K082269

E. 510(k) Summary

DEC 12 2008

E.1 Company Identification

Company Contact:	VISAGE IMAGING, INC 1815 ASTON AVENUE, SUITE 107 CARLSBAD, CALIFORNIA, 92008 UNITED STATES OF AMERICA
Registration No.:	3000131217
Owner/Operator No.:	9040273

E.2 Official Correspondent

Name/Contact:	Stefan Strowich Lepsiusstrasse 70 12163 Berlin Germany Tel.: +49 30 70096841 Fax: +49 30 70096811

E.3 Date of Submission

August 8, 2008

E.4 Device Name

Trade name:	VISAGE PACS/CS
Release Version:	6.0 / 3.1
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
Previous 510(k) No.:	K072205

E.5 Substantial Equivalence

The Visage PACS 6.0/CS 3.1 Software is substantially equivalent, in the opinion of Visage Imaging Inc., to:

Trade name:	Visage PACS/CS 5.0
510(k) No.:	K072205
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
USATrade name:	Aquarius Workstation
510(k) No.:	K011142
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
Manufacturer:	TeraRecon, Inc. 200 Gregory Lane, Suite C-100 Pleasant Hill, CA 94523-3389 USA

E.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
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 enterprise. 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.

Since version VISAGE PACS/CS 5.0 the presentation of the versions of the main components has been changed to the new form VISAGE PACS *(version number)*/CS *(version number)*. This change only adheres to the brand name and does not involve any technical changes of the version. In case of VISAGE PACS/CS 5.0 the brand name changes into VISAGE PACS 5.0/CS 2.2. All new versions now contain the same format as the current version is VISAGE PACS 6.0/CS 3.1.

E.6.1 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.

E.6.2 Description of Modification

This is to describe the significant changes in VISAGE PACS 6.0/CS 3.1.
The new version of the software provides the user with addition and improved functions in the cardiac analysis, oncology, and neuro option.
In the cardiac option the user can now automatically remove the chest wall, manually rotate the valve plane of the LV and identify the extent of calcified plaque in coronary arteries.
In the oncology option the user can now calculate standard uptake values based on data from PET-CT and has a streamlined workflow for lesion analysis.
In the neuro option the user now has a time-value curve in multiphase studies, can perform a brain perfusion analysis, and can mirror the region of interest for a brain symmetry analysis.
Beside these changes the performance of segmentation and removal tools has been improved.
There are also some general improvements regarding the computation performance of the application. It has also been updated to be fully compliant with the operating system Microsoft Vista.
A detailed list of all new features and performances is given in chapter N of this submission.

E.7 Intended Use

Visage PACS/CS is a system for distributing, viewing, processing, and archiving medical images within and outside health care environments.

The **Visage PACS/CS** server receives image data in DICOM format via the hospital network. This provides universal connections to archives, modalities, and workstations.

The supported modalities are listed in the DICOM Conformance Statement.

Visage PACS/CS is to be used only by trained and instructed health care professionals. It 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.

Only DICOM for presentation images can be used on an FDA approved monitor for mammography for primary image diagnosis.

Only uncompressed or non-lossy compressed images must be used for primary image diagnosis in mammography.

E.8 Safety and Effectiveness

E.8.1 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 user's 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.

E.8.2 Validation and Effectiveness

The VISAGE PACS 6.0/CS 3.1 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 6.0/CS 3.1 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.

Visage Imaging has validated the software taken scanners from different manufacturers into consideration. Different models were chosen in order to achieve results independent from a specific vendor. For the validation of the software imaging data deriving from CT scanners of Siemens, Philips, and GE have been used. For the validation of the software regarding cardiac CTA imaging, data from Siemens and Philips have been used.

While different scanner models have been used for the validation the software it is intended to be used at a wider range. In order to ensure that the software can safely display and process imaging data from various vendor products only the standard DICOM data will be read out and used for further processing and display. Please refer to the attached DICOM conformity statement which provides evidence that the software is fully compatible with DICOM 3.0.

Any additional or proprietary imaging data provided by a specific manufacturer of CT scanners or any other data source will not be used by Visage PACS/CS for further processing and display.

E.9 Substantial Equivalence Comparison

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 newly introduced key features of the device can be divided into 4 sections as there are features regarding cardiac analysis options, oncology options, neuro options and other key clinical functions.

The cardiac analysis options with its new automatic chest wall removal, manual rotation of valve plane for left ventricle, computation of myocardial mass and calcium scoring applications and protocols are substantially equivalent to the Aquarius Workstation.

The automatic SUV calculation and streamlined workflow for lesion analysis within the oncology options are also equivalent to such functions of the Aquarius Workstation

New features for the neuro section like the time-value curve in multi phase studies, brain perfusion analysis and region of interest mirroring are equivalent to the Aquarius Workstation too.

There are also equivalent functions in the Aquarius Workstation for the other key clinical functions like one-click save and load of work, interactive segmentation of anatomical structures or segmentation based on advanced interpolation, improved semi-automatic segmentation tools as well as reformatted DICOM output, time-value curve in multi-phase studies, subtraction for multi phase images (CT and MR), stacked curved reformats, display of current cross section positions in CPR, semi-automatic tools for bone removal, measurement of cobb angle for multiple vertebrae, automatic dynamic protocols for viewing series side by side and multiphase studies as well as direct integration with RIS, selection and import of DICOM files and patient CDs from client computers (Cs viewer) and MPR and 3D visualization of 3D image series with gantry tilt.

E.9.1 Substantial Equivalence

Any differences between the VISAGE PACS 6.0/CS 3.1 software and the substantially equivalent device have no significant influence on safety and effectiveness.

Visage Imaging, Inc.
1815 Aston Avenue, Suite 107
Carlsbad, CA 92008
United States of America

E.9.2 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

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 2008

Mr. Stefen Strowich
Official Correspondent
Visage Imaging, Inc.
Lepsiusstrasse 70, Berlin 12163
GERMANY

Re: K082269
Trade/Device Name: VISAGE PACS 6.0/CS 3.1
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 14, 2008
Received: November 17, 2008

Dear Mr. Strowich:

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 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). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (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,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

D. Statement of Indications for Use

510(k) Number (if known): **K082269**
Device Name: **VISAGE PACS 6.0/CS 3.1**
Indications for Use:

Visage PACS/CS is a system for distributing, viewing, processing, and archiving medical images within and outside health care environments.

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

Besides general image interpretation and processing tools, Visage PACS/CS provides specific tool sets for several clinical applications, including:

- CT/MR angiography, e.g. for vascular analysis and stent planning
- Cardiac analysis, including calcium scoring and functional assessment of cardiac CT data
- Neuroradiology, including CT and MR brain perfusion analysis
- Oncology, including SUV analysis and lesion marking and analysis

Visage PACS/CS is to be used only by trained and instructed health care professionals. It 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.

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Only uncompressed or non-lossy compressed images must be used for primary image diagnosis in mammography.

Prescription Use ___X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K082269