

K970174

FreePix DICOM/HTTP Gateway - 510(k) Summary Information

The FreePix/PixPACS ('FreePix') is a standalone gateway/server system, connected to a TCP/IP network. It performs transparent online protocol and format conversion between the DICOM 3.0 protocol/format and the HTTP/HTML protocol/format. The FreePix enables any HTTP/HTML compliant Web Browser, running on any computer platform (e.g. PC, Macintosh, UNIX), to access and display image and archive data obtained from DICOM 3.0 compliant systems connected on the same network.

The Intended Use of this device is "to allow standard Web Browsers or DICOM devices, connected via LAN or WAN, to access and view DICOM images stored on a central DICOM 3.0 archive".

The FreePix system normally consists of a standard IBM-compatible PC (e.g. Pentium Pro 200 MHz CPU with 32 MB RAM, 2 GB HDD, optional 9 GB HDD), using off-the-shelf components, running the Linux/UNIX 2.x OS (operating system).

In addition to the basic OS, the FreePix configuration consists of an off-the-shelf Web Server package (httpd), an off-the-shelf SQL-based relational database engine and the Mallinckrodt Institute of Radiology (MIR) based DICOM 3.0 server.

The proprietary software of the FreePix consists of relatively small DICOM-to-Web CGI programs which interface the Web clients to the database engine via the MIR based DICOM package, as well as a set of user configuration and authentication utilities to enforce customizable access control.

Note that the off-the-shelf Web Browsers (and/or the computers they run on) needed to actually view images are not manufactured by PixeLinks and are not part of this submission.

The FreePix server system is tested prior to use by utilizing a standard set of test data, i.e. DICOM images from multiple modalities obtained from various medical imaging manufacturers. This data set, maintained on a CD-ROM, is sent to the FreePix via a DICOM C-Store ('push') operation on the TCP/IP LAN, is stored by the FreePix on its local archive, and is subsequently retrieved for viewing by LAN based Web Browsers. Any error whatsoever, encountered during the data push or retrieve phases, indicates a fault which must be identified and corrected prior to actual use. These tests can be conveniently re-performed at any stage during product development, manufacturing, installation and post-installation maintenance to verify the proper performance of the hardware and software of the FreePix.

Virtually all modern, LAN based, medical imaging clinics can be selected as predicate devices for the FreePix and its related (but not submitted) client systems. As a typical

example, we selected the configuration of the GE CT HiLight with an independent remote viewing station (when used for viewing and not post-processing).

Table - Comparison between FreePix and SE Device

Feature	CT HiLight + Viewing	FreePix + Web Browsers
LAN	TCP/IP, Ethernet	TCP/IP, Ethernet
Protocol	GE, DICOM 3.0	DICOM 3.0, HTTP
Catalogs	Patient, Study, Series, Image	Patient, Study, Series, Image
Image Depth (in bits)	Raw image 16, display 8	Raw image 16 (max), display 8
Windowing	Local at Viewing Station	performed by FreePix server
Processing	Yes	viewing only
Image size (max)	1024x1024 special mode 512x512 standard mode	512x512, 1024x1024 or other
Local Storage	Yes	Yes

Based on the above comparison, it is our opinion that in terms of safety and effectiveness, the configuration of the FreePix gateway/server coupled with the DICOM 3.0 data source and HTTP/HTML viewing station on a TCP/IP LAN is substantially equivalent to the configuration when viewing (non-processing) is performed on an independent viewing station coupled with the scanner of the predicate device, or generically viewing patient or image data using the standard viewing stations attached to the existing digital imaging modalities.

Contact Information:

PixLinks Inc, Attention: S. Beer

35 Airport Rd., Suite 310, Morristown, NJ 07960, Tel: 1-201-267-2341

Device Name(s): FreePix DICOM to HTTP Gateway, PixPACS