FAX COVER SHEET

Voice Phone Number: 240-276-3788

FDA/Center for Devices and
Radiological Health
Office of Device Evaluation
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

TO: See addressee on next page
FROM: 510(k) Document Mail Center

Comments: Fax copy of the letter being mailed to you.

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.

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.

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)

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