1. 510(k) Summary

510(k) Summary

[As required by 21 CFR 807.92(c)]

1.0 Submitter Information

1.1 DeJarnette Research Systems
401 Washington Avenue Suite 700
Towson MD 21204

1.2 Contact: Eric John Finegan
Voice: +1 (410) 583 - 0680
Fax: +1 (410) 583 - 0696
E-mail: info@dejarnette.com

1.3 Date Prepared: 8 Sept 1997

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 Computed Radiography Acquisition Station and/or Software
[DeJarnette Research Systems, Inc.]

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 or configured 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.

5.0 Intended Use:

The Imageshare Computed Radiography Acquisition Station and/or Software is a bi-directional gateway that sends or receives digital images to/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 device have no significant influence on safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Eric John Finegan
Regulatory Manager
DEJARNETTE Research Systems
401 Washington Avenue
Suite 700
Towson, MD 21204

Re: K973421
Imageshare Computed Radiography
Acquisition Station and/or Software
Dated: September 8, 1997
Received: September 10, 1997
Unclassified/Procode: 90 LMD

DEC - 5 1997

Dear Mr. Finegan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Statement of Indications for Use

Device: Imageshare Computed Radiography Acquisition Station and/or Software

Statement of Indications for Use

[As required by 21 CFR 801.109]

The Imageshare Computed Radiography Acquisition Station and/or Software is a bi-directional gateway that sends or receives digital images to/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.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K913462

Prescription Use HRS OR Over-The-Counter Use _____
(Per 21 CFR 801.109)