1. 510(k) Summary

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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 Sept 1996

2.0 Device Identification

2.1 Trade Name: Imageshare Secondary Capture 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™ (DeJarnette Research Systems, Inc.)

Imaging Workbench™ (BRIT Systems, Inc.)

FISS™ (Star Technologies, Inc.)

RadWorks™ (Applicare Medical Imaging B.V.)

4.0 Device Description

4.1 Function:

The Imageshare Secondary Capture Acquisition Station is 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 source (film digitizer, video source, ultrasound, print output, etc.) and routes them automatically through a conversion to a destination based on information contained in the message source, encoded data and data entered by an operator through a user interface. The Imageshare Secondary Capture Acquisition Station stores the data on its local hard disk until the destination application acknowledges the successful transmission. Images not delivered to their destination are queued for retransmission until the remote destination confirms receipt of the message. Image delivery is also guaranteed when the Imageshare Secondary Capture Acquisition Station loses power and is restarted.

The Imageshare Secondary Capture Acquisition Station is adaptable to various PACS environments. The configuration can be modified by the system administrator to adapt the Imageshare Secondary Capture Acquisition Station to perform functions specific to the site.

4.2 Physical and Performance Characteristics:

The Imageshare Secondary Capture 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, and finally the limitation of the image capture device. 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 Secondary Capture Acquisition Station and/or Software is a uni-directional gateway that receives digital or analog images from various image sources (including, but not limited to, film digitizers, video signal outputs or print output from imaging modalities, or other imaging sources). The incoming data formats are bitmapped, raster images or proprietary to the modality source vendor. The Imageshare Secondary Capture 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 Secondary Capture 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.

Any differences between the Imageshare Secondary Capture Acquisition Station and/or Software and the predicate devices have no significant influence on safety or efficacy. No new issues of safety and effectiveness are raised.