K072205

E. 510(k) Summary

AUG 29 2007

E.1 Company Identification

Company Contact:	Mercury Computer Systems, Inc. 199 Riverneck Road Chelmsford, MA 01824-2820 United States of America
Registration No.:	3000131217
Owner/Operator No.:	9040273

E.2 Official Correspondent

Name/Contact:	David Quimby 199 Riverneck Road Chelmsford, MA 01824-2820 United States of America Tel.: 978-967-1699 Fax: 978-256-0588

E.3 Date of Submission

August 22, 2007

E.4 Device Name

Trade name:	VISAGE PACS/CS
Release Version:	5.0
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
Previous 510(k) No.:	K062490
Guidance document:	Guidance for the submission of premarket notifications for medical image management systems (issued on July 27, 2000)

E.5 Substantial Equivalence

The Visage PACS/CS 5.0 Software is substantially equivalent, in the opinion of Mercury Computer Systems Inc., to:

Trade name:	AquariusNet Server/Thin client
510(k) No.:	K012086

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.

E.6.1 Description of Modification

This is to describe the significant changes associated with the implementation of the cardiac analysis option.
With the new version of the software the user can import cardiac CT time series in order to utilize them for the LV analysis (analysis of the left ventricle).
The LV analysis tool card helps with the analysis of the left ventricle in cardiac CT time series, which show the heart in various phases of one heart beat. This toolcard guides the user through an LV analysis step by step. After the user has completed the last step the LV Results tool card is displayed as a floating window. The user can review his/her results now and export them to a report.
The LV tools support the physician in finding the left ventricle in the image data.
The LV tool card supports the user to find and display the long and short axes of the left ventricle and to segment the left ventricle. It supports the user to calculate the total volume of the left ventricle over one heart cycle, the stroke volume and the ejection fraction of the various LV regions and the accumulated wall motion.

E.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 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.

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 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.

Substantial Equivalence comparison chart regarding the modification:

	SE-DEVICE	PREDICATE DEVICES	
Product	**Visage PACS/CS 5.0**	**Visage PACS/CS 4.1**	**AquariusNet Server/Thin client**
Company Name	Mercury Computer Systems, Inc.	Mercury Computer Systems, Inc.	TeraRecon, Inc.
510 (k) number	TBD	K062490	K012086
New Features in Version 5.0			
Cardiac Analysis Option			
Volume measurements	Yes	No	Yes
Semi-automatic coronary artery segmentation	Yes	No	Yes
Coronary artery navigation and measurement	Yes	No	Yes
Functional analysis of the left ventricle (wall motion, ejection fraction)	Yes	No	Yes
Additional Features			
Vessel segmentation tool with increased specificity and improved performance	Yes	No	Yes
Fusion and side-by-side registration as separate concepts	Yes	No	Yes
Pixel probing support in fusion mode	Yes	No	Yes
Change of algorithm for curved slices	Yes	No	Yes
Automatic generation of thick slices	Yes	No	Yes
Improved bone removal for CT runoff studies	Yes	No	Yes

	SE-DEVICE	PREDICATE DEVICES	
Product	Visage PACS/CS 5.0	Visage PACS/CS 4.1	AquariusNet Server/Thin client
Changed curved planar reformat (CPR) viewer	Yes	No	Yes
Changed lumen view	Yes	No	Yes
4D cardiac CT data support	Yes	No	Yes
Coronary artery navigation and measurement	Yes	No	Yes
Automatic short/long axis view	Yes	No	Yes
Semi-automatic segmentation of left ventricle and coronary artery	Yes	No	Yes
Functional analysis of left ventricle	Yes	No	Yes
Volume measurement	Yes	No	Yes
Remaining feature as from K062490 see complete table in U.1			

E.9 Safety and Effectiveness

E.9.1 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.9.2 Validation and Effectiveness

The VISAGE PACS/CS 5.0 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 5.0 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.

E.9.3 Substantial Equivalence

Any differences between the VISAGE PACS/CS 5.0 Software and the substantially equivalent device have no significant influence on safety and effectiveness.

E.9.4 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.

E.9.5 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

Mercury Computer Systems, Inc.
c/o Martin Gabler
Prosystem AG
BEIM STROHHAUSE 27
HAMBURG,
GERMANY 20097

AUG 29 2007

Re: K072205
VISAGE PACS/CS 5.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 6, 2007
Received: August 8, 2007

Dear Mr. Gabler:

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

D. Statement of Indications for Use

510(k) Number (if known): _____

Device Name: VISAGE PACS/CS 5.0

Indications for 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:

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

J.Whang

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072405