A.1 510(k) Summary of Safety and Effectiveness

A.1.1 Company Identification

Mercury Computer Systems, Inc.
199 Riverneck Road
Chelmsford, MA 01824-2820
United States of America

A.1.2 Official Correspondent

OCT 27 2006

Richard Glasheen
199 Riverneck Road
Chelmsford, MA 01824-2820
United States of America
Tel.: 978-967-1843
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E-Mail: rglashee@mc.com

A.1.3 Date of Submission

24 Aug 2006

A.1.4 Device Name

Trade name:	VISAGE PACS/CS
Release Version:	4.1
Common name:	VISAGE PACS/CS
Classification Name:	Picture Archiving and Communications System
Reference:	per 21 CFR 892.2050
Class:	II
Review Panel:	Radiology
Product Classification:	90 LLZ, Picture Archiving and Communications System

Guidance document: Guidance for the submission of premarket notifications for medical image management systems (issued on july 27, 2000)

A.1.5 Substantial Equivalence

The Visage PACS/CS Software is substantially equivalent, in the opinion of Mercury Computer Systems Inc., to TeraRecon AquariusNet Server/Thin client (K012086, Class II).

A.1.6 Device Description

Visage PACS is a system to distribute, view, and process medical images and reports within and outside of health care environments. It consists of the following components:

- Visage PACS Storage
- Visage PACS Web
- Visage CS

Visage PACS Storage

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A server receives image data in DICOM format via the hospital network. This provides universal connections to archives, modalities and workstations. The modalities that are supported by Visage PACS Storage are listed in the DICOM Conformance Statement.

Visage PACS Storage offers an archiving option for long-term storage of image data. Only the data consistency on archive media is guaranteed, the system provider has to take own appropriate means (e.g. redundancy) for safety against data loss caused by media destruction. Without the archiving option, the Visage PACS system features no components for long-term data archiving. Additional archiving on film or in digital form is therefore necessary.

Visage PACS Web
Data that are stored on the Visage PACS Storage server can be accessed simultaneously by multiple web-based viewing stations within a healthcare enterprise or from elsewhere outside through web clients.
The image data transfer is done in DICOM format via the Intranet or the Internet, for example to stations located in a doctor's office, throughout hospitals or a physician's home. Strong data encryption is provided (SSL) to ensure a secure data transfer. Images can be viewed directly within a web browser (Internet Explorer). The system offers simple functions for image manipulation and measurements.
Reports can be viewed together with the images on one page.

Visage CS
Visage CS is a client server system that uses thin client technology for distribution of 3D image data generated from image data of state-of-the-art scanning modalities.
The thin client viewer allows to view and process 3D image data. No DICOM data is transferred to the client. It remains on the 3D Application Server at any time, ensuring safe and consistent access to large 3D data throughout the hospital enerprise. Instead of image data, a stream of compressed screen content information is transmitted during interaction. If Visage CS is used in un-secure networks (e.g. WAN) third party VPN (Virtual Private Network) solutions have to be used to secure the data transfer between the Visage Server and the client machines.

A.1.7 Intended Use

Visage PACS is a system for distributing, viewing, and processing medical images and reports within and outside health care environments. It is to be used only by trained and instructed health care professionals. Visage PACS consists of the following components:

- Visage PACS Storage
- Visage PACS Web
- Visage CS

Integration with other hospital information systems (HIS, RIS, CIS) is provided via special interfaces.

Visage PACS Storage
A server receives image data in DICOM format via the hospital network. This provides universal connections to archives, modalities, and workstations. The modalities that are supported by Visage PACS Storage are listed in the DICOM Conformance Statement.

Visage PACS Storage offers an archiving option for long-term storage of image data. The system guarantees the consistency of the data stored on archiving media but does not prevent data loss caused by media destruction.

Visage PACS Web

Data that are stored on the Visage PACS Storage server can be accessed simultaneously by multiple web-based viewing stations within or outside a healthcare enterprise through web clients.
The image data are transferred in DICOM format via the Intranet or the Internet, for example to stations located in a doctor's office, throughout hospitals or a physician's home. Strong data encryption is provided (SSL) to ensure secure data transfer. Images can be viewed directly within a web browser (Internet Explorer). The system offers simple functions for image manipulation and measurements. Reports can be viewed together with the images on one page.

