K050667

MAR 2 9 2005

Section B-I Summary

510(k) Summary
Prepared February 7, 2005

Submitted by: R2 Technology, Inc.
1195 W. Fremont Avenue
Sunnyvale, CA 94087

Contact Person: Richard Ball, Director of Regulatory Affairs

Product Name: R2 Family of Image Display Units with
R2 Uniform Display Software (UDS)

Common Name: Medical Imaging Workstation

Classification: LLZ; Class II; CFR 21 892.2050

Predicate Devices:

K023003	R2 CT ImageChecker for CT
K042697	ICAD Second Look Viewer
K031248	MiraMedica Consultiva
K800751	RadX, Mammolux Changers

Description of Device:
The R2 family of Image Display Units are a combination of dedicated computer software and hardware. The System uses an off-the-shelf personal computer with Windows-based CPUs, a hard drive, and various sizes of off the shelf monitors. Despite the variability in physical dimensions, all monitor display units have the identical functional specifications.
R2 Uniform Image Display Software (UDS) is provided with all R2 image display units. This version of display software provides an updated user interface and CAD mark display features

Intended Use:
The family of R2 Image Display Units with UDS software is intended to display low resolution, non-diagnostic medical images with annotations such as pre-computed regions-of-interest or pre-computed CAD marks from medical scanning devices.

Comparison with Predicate Devices:
The Submission device and the predicate devices have the same intended use and equivalent technological specifications. All devices support DICOM protocol for communication of images and other medical imaging devices.

Studies:
The family of Image Display Units with UDS Software will undergo design verification tests for conformance with specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2005

R2 Technology, Inc.
% Mr. Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
Underwriters Laboratories, Inc.
1655 Scott Boulevard
SANTA CLARA CA 95050-4169

Re: K050667
Trade/Device Name: R2 Family of Image Display Units with Uniform Display Software (UDS)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 10, 2005
Received: March 15, 2005

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section B-II Indications For Use

Device Name: R2 Family of Image Display Units with
R2 Uniform Display Software (UDS)

The family of R2 Image Display Units with UDS software is intended to display low resolution, non-diagnostic medical images with annotations such as pre-computed regions-of-interest or pre-computed CAD marks from medical scanning devices.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

/Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050667