Section F 510(k) Summary

SEP 30 2011

F.1 Submission Date

07/19/2011

F.2 Submitter/Owner

Computer Programs and Systems, Incorporated (CPSI)

F.2.A Owner / Operator Number

905588

F.2.B Establishment Registration Number

3004120479

F.2.C Contact Person

Michael Hunt, Software Services, CPSI

F.2.D Address

6600 Wall Street
Mobile, AL 36695

F.2.E Phone

1.800.711.2774

F.2.F Fax

251.639.8214

F.3 Device Trade Name

ImageLink

F.4 Common Name

Picture Archiving Communications System (PACS)

F.5 Classification Names

Product Code:	LLZ
Device:	System, Image Processing Radilogical
Regulation:	21 CFR 892.2050

F.6 Predicate Device

The legally marketed device to which CPSI claims equivalence is found in 510(k) number K043415 and is called Centricity PACS System, manufactured by GE Medical Systems, Information Technologies.

F.7 Device Description

ImageLink is designed to fit seamlessly into the hospital's existing IT infrastructure, integrating with the CPSI HIS/RIS systems. Patient and order information is shared with CPSI clinical applications providing real-time update of the PACS worklist and DICOM Modality Worklist files, notification of completed orders and signed transcriptions, and quick access to the study throughout the enterprise.

This product conforms to recognized industry standards such as DICOM, JPEG, ACR, and others as applicable.

Support for the following modalities will be provided:

- CR
- CT
- MR
- NM
- RF
- US
- DX
- PT
- XA
- OT
- MG

The CPSI ImageLink application software includes the following major components: ImageLink Server, ImageLink Viewer, and ImageLink/ChartLink Interface for web viewing. These software applications, combined with the hardware platform and networking infrastructure, make up the ImageLink System.

F.8 Intended Use

ImageLink™ is an integrated medical imaging solution that allows for the storage, manipulation, and annotation of high resolution digital radiological images from multiple source modalities. It enhances the efficiency of diagnostic decision making and includes a feature-rich viewer with customizable worklists and hanging protocols that can be organized to meet the unique requirements and style of the individual radiologist.

F.9 Technology

The ImageLink Server provides a scalable, storage solution for medical images. Utilizing standard DICOM communications protocols, the server accepts images stored to it from authorized modalities, and also provides these modalities with worklists. The server also provides medical image studies to the ImageLink viewer when requested.

All archived image data is preserved in the format in which is it received by the ImageLink Server. The ImageLink server employs presentation states to store any changes such as annotations, editing, or image manipulations performed on the images. All manipulations and annotations can be reversed in the system to provide the user with the original images unchanged.

The ImageLink Viewer is used to view, analyze, edit, compare, annotate, store, and

distribute images and data stored in the ImageLink server.

The ImageLink/ChartLink web interface allows the viewing of medical images from the archive, over secure web connections through the CPSI ChartLink application. The application can be accessed internally by hospital uses or with authentications, externally over the World Wide Web. The web interface is not intended for primary diagnosis.

Diagnostic workstations running the viewer must meet minimum requirements for safety, performance and effectiveness including display capabilities of no less than 3 mega pixels.

F.10 Test Summary

The design and development process of ImageLink™ complies with standards listed in section I of this submission. Further ImageLink was developed and modified with change control principles based upon 21 CFR 820.30 as specified in section Q.1. Overall Quality Assurance activities of ImageLink is furthered by adherence to the principles of Risk Analysis in ISO 14971.

F.11 Summary of Characteristics to that of the Predicate

CPSI ImageLink™ is substantially equivalent to its predicate device, GE Medical Systems, Information Technologies Centricity PACS System (K043415). Both devices are similar in intended use, device description, materials used, the target population and intended environment for use. Both devices consist of a hardware platform, server application software, image viewing software, and web tools. There are minor differences in terms of technology employed as well as minor functional differences with configurable hotkeys, integration with historical reports and voice clip. These differences do not detract from the equivalence claim.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Michael Hunt
Software Analysits, Software Services
Computer Programs and Systems, Inc. (CPSI)
6600 Wall Street
MOBILE AL 36695

SEP 30 2011

Re: K112096
Trade/Device Name: ImageLink™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 19, 2011
Received: July 22, 2011

Dear Mr. Hunt:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K112096
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Section E Indications for Use Statement

E.1 Statement

Indications for Use

510(k) Number (if known):

Device Name: ImageLink™

Indications For Use:

ImageLink™ is an integrated medical imaging solution that allows for the storage, manipulation, and annotation of high resolution digital radiological images from multiple source modalities. It enhances the efficiency of diagnostic decision making and includes a feature-rich viewer with customizable worklists and hanging protocols that can be organized to meet the unique requirements and style of the individual radiologist.

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)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112096