Visage CS
Visage CS is a client server system that uses thin client technology for distribution of 3D image data generated from image data of state-of-the-art scanning modalities.
The thin client viewer allows viewing and processing of 3D image data. No DICOM data is transferred to the client. It remains on the 3D Application Server at all times, ensuring safe and consistent access to large volumes of 3D data throughout the hospital enterprise. Instead of image data, a stream of compressed screen content information is transmitted during interaction.
If Visage CS is used in insecure networks (e.g. WAN), third party VPN (Virtual Private Network) solutions have to be used to secure data transfer between the Visage Server and the client machines.

Important Usage Notes

Visage PACS can support physicians and/or their medical staff in providing their own diagnosis for medical cases. The final decision regarding diagnoses, however, resides with the doctors and/or their medical staff in their own area of responsibility.

Although the web and thin client technologies allow the software to be run on a variety of hardware platforms, for diagnostic purposes the user must make sure that the display hardware used for reading the images complies with state-of-the-art diagnostic requirements and currently valid laws.

Mammographic images compressed by a *lossy* method and *digitized film* screen images must not be reviewed for primary image interpretations.

The computers hosting the server-side software of Visage PACS/CS must be operated in a server room ensuring the appropriate operating and environmental conditions and access control.

A.1.8 Software Development

Mercury Computer Systems, Inc. certifies that the VISAGE PACS/CS 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.

All employees receive the appropriate quality system training.

The Mercury Computer Systems, Inc. Quality System is in compliance with the following voluntary and mandatory standards and regulations:

Standard/Regulation	Title
21 CFR 820	Quality Systems Regulation
ISO 9001:2000	Quality Management Systems – Requirements
ISO 13485:2003	Quality Systems – Medical Devices – Particular requirements for the application of ISO 9001

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93/42/EEC	Medical Device Directive
(IEC) 60601-1-4	International Electrotechnical Commission

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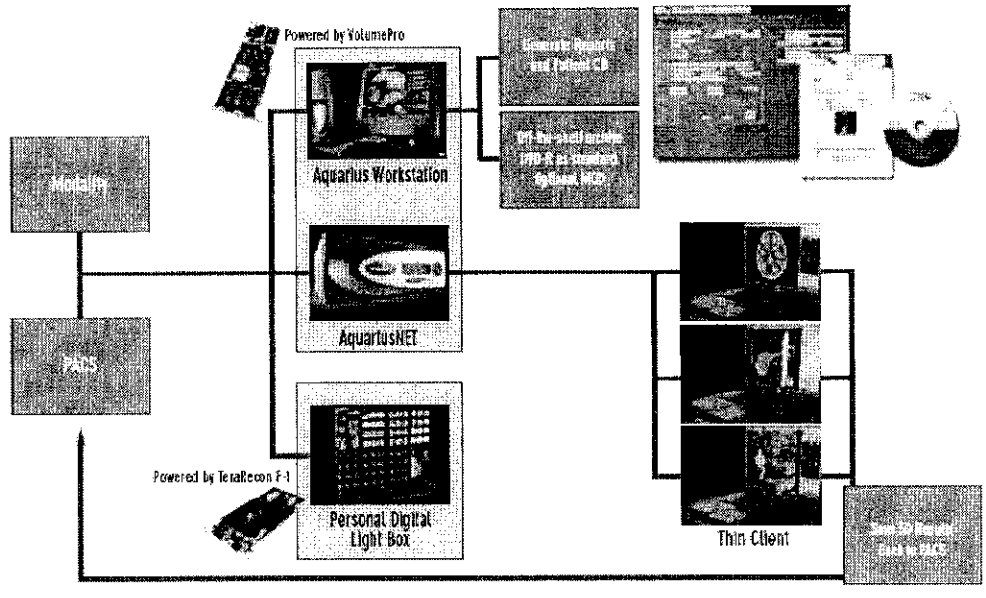
A.1.9 Substantial Equivalence Comparison Chart

Annotation:

Our Visage product line consists of 2D Web based PACS software and a separate 3D Visage Server and Thin Clients to give the end user a complete 2D/3D PACS experience. The software backend of the Visage product is based on the RADIN 3.0 product that received 510(k) approval (K043483) from the FDA In 2004. RADIN 3.1 was granted 510(k) approval to Sohard AG which was acquired by Mercury Computer Systems, Inc. in 2005.

