K071492

3.0 510(K) SUMMARY

AUG 2 8 2007

Submission Date: May 25, 2007

Submitter Information:

Company Name: Riverain Medical Group, LLC.

Company Address: 3020 South Tech Blvd., Miamisburg, OH 45342-4860

Contact Person: Jennifer Steinke
Director, Regulatory Affairs and Quality Assurance
Riverain Medical
800.990.3387
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Device Information:

Trade Name: FirstView™

Common Name: System, Image Processing, Radiological

Classification Name: Picture archiving and communications system

Device Class: Class II, 21 CFR §892.2050

Predicate Devices:

R2 Breast Imaging Workstation (K051743)
R2 TECHNOLOGY, INC
Class II

Centricity PACS System (K043415)
GE Medical Systems
Class II

Platinum Reading, Review, and Analysis Workstation (K981217)
GE Medical Systems
Class II

Device Description:

The FirstView™ consists of a dedicated server that has been programmed with a database and server software, as well as client software that is loaded onto an existing workstation. New images, which may be a chest x-ray or CAD result, are sent to the FirstView™ server from a DICOM-compliant device, such as the RS-2000D or RS-

Digital or from the PACS network, prompting FirstView to query the PACS for additional images related to that study. The FirstView™ server manages the images within its Riverain proprietary database.

Intended Use: The FirstView™ is intended to display and manipulate x-ray images.

Indications for Use: The FirstView™ is indicated for displaying and manipulating chest x-ray images. It acts as an interface with the CAD component, if installed or available at the clinical site, and provides display of information contained within the DICOM header of the images. This device is intended to be used by trained professionals, such as physicians, radiologists, and technicians.

Comparison to Predicate Device:

FirstView™ is substantially equivalent to the cited predicate devices. Differences in the design and performance from the cited predicate devices do not affect either the safety or effectiveness of the FirstView™ for its intended use.

Conclusion: FirstView™ has the same intended use and technology as the legally-marketed predicate devices. Riverain Medical Group, LLC, has determined that the FirstView™ is as safe and effective as the predicate devices that have been identified in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Jennifer Steinke
Director, Regulatory Affairs and Quality Assurance
Riverain Medical Group, LLC
3020 South Tech Blvd.
MIAMISBURG OH 45342-4860

AUG 2 8 2007

Re: K071492
Trade/Device Name: FirstView™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 1, 2007
Received: August 2, 2007

Dear Ms. Steinke:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (240) 276-3150
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

2.0 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K071492

Device Name: FirstView™

Indications for Use:

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

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071492