

1. 510(k) Summary

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[As required by 21 CFR 807.92(c)]

NOV - 7 1996

K 963628

1.0 Submitter Information

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1.3 Date Prepared: 9 Sept 1996

2.0 Device Identification

- 2.1 Trade Name: Imageshare Computed Radiography Acquisition Station and/or Software
- 2.2 Common Name: Gateway to Digital Imaging Network
- 2.3 Classification Name: System, Digital Image Communication, accessory

3.0 Predicate Devices

Imageshare 910
Fuji Computed Radiography DMS CRT Image Console HI-C654™
CEMAX ScanLink IV™ QA Station
Analogic SD100 CR Gateway

4.0 Device Description

4.1 Function:

The Imageshare Computed Radiography Acquisition Station and/or Software is designed to operate on a general purpose computer system running an image acquisition software application to receive, reformat and transmit image and demographic information. The system receives the image messages from a Computed Radiography or other image source and routes them automatically through a conversion to a destination based on information contained in the message source, encoded data or data entered by an operator through a user interface. The Imageshare Computed Radiography Acquisition Station stores the data on its local hard disk until the destination application acknowledges the successful transmission. Image delivery is also guaranteed when the Imageshare Computed Radiography Acquisition Station loses power and is restarted.

4.2 Physical and Performance Characteristics:

The Imageshare Computed Radiography Acquisition Station and/or Software is designed to run on off-the-shelf, general purpose computing equipment. The application software is designed for maximum portability across operating systems and hardware platforms. Performance of the application software is primarily a function of network load; secondarily a function of the hardware platform's computational speed. Intrinsic performance of the application does not change significantly as it is ported from one operating system to another.

FDA/CDR/11443
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5.0 Intended Use:

The Imageshare Computed Radiography Acquisition Station and/or Software is a uni-directional gateway that receives digital images from various image sources (including, but not limited to, Fuji CR, Fuji HI-C654, Analogic Corporation's DASM, Computed Radiography or Direct Radiography devices). The incoming data formats may be raw CR data, processed CR data or data formats proprietary to the modality source vendor. The Imageshare Computed Radiography Acquisition Station and/or Software converts the data to DICOM, ACR-NEMA v2.0, SPI format or other proprietary data format and transmits the data to one or more user-specified nodes across a standard, general purpose computing network.

6.0 Statement of Substantial Equivalence:

The Imageshare Computed Radiography Acquisition Station and/or Software is substantially equivalent to previously marketed devices (as listed above in Part 3) in design, composition, function, intended use, safety and efficacy. No new issues of safety and effectiveness are raised.

Any differences between the Imageshare Computed Radiography Acquisition Station and the predicate devices have no significant influence on safety or efficacy.