TeraRecon unites 2D/3D into one System, AquariusNet Server and Thin Clients, but has no PACS functionality. TeraRecon also provides the same Thin Client software suite on a stand- alone workstation, Aquarius Blue.



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Substantial Equivalence comparison Chart

Product	Visage PACS/CS 4.1	AquariusNet Server/Thin client	RADIN 3.0
Company Name	Mercury Computer Systems, Inc.	TeraRecon, Inc.	Mercury Computer Systems, Inc. Formally SoHard AG
510 (k) number	TBD	K012086	K043483
General			
Networking	TCP/IP	Yes	TCP/IP
Image Acquisition/Communication	DICOM Compliant	Yes	DICOM Compliant
Image file formats	DICOM 3.0	Yes	DICOM 3.0
Imaging modalities	Multi Modality	Yes	Multi Modality
Platform	PC	PC	PC
Operating System	Windows	Windows	Windows
Standard Microsoft Technology	Yes	Yes	Yes
DICOM 3.0 Compliant	Yes	Yes	Yes
Patient Demographics	Yes	Yes	Yes
DICOM Storage SCP	Yes	Yes	Yes
DICOM Storage SCU	Yes	Yes	Yes
DICOM Query/Retrieve SCU/SCP	Yes	Yes	Yes
DICOM Storage Commitment	Yes	Yes	No
HIPAA compliant	Yes	Yes	Yes
Secure data transmission	SSL encryption, VPN encryption	VPN, encryption	Yes
User authentication	Yes	Yes	Yes
User Account	Yes	Yes	Yes
User groups	Yes	Yes	Yes
User Levels	Yes	No	Yes
	Visage PACS/CS Online		
Scalability			
Concurrent user model	Yes	Yes	Yes

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Data Storage Format			
Original Format	Yes	Yes	Yes
JPEG Lossless	Yes	Yes	Yes
JPEG Lossy	Yes (5-100%)	Yes	Yes (5-100%)
Wavelet	Yes (5-100%)	Yes (0-100%)	Yes (5-100%)
Storage Space Management			
Intelligent storage management	Yes	Yes	Yes
Data Storage Device			
RAID, SAN, NAS	250GB to several TB	RAID, SAN, NAS	
DICOM Network			
DICOM Conformance	DICOM 3.0	DICOM 3.0	DICOM 3.0
Hardware and Software Requirements for server			
Hardware	PC 2x Pentium III 1,4 GHz or PC 1x Pentium IV 3GHz (Hyperthreading), >= 1GB RAM 2x 60 GB Harddisk SCSI or SATA	Workstation Latest Dell Power Solution VolumePro (Terrarecon) Graphics Board, Pentium 4 Intel processor, 2.0 GHz or faster 512MB of SDRAM system memory 120GB Hard Disk Drive storage	PC Pentium III, min 500MHz 512 MB RAM 20 GB Harddisk
Software	Windows 2003 Server Internet Explorer 6	Windows NT 4.0, Windows 2000, Win 2003	Windows 2003 Server Internet Explorer 6
Workflow Features			
DICOM report interface	Yes	Yes	Yes
File based report interface	Yes	Yes	Yes
URL interface for OEM integration	Yes	Yes	Yes

