

510(k) Summary

K990241

1. Company Identification

AccuImage Diagnostics Corporation
400 Oyster Point Blvd. Suite 114
S. San Francisco, CA 94080
Toll Free: (877) 875-0192

2. Official Correspondent

Gary J. Allsebrook
Regulatory Affairs

3. Date of Submission

June 25, 1999

4. Device Name

Classification Name: Computed Imaging Device

Common/Usual Name: Picture Archiving and Communications System (PACS)

Proprietary Name: **AccuImage Diagnostics Corporation, *AccuView Diagnostic Imaging Software Package* with *AccuScore, AccuAnalyze, AccuScope, AccuShade, AccuVRT* and *AccuMIP* Plug-ins**

5. Substantial Equivalence

AccuImage, AIDP (AccuImage Display Processor), K961023; *AccuView*, with *AccuShade, AccuAnalyze, AccuVRT* and *AccuMIP*.

Imatron, Ultra Access, K972903; *AccuScore*.

InSight™, Diagnostic Imaging Workstation, K982535, and Picker, Voxel Q, Voyager, K962010; *AccuScope*.

6. Device Description and Intended Use

The AccuView Diagnostic Imaging Workstation Software Package with Plug-ins receive image files from medical scanning devices, such as CT or MRI and performs real-time viewing, image manipulation, three and four dimensional visualization, communication, and archiving. All of the functions are supported on standard personal computer platform for ease of cost and maintenance. The use of Microsoft Windows 95/98/NT operating system makes the AccuView Diagnostic Imaging Workstation Software Package with Plug-ins easy to use and capable of being integrated with other computer needs.

7. Software

AccuImage Diagnostics Corporation certifies that the AccuView Diagnostic Imaging Workstation Software Package with Plug-ins are 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.

8. 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 components . 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".

9. Safety Concerns

The hardware is "off-the-shelf" and complies with applicable electrical safety standards for standard PC hardware and peripherals.

10. Substantial Equivalence

The following product(s) provides functions, which are substantially equivalent to this product:

AccuView (with AccuShade, AccuAnalyze, AccuVRT and AccuMIP Plugins

Manufacturer:	Acculmage	Acculmage
Product Name:	AccuView (with AccuShade, AccuAnalyze, AccuVRT and AccuMIP Plugins)	AIDP (Predicate Device)
510(k) Number:		K961023
Computer Platform:	Standard PC/Windows 95/98/NT, Dual 400 MHz Pentium processor, 512 MByte RAM	Pentium/Windows 95, Single 300 MHz Pentium processor, 256 MByte RAM
Communications	GPIB, TCP/IP	GPIB, TCP/IP
Image Format In:	Imatron Proprietary, ACR NEMA 2.0, DICOM 3.0	Imatron Proprietary, ACR NEMA 2.0, DICOM 3.0
Image Format Out:	BMP, TIFF, DICOM 3.0	BMP
Image Archive:	SCSI 2-20Gbyte, CD-ROM	IDE Disk Drive, 1+Gbyte, CD-ROM
Image Display:	Color/Greyscale, CRT or Laptop LCD Up to 1024x768, 8, 16 or 24 Bits	Color/Greyscale, CRT or Laptop LCD, Up to 512x512, 12 Bits
Image Processing:	Window Level, Pan, Zoom, Variable Smooth Filter, Cine Display	Window Level, Pan, Zoom, Variable Smooth Filter, Cine Display
Image Edit:	Manual segmentation by drawing a contour. Segmentation by CT number threshold.	Manual segmentation by drawing a contour. Segmentation by CT number threshold.
Volume Rendering:	Maximum, or Minimum Intensity Projection (MIP MinIP) Radiographic Projection, Color Rendering, Surface Rendering, Quick Volume Rendering, Volume Rendering	Maximum, or Minimum Intensity Projection (MIP MinIP) Radiographic Projection, Color Rendering, Surface Rendering, Quick Volume Rendering, Volume Rendering

