K123526

DEC 27 2012

3.0 510(K) SUMMARY

Submission Date: November 15, 2012

Submitter Information:

Company Name: Riverain Technologies, LLC.

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Riverain Technologies
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Device Information:

Trade Name: ClearRead +Confirm™
Regulation Number: 21 CFR §892.2050
Regulation Name: System, Image Processing, Radiological
Regulatory Class: Class II
Product Code: LLZ

Predicate Devices: ClearRead Bone Suppression (SoftView)
(K092363)
Riverain Technologies, LLC
Class II

DRX-Revolution
(K120062)
Carestream Health, Inc.
Class II

Device Description: ClearRead +Confirm is a dedicated post-processing application that generates an enhanced, secondary digital radiographic image of the chest to facilitate confirmation of line/tubes.

Intended Use: ClearRead +Confirm is intended to generate an enhanced, secondary digital radiographic image of the chest to facilitate confirmation of line/tubes.

Indications for Use:

ClearRead +Confirm is intended to generate an enhanced, secondary digital radiographic image of the chest to facilitate confirmation of line/tubes. The enhanced AP or PA image of the chest provides improved visibility of lines and tubes. The ClearRead +Confirm image provides adjunctive information and is not a substitute for the original PA/AP image. This device is intended to be used by trained professionals, such as physicians, radiologists, and technicians, on patients with lines and tubes and is not intended to be used on pediatric patients.

Comparison to Predicate Devices Technical Characteristics:

ClearRead +Confirm uses the same bone suppression mechanism as the Riverain ClearRead Bone Suppression predicate device, with enhancements to improve the visibility of lines and tubes. ClearRead +Confirm and ClearRead Bone Suppression also share a common user platform for DICOM communication and system configuration.

ClearRead +Confirm and the Carestream DRX-Revolution are similar in that both include software with the ability to enhance lines and tubes on AP/PA chest radiographs.

Differences in the design and performance from the cited predicate devices do not affect either the safety or the effectiveness of ClearRead +Confirm for its intended use.

Testing Summary:

Functional verification testing and development validation were conducted to verify that the design output met the design input requirements. Documentation outlining the functional verification testing of the ClearRead +Confirm software (E030-D V&V Test Plan and E032-A V&V Test Report) is provided in Appendix B.

Clinical validation was conducted in a multi-reader multi-case (MRMC) study to validate that the device conformed to the defined user needs and intended uses. The reader study measured the reduction in time required by the radiologists to localize the tips of tubes, lines, and electrical cardiac wires (TLW) when using ClearRead +Confirm. The study also measured the radiologists' accuracy in localizing the TLW when using ClearRead +Confirm. ClearRead Confirm was found to significantly decrease read times in analyses both including and excluding outliers. The

difference from true locations in ClearRead Confirm reads and unaided reads were not found to be statistically significant. The results indicated that ClearRead +Confirm is a useful adjunct for the interpretation of chest radiographs when looking for TLW. Documentation of clinical validation testing in the ClearRead +Confirm Reader Study (E045-A Protocol and E046-A Report) is provided in Appendices C and D.

Substantial Equivalence: The reader study described above used similar methods to the reader study that was reviewed by FDA when clearing the ClearRead Bone Suppression predicate device (K092363). In both cases, an image processing application generates a secondary image for the radiologist to view. Both devices enable reviewing, storing, printing, and distribution of DICOM-compliant images across hospital networks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 27,2012

Ms. Jennifer Butsch
Director Regulatory Affairs & Quality Assurance
Riverain Technologies
3020 South Tech Blvd.
MIAMISBURG, OH 45324

Re: K123526
Trade/Device Name: ClearRead +Confirm 1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: LLZ
Dated: November 15, 2012
Received: November 15, 2012

Dear Ms. Butsch:

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 (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Michael D. O'Hara

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123526

Device Name: ClearRead +Confirm™

Indications For Use:

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

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) K123526