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Creation of patient media (DVD) according to DICOM standard	Yes	Yes	Yes
	Visage PACS/CS 3D Server		
Scalability	Yes	Yes	Yes
Data Storage Format			
Volume Data	Yes	Yes	
Hardware and Software Requirements			
Hardware	Minimum 2x dual core Opteron, 8GB RAM, graphic adapter 2x FX4500, 1x 160GB Harddisk	Workstation Latest Dell Power Solution VolumePro (Terarecon) Graphics Board, Pentium 4 Intel processor, 2.0 GHz or faster 512MB of SDRAM system memory 120GB Hard Disk Drive storage	Pentium 2 GHz 512 MB RAM 50-100 GB Harddisk
Software	SuSe Linux version 10.0	Windows NT 4.0, Windows 2000, Win 2003	Windows 2003 Server Internet Explorer 6
Workflow Features			
URL interface for OEM integration	Yes	Yes, added capability	Yes
	Visage PACS/CS Archive		
Storage Modules			
Harddisk RAID	Yes	Yes	
SAN systems	Yes	Yes	
NAS systems	Yes	Yes	
Data Security			
Data verification on media	Yes	No	Yes
Manipulation detection	Yes	No	Yes

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Database consistency check	Yes	No	Yes
Archive type	PACS	PACS or UNC mount point storage	PACS
Hardware and Software Requirements			
Hardware	Pentium 2 GHz 512 MB RAM 50-100 GB Harddisk	Standard Dell High Performance Product	
Software	Windows 2003 Server Internet Explorer 6	Windows NT 4.0, Windows 2000	
	Visage PACS/CS WEB Client		
Key Features			
Full DICOM images on clients	Yes	Yes	No
No Software Installation, just Internet Explorer needed	Yes	No, thin client also for 2D part. Also has activeX client that can run within IE and does not require client download.	Yes
Supported Modalities	CR, CT, DR, DS, DX, ES, GM, IO, MG, MR, NM, PT, OT, RF, RT, US, XA, XC	CR,CT,MR,DR, US, PT, NM, DX, OT, RF, SC, XF, XA	CR, CT, DR, DS, DX, ES, GM, IO, MG, MR, NM, PT, OT, RF, RT, US, XA, XC
Supported Image Types			
Greyscale, Color, Multiframe	Yes	Yes	Yes
Image Manipulation Functions			
Zoom	Yes	Yes	Yes
Quick Zoom	Yes	Yes	Yes
Magnifying glass	Yes	No	Yes
Pan	Yes	Yes	Yes
Window leveling	Yes	Yes	Yes
Edge enhancement	Yes	Yes	Yes
Grayscale inversion	Yes	Yes	Yes
Rotating, flipping	Yes	Yes	Yes

MPR, MIP	Yes	Yes	No
Measurement Functions			
Distance	Yes	Yes	Yes
Angulation	Yes	Yes	Yes
Area	Yes	Yes	Yes
Greyscale densitiy (probe)	Yes	Yes	Yes
Manual distance calibration	Yes	Yes	Yes
Cine Mode	Yes	Yes	Yes
Workflow features			
Database Filters	Yes	Yes	Yes
DICOM query/retrieve from archives and work-stations	Yes	Yes	Yes
Change user and group assignment of patients	Yes	Yes	Yes
Multiple series load-ing	Yes	Yes	Yes
Preloading of im-ages to the client	Yes	No – Not needed	Yes
Study availability status	Yes	No – if study is in the worklist it is available. Load time from PACS archive for 500 im-age CT dataset is <30 secs	Yes
Display of images together with reports	Yes	Yes	Yes
Creation and Modifi-cation of advanced report annotations	Yes	Yes	Yes
Easy integration with RIS/HIS systems	Yes	No	Yes
Windows Copy and Print Functions	Yes	Yes	Yes
DICOM print	Yes	Yes	
Hardware and Soft-ware Requirements			

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Hardware	Minimum Pentium III 500 MHz, 256 MB RAM, Standard PC graphics card 1024 * 768 true color, 2 GB Harddisk space, Network or telephone adapter	300MHz Pentium® MMX ,Standard 2D video graphics adapter	Pentium III 500 MHz, (Pentium IV 2 GHz recommended) 128 MB RAM (512 MB recommended) Standard PC graphics card, 1024 * 768 minimum resolution 2 GB Harddisk Network or telephone adapter
Software	Microsoft Windows 2000 or XP Internet Explorer 6.0	Windows 2000, NT, XP, or 98 , Win 2003	Microsoft Windows 2000 or XP Internet Explorer 5.5 or 6.0
Additional Features			
Multiple Monitor Support	Yes	Yes	Yes
Support for High Resolution Monitors	Yes	Yes – No upper limit	
	Visage PACS/CS 3D Thin Client		
Key Features			Thin Client Not supported by RADIN
Supported Modalities	CT, MR, PT	CT, MR, PT, US, CR, DR, XA, NM, FL	CT, MR, PT
Supported Image Types			
Greyscale	Yes	Yes	
Image Manipulation Functions			
Zoom	Yes	Yes	
Pan	Yes	Yes	
Window leveling	Yes	Yes	
Grayscale inversion	Yes	Yes	
3D Volume Navigation	Yes	Yes	
MPR, MIP	Yes	Yes	
Measurement Functions			