AccuScore Plugin

	Accuimage	Imatron
Manufacturer Name:	AccuScore	Ultra Access (Predicate Device feature)
510(K) Number		K972903
Computer Platform:	Standard PC/Windows 95/98/NT, Dual 400 MHz Pentium processor, 512 MByte RAM	UNIX Operating System, Ultra SPARC Sun Workstation, 512 MByte RAM
Image Format In:	Imatron Proprietary, ACR NEMA 2.0, DICOM 3.0	Imatron Proprietary, ACR/NEMA 2.0, DICOM 3.0
Image Format Out:	BMP, TIFF, DICOM 3.0	DICOM 3.0
Image Archive:	SCSI 2-20Gbyte, CD-ROM	SCSI 10 Gbyte
Image Display:	Color/Greyscale, CRT or Laptop LCD Up to 1024x768, 8, 16 or 24 Bits	Color/Greyscale, CRT 1680x1200, 24 Bits
Image Processing:	Window Level, Pan, Zoom, Variable Smooth Filter, Cine Display, Slab views, Lesion editing	Window Level, Pan, Zoom, Variable Smooth Filter, Cine Display, Slab views, Examination of 3D volume for calcium
Calcium Scoring:	3D calcium score using volumetric Agatston algorithm, Equivalent calcium mass and volume determination, Manual identification of regions considered to be calcium	3D calcium score using volumetric Agatston Algorithm, 2D traditional Agatston algorithm score, Equivalent calcium mass and volume computation, Automated heart surface finding, Automatic coronary artery identification, Semi-automated identification of regions that are considered calcium, User override of automatically identified regions
Output Document:	Integrated report generation tool with user defined templates, Image annotation capacity	Integrated report generation tool with user defined templates
Database management	Yes	Yes

AccuScope Plugin

Manufacturer:	AccuImage	N.I.T.	Picker
Name:	AccuScope	Insight Diagnostic Imaging Workstation (Predicate Device Feature)	Voxel Q™, Voyager™ Package (Predicate Device Feature)
510(k) Number:		K982535	K962010
Computer Platform:	Standard PC/Windows 95/98/NT, Dual 400 MHz Pentium processor, 512 MByte RAM	Standard PC/Windows 95/98/NT, Dual 400 MHz Pentium processor, 512 MByte RAM	UNIX Operating System, SGI Workstation, 256 MByte RAM, Proprietary Array Processor
Image Format In:	Imatron Proprietary, ACR NEMA 2.0, DICOM 3.0	Imatron Proprietary, ACR NEMA 2.0, DICOM 3.0	Picker Proprietary, DICOM 3.0
Image Format Out:	BMP, TIFF, DICOM 3.0	DICOM 3.0	Picker Proprietary, DICOM 3.0
Image Archive:	SCSI 2-20Gbyte, CD-ROM	SCSI 2-20Gbyte, CD-ROM	SCSI 4 GByte, DAT(Digital Archive Tape), MOD
Image Display:	Color/Greyscale, CRT or Laptop LCD Up to 1024x768, 8, 16 or 24 Bits	Color/Greyscale, CRT or Laptop LCD Up to 1024x768, 8, 16 or 24 Bits	Color/Greyscale, CRT 1680x1200, 24 Bits
Image Processing:	Window Level, Pan, Zoom, Variable Smooth Filter, Cine Display, Axial/Coronal/Sagittal inspection	Window Level, Pan, Zoom, Variable Smooth Filter, Cine Display, Axial/Coronal/Sagittal inspection	Window Level, Pan, Zoom, Variable Smooth Filter, Cine Display, Axial/Coronal/Sagittal inspection
Major Functionality:	Fly through anatomic cavities and render the data on the surface of the lumen	Fly through anatomic cavities and render the data on the surface of the lumen	Fly through anatomic cavities and render the data on the surface of the lumen as well as the surrounding organs
Volume Rendering of Flight Path	Yes	Yes, Real-time	Yes, via 4-D Angio™ Volume Rendering
Surface Rendering of Flight Path	No	Yes	Yes
Auto-Flight Path Calculation	Yes	No	Yes
Auto Collision Detect	Yes	No	Yes
User-directed flight control	Yes	Yes	Yes
Adjustable Field-of-View	Yes	No	No
Cine Display of Flight-Path	Yes, AVI and MPEG format	Yes, AVI format	Yes, Proprietary format



SEP 23 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850AccuImage Diagnostics Corporation
C/O Mr. Gary J. Allsebrook
Regulatory Management Services
16303 Panoramic Way
San Leandro, CA 94578-1116Re: K990241
AccuView Diagnostic Imaging Workstation
with AccuScore, AccuAnalyze, AccuShade,
AccuVRT and AccuMIP Plug-Ins
Dated: June 23, 1999
Received: June 28, 1999
Product Code: 90 LLZ
Regulatory Class: II (two)
21 CFR 892.2050

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 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): K990241

Device Name: Acculmage, AccuView Diagnostic Imaging Workstation

Indications For Use:

The product is an image processing workstation software package designed to run on standard PC hardware. The hardware is all "off-the-shelf" standard computer components and may be purchased independently by the end user or supplied by Acculmage. The Acculmage, AccuView software receives image files from medical scanning devices, such as CT or MRI and perform real time viewing, image manipulation, 3D and 4D visualization, communication, and archiving.

(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)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990241