by the DAS, it will provide for either uncompressed,

losslessly compressed, or lossily compressed image transmission to clients. The form of compression available is the full spectrum of compression algorithms currently supported by DICOM, as well as Wavelet compression through a specialized transfer syntax. Compressed images are *only* provided to a client which has explicitly requested a compressed transmission, and then *only* in the format which was requested by the client. The standard DICOM header of the file sent to a client identifies any use of compression. Any client requesting use of compression techniques *must* identify any such images, when displayed, with an indication of any use of lossy compression.

It is our recommendation that lossy compression not be used by clients which support diagnostic processes.

10. Substantial Equivalence

The following products provide functions which are substantially equivalent to this product:

	FDI	FUJI	Lockheed	Kodak	Base-Ten	Autocyt
Product Name	DAS/ DIS	DMS	EchoNet Server	KDS-MIIL	uPACS 1.7	AMICAS
510(k)		K960326	K960946	K960981	K961160	K970064
Platform						
Hardware	Intel	?	Intel	Sun	Intel	Intel
Operating System	Win NT	?	UNIX	UNIX	Win 95	?
Network Technology						
Ethernet	yes	yes	yes	yes	yes	yes
FDDI	yes	no	yes	yes	no	?
ATM	yes	no	yes	yes	no	no
Storage Technology						
Magnetic Disk	yes	yes	yes	yes	yes	yes
Optical Disk	yes	yes	yes	no	yes	?
CD-ROM	yes	no	?	yes	yes	yes
Magnetic Tape	yes	no	yes	?	?	no
Storage Capacity						
Magnetic Disk	96GB	?	?	100GB	?	?
Optical Disk/CD-ROM	2.5TB	1.0TB	?	116GB	?	?
Magnetic Tape	Note 1	no	?	N/A	N/A	N/A
Functions						
Image Viewing	yes	no	yes	no	yes	yes
Image Manipulation	yes	no	yes	no	yes	yes
DICOM-3 Storage	yes	no	?	yes	no	yes
DICOM-3 Query/Retrieve	yes	no	?	yes	no	?
HIS/RIS Interface	yes	no	no	no	no	no
TCP/IP	yes	yes	yes	yes	yes	yes
Storage Compression						
Uncompressed	yes	no	yes	yes	yes	yes
Lossless	yes	yes	yes	?	?	yes
Lossy	no	no	yes	?	?	no
Transmission Compression						
Uncompressed	yes	no	no	yes	yes	yes
Lossless	yes	yes	yes	?	?	yes
Lossy	yes	no	yes	?	?	?

Note 1: offline storage of tape is not limited.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 1998

Parameter Developments, Inc.
c/o Gary J. Allsebrook
Regulatory Management Services
16303 Panoramic Way
San Leandro, CA 94578

Re: K980243
DICOM Archival Server (DAS)/DICOM IntraNet Service (DIS)
Dated: January 21, 1998
Received: January 23, 1998
Regulatory class: Unclassified
21 CFR 892.2010/Procode: 90 LMB

Dear Mr. Allsebrook:

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 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,

Lillian Yin, Ph.D.
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): K980243

Device Name: DICOM Archival Server (DAS)/DICOM IntraNET Service (DIS)

Indications for Use: The DICOM Archival Server (DAS)/DICOM IntraNET Service (DIS), software product, provides for the centralized management and storage of radiographic studies, replacing or augmenting the historical film-based processes.

The operating environment is provided by Microsoft's © NT©operating system, Release 4 and later only. This environment provides for all communication (i.e. TCP/IP), file storage (e.g. NTFS), security management and display management processes. It also insulates the DAS/DIS from detail hardware management processes, allowing customers to make whatever choices in these areas that best serve them.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980243