Distance	Yes	Yes	Yes
Angulation	Yes	Yes	Yes
Area	Yes	Yes	Yes
Greyscale density (probe)	Yes	Yes	Yes
Annotations	Yes	Yes	Yes
Cine Mode	Yes	Yes	Yes
Workflow features			
Database Filters	Yes	Yes	
DICOM query/retrieve from archives and work-stations	Yes	Yes	
Multiple series load-ing	Yes	Yes	
Easy integration with RIS/HIS systems	Yes	No	
Windows Copy and Print Functions	Yes	Yes	
result image export	Yes	Yes	
predefined protocols and layouts for each modality and screen setup	Yes	Yes	
User defined color and 3D rendering schemes	Yes	Yes	
Large Vessel Ap-plication			
Freehand cropping and patient table removal	Yes	Yes	
Curved reformatting	Yes	Yes	
Semi-automatic large vessel seg-mentation	Yes	Yes	
Quick navigation along vessels	Yes	Yes	
Easy measurement of vessel cross sec-tion	Yes	Yes	
PET/CT and NM Application			
Optimized for com-bined PET/CT mo-dalities	Yes	Yes	

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Predefined PET/CT protocols and NM colormaps	Yes	Yes	
MPR and VRT fusion display, inverse MIP	Yes	Yes	
Manual correction of spatial registration	Yes	Yes	
Hardware and Software Requirements			
Hardware	The thin client runs on any x86 compatible processor supporting the MMX instruction set (e.g. Intel Pentium I MMX, AMD K6, or higher).	300MHz Pentium® MMX ,Standard 2D video graphics adapter	
Software	Microsoft Windows 2000 or XP	Windows 98, NT, 2000, XP, Win 2003	
Advanced 3D Visualization Features			
3D and 4D Navigation	Yes	Yes	
Orthogonal and perspective viewing projection	Yes	Yes	
VRT, SVRT	Yes	Yes	
Cropping and clipping	Yes	Yes	
Additional Features			
Mulitple Monitor Support	Yes	Yes	

Hardware and Software Requirements			
Hardware	Pentium 2 GHz 512 MB RAM 50-100 GB Harddisk	Standard Dell High Performance Product	
Software	Windows 2003 Server Internet Explorer 6	Windows NT 4.0, Windows 2000	
	Visage PACS/CS WEB Client	**AquariusNet Server/Thin client**	**RADIN 3.0**
Key Features			
Full DICOM images on clients	Yes	Yes	
No Software Installation, just Internet Explorer needed	Yes	No, thin client also for 2D part. Also has activeX client that can run within IE and does not require client download.	Yes
Supported Modalities	CR, CT, DR, DS, DX, ES, GM, IO, MG, MR, NM, PT, OT, RF, RT, US, XA, XC	CR,CT,MR,DR, US, PT, NM, DX, OT, RF, SC, XF, XA	CR, CT, DR, DS, DX, ES, GM, IO, MG, MR, NM, PT, OT, RF, RT, US, XA, XC
Supported Image Types			
Greyscale, Color, Multiframe	Yes	Yes	Yes
Image Manipulation Functions			
Zoom	Yes	Yes	Yes
Quick Zoom	Yes	Yes	Yes
Magnifying glass	Yes	No	Yes
Pan	Yes	Yes	Yes
Window leveling	Yes	Yes	Yes
Edge enhancement	Yes	Yes	Yes
Grayscale inversion	Yes	Yes	Yes
Rotating, flipping	Yes	Yes	Yes
MPR, MIP	Yes	Yes	No
Measurement Functions			
Distance	Yes	Yes	Yes
Angulation	Yes	Yes	Yes
Area	Yes	Yes	Yes
Greyscale densitiy (probe)	Yes	Yes	Yes
Manual distance calibration	Yes	Yes	Yes
Cine Mode	Yes	Yes	Yes
Workflow features			
Database Filters	Yes	Yes	Yes
DICOM query/retrieve from archives and workstations	Yes	Yes	Yes

