

K974130

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
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1.3 Date Prepared: 30 October 1997

2.0 Device Identification

2.1 Trade Name: VisiShare Imaging System and/or Software
2.2 Common Name: Digital Imaging Communication System
2.3 Classification Name: System, Digital Image Communication

3.0 Predicate Devices

MagicView 50 Teleradiology System [Siemens]
RadWorks Medical Imaging Software [Applicare Medical Imaging, B.V.]
AutoRad [Cemax-Icon]

4.0 Device Description**4.1 Function:**

The VisiShare Imaging System is designed to accept images from various modalities or digital image networks and allow the operator to view, retrieve, store and manipulate medical images in a variety of formats.

The VisiShare is a modular system that uses network and proprietary interfaces for communication between the modules. Network interfaces enable the various modules to reside on local or remote machines. System is designed for low-end and high-end systems, supporting single or multiple monitor configurations.

4.2 Physical and Performance Characteristics:

The VisiShare Imaging System 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 performance of the display controller. Intrinsic performance of the application does not change significantly as it is ported from one operating system to another.

5.0 Intended Use:

The VisiShare Imaging System and/or Software is a digital imaging viewing system that receives digital images and patient demographic information from various imaging sources. The incoming data formats are standard medical image formats, proprietary image formats, and common non-medical image formats. The VisiShare allows the operator to manage, view, retrieve and store images, modify image parameters and annotate image for the purposes of radiological interpretation.

6.0 Statement of Substantial Equivalence:

The VisiShare Imaging System and/or Software is substantially equivalent to the previously marketed devices (as listed above in Part 3) in design, composition, function, intended use, safety and efficacy.

Any differences between the VisiShare Imaging System and/or Software and the predicate devices have no significant influence on safety or efficacy.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 1998

Eric John Finegan
Regulatory Manager
DeJarnette Research Systems, Inc.
401 Washington Avenue, Suite 700
Towson, Maryland 21204

Re: K974130
Visishare Imaging System and/or
Software
Dated: October 31, 1997
Received: November 3, 1997
Regulatory class: Unclassified
Procode: 90 LMD

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 that, 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, 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: VisiShare Imaging System and/or Software

Statement of Indications for Use

[As required by 21 CFR 801.109]

The VisiShare Imaging System and/or Software is a digital imaging viewing system that receives digital images and patient demographic information from various imaging sources. The incoming data formats are standard medical image formats, proprietary image formats, and common non-medical image formats. The VisiShare allows the operator to manage, view, retrieve and store images, modify image parameters and annotate image for the purposes of radiological interpretation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. DeGroot

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number: K974130

Prescription Use (Per 21 CFR 801.109)

OR

Over-The-Counter Use