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1. 510(k) Summary

K963592

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[As required by 21 CFR 807.92(c)]

1.0 Submitter Information

1.1 DeJarnette Research Systems
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1.3 Date Prepared: 6 September 1996

2.0 Device Identification

2.1 Trade Name: Imageshare Protocol Converting Gateway 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 (DeJarnette Research Systems, Inc.)

Merge MVP (Merge Technologies, Inc.)

4.0 Device Description

4.1 Function: The Imageshare Protocol Converting Gateway is a general purpose computer system running a protocol conversion software application that uses defined configuration to receive, reformat and transmit image and demographic information. The system receives the image messages from a source and routes them automatically them through a conversion to a remote destination based on information contained in both the message source and encoded data. The system requires no user interaction when in operation. The Imageshare Protocol Converting Gateway stores the image data on its local hard disk until the destination application acknowledges the successful transmission. Images that are not delivered to their destination are queued for retransmission until the remote destination confirms receiving the message. This is also true when the Imageshare Protocol Converting Gateway loses power and is restarted.

The Imageshare Protocol Converting Gateway is adaptable to various PACS environments. The configuration can be modified by the system administrator to adapt the Imageshare Protocol Converting Gateway to perform the desired supported conversions.

4.2 Physical and Performance Characteristics:

The Imageshare Protocol Converting Gateway is designed to run on off-the-shelf, general purpose computing equipment. The application software is designed for maximum portabililty 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.

5.0 Intended Use:

The Imageshare Protocol Converting Gateway and/or Software is a uni-directional (or optionally, bi-directional) gateway that receives digital images from various image sources (including, but not limited to, CT scanners, MR scanners, Ultrasound systems, R/F units, Computed and Direct Radiography devices, secondary capture devices, imaging gateways, or other imaging sources). The incoming data formats are DICOM, ACR-NEMA v2.0, SPI (Standard Product Interconnect) or proprietary to the modality source vendor. The Imageshare Protocol Converting Gateway converts them into DICOM, ACR-NEMA v2.0, SPI format or 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 Protocol Converting Gateway 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.

Any differences between the Imageshare Protocol Converting Gateway and/or Software and the predicate devices have no significant influence on safety or efficacy.