A.1.10Safety and Effectiveness

A.1.10.1 General Safety and Effectiveness Concerns

VISAGE PACS/CS is a medical device that is to be used by trained health care professionals who are responsible for the correct and accurate use of medical images e.g. as a means for providing diagnosis.

The device labeling contains instructions for use and the intended use/indications for use. Warnings, faults etc are explained in the users manual.

Data that are compressed are properly identified in the image information as being compressed as specified by the DICOM standard. This compression identification remains with the image for the entire life of the image. The correctness of the compression 3rd party software is validated by the testing routine for 3rd party components during the system/integration test.

A.1.10.2 Validation and Effectiveness

The VISAGE PACS/CS risk analysis has been performed to identify all potential safety or health hazards during system operation. The hazards are controlled by a risk management plan, including hazard analysis, verification and validation tests (according to our software development process) and evaluations by hospitals.

According to our risk analysis and risk management there are no software components within the VISAGE PACS/CS Software, whose failure or latent design flaw would be expected to result in death or injury to a patient.

Requirement tracing covering specification, design, implementation and verification/validation ensures the fulfillment of all phase requirements, EHR and DMR ensures direct access to all documents.

Integration test plan defines full testing at integration and system testing level. According to this test plan integration and system testing including full testing of hazard mitigation has been performed.

Decision Reviews at the conclusion of each software development phase ensure the fulfillment of the phase results and the validity of the Intended Use and the risk analysis.

Testing is an integral part of our Software Design Process.

A.1.10.3 Substantial Equivalence

Any differences between the VISAGE PACS/CS Software and the substantially equivalent device have no significant influence on safety and effectiveness.

A.1.10.4 Technological characteristics

VISAGE PACS/CS is a stand-alone software package used on general purpose hardware, as long as the minimum hardware requirements specified in the manuals are met.

It is based upon standard Microsoft™ technology.

The device does not contact the patient, nor does it control any life sustaining devices.

A physician, providing ample opportunity for competent human intervention interprets images and information delivered by VISAGE PACS/CS.

A.1.10.5 Conclusion

We believe that the 510(k) premarket notification contains adequate information and data to enable FDA to determine substantial equivalence to the predicate device.

VISAGE PACS/CS has been and will be manufactured in accordance with the mandatory and voluntary standards listed in this submission.

This submission contains the result of the hazard analysis and all potential hazards have been classified as minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT 27 2006

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Official Correspondent
Mercury Computer Systems, Inc.
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CHELMSFORD MA 01824-2820

Re: K062490
Trade/Device Name: VISAGE PACS/CS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 24, 2006
Received: August 31, 2006

Dear Mr. Glasheen:

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 (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 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 this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 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

Section D: Statement of Indications for Use

Amended Version 1: Indication for Use
Amendment Date: 17 Oct 2006

510(k) Number: **K062490**
Device Name: VISAGE PACS/CS
Indications for Use:

Visage PACS/CS: is a system for distributing, viewing, and processing medical images and reports within and outside health care environments. It is to be used only by trained and instructed health care professionals. Visage PACS consists of the following components:

Visage PACS Storage: Visage PACS Storage offers an archiving option for long-term storage of image data

Visage PACS Web: Data that are stored on the Visage PACS Storage server can be accessed simultaneously by multiple web-based viewing stations within or outside a healthcare enterprise through web clients.

Visage CS: Visage CS is a client server system that uses thin client technology for distribution of 3D image data generated from image data of state-of-the-art scanning modalities

Integration with other hospital information systems (HIS, RIS, CIS) is provided via special interfaces.

Prescription Use ✓

David A. Lyerman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062490