DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 9, 2016

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

Re: K161201
Trade/Device Name: ClearRead CT
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: OEB, LLZ
Dated: September 6, 2016
Received: September 7, 2016

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161201

Device Name
ClearRead CT

Indications for Use *(Describe)*

ClearRead CT™ is comprised of computer assisted reading tools designed to aid the radiologist in the detection of pulmonary nodules during review of CT examinations of the chest on an asymptomatic population. The ClearRead CT requires both lungs be in the field of view. ClearRead CT provides adjunctive information and is not intended to be used without the original CT series.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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1.0 510(K) SUMMARY

Submission Date: April 25, 2016

Submitter Information:

Company Name: Riverain Technologies, LLC.

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

Contact Person: Jennifer Butsch
Director, Regulatory Affairs and Quality Assurance
Riverain Technologies
800.990.3387
937.425.6493
jbutsch@riveraintech.com

Device Information:

Trade Name: ClearRead CT ™
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: OEB/LLZ

Device Description: ClearRead CT is a dedicated post-processing application that generates a secondary vessel suppressed Lung CT series with CADe marks and associated region descriptors intended to aid the radiologist in the detection of pulmonary nodules.

Indications for Use: **ClearRead CT™** is comprised of computer assisted reading tools designed to aid the radiologist in the detection of pulmonary nodules during review of CT examinations of the chest on an asymptomatic population. The ClearRead CT requires both lungs be in the field of view. ClearRead CT provides adjunctive information and is not intended to be used without the original CT series.

Predicate Devices: syngo.CT Lung CAD
(K143196)
Siemens AG Medical Solutions
Class II

syngo.PET&CT Oncology
(K093621)

Siemens AG Medical Solutions
Class II

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

Comparison to Predicate Device Technical Characteristics:

Riverain is of the opinion that the ClearRead CT is substantially equivalent, both in intended use and technical characteristics to the listed predicate devices. Differences in the design and performance from the cited predicate devices do not affect either the safety or the effectiveness of ClearRead CT for its intended use.

	Predicate: ***syngo.CT Lung CAD*** *(*Siemens AG Medical Solutions) K143196	**Predicate:** ***syngo.PET & CT Oncology*** *(*Siemens AG Medical Solutions) K093621	**Predicate:** ***ClearRead Bone Suppression*** *(*Riverain Technologies) K092363	**Subject Device:** ClearRead CT (Riverain Technologies)
Product Code	OEB	LLZ	LLZ	OEB/LLZ
Intended Use	Computer-aided detection tool designed to assist radiologists in the detection of solid pulmonary nodules during review of MDCT examinations of the chest	Viewing, manipulation, 3D-Visualization, and comparison of medical images from multiple imaging modalities.	Generating bone suppressed image from an original PA/AP chest radiograph	Computer assisted reading tools designed to aid the radiologist in the detection of pulmonary nodules during review of CT examinations of the chest

Testing Summary:

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 area under the curve (AUC) of the localization receiver operating characteristic (LROC) response when using ClearRead CT relative to the unaided read. The study also measured the radiologists' interpretation time when using ClearRead CT relative to unaided interpretations. ClearRead CT was found to significantly increase the AUC, indicating use of the device is superior to the unaided read for detecting nodules. ClearRead CT was found to decrease read times with and without outliers.

Developmental testing was conducted to verify requirements according to the ClearRead CT device specifications. The Risk Analysis was completed and risk control measures

implemented to mitigate hazards. Documentation required for software with a Moderate Level of Concern is included as part of the submission. Device labeling together with results from verification & validation testing demonstrate the device is safe and effective.

Conclusion:

In preparing this 510(k) submission, Riverain has carefully considered the relevant statutory and regulatory requirements, and believes that the information contained within satisfies the requirements for demonstrating substantial equivalence.