Telerad Tech™ Smarter Healthcare On Demand	Telerad Tech Private Limited	
	510(k) Summary	Annexure 05

Date prepared:

1st February 2013

Submitter information: 807.92(a) (1)

Mr. Ricky Bedi, CEO

TELERAD TECH Private Limited

Plot # 7G, Vishveshwaraiah Industrial Area.

Whitefield, Bangalore- 560048, India.

Tel: +91-80-40187500, Email: ricky.bedi@teleradtech.com

Name and classification of device: 807.92(a)(2)

Trade name: RADSpa™

Common Name: Picture Archive Communication System (PACS)

Classification name: system, Image processing, Radiological

Class: Class II

Product code: LLZ

Regulation number: 892.2050

Predicate device:

For RADSpa™ MPR/MIP/3Dapplication:

Manufacturer: Calgary Scientific, Inc.

Trade name: ResolutionMDTM 2.1

Common name: Picture Archive Communication System (PACS)

510(k) number: K082693

Classification name: system, Image processing, Radiological

Class: Class II

Product code: LLZ

Regulation number: 892.2050

For RADSpa™ PACS and Viewer:

Manufacturer: eRAD Inc.

Trade name: eRAD PACS

Common name: Picture Archive Communication System (PACS)

510(k) number: K061421

Classification name: PACS

Class: Class II

Product code: LLZ

Regulation number: 892.2050

Device description: 21 CFR 807.92 (a)(4)

RADSpa™ is a software device that consists of RADSpa™ PACS and Viewer&RADSpa™ 2D/MPR/MIP/3D viewer.

RADSpa™ PACS components (server-side) enable receiving, storing and sending DICOM images and managing the workflow required for radiologists. The components are developed using .NET and runs on Windows OS. The images are stored in the file system and the workflow-related data in a RDBMS database

RADSpa MPR/MIP/3Dviewer components run on Windows OS and enable downloading of images from RADSpa™ server and viewing and manipulating of those images on the workstation

Overall features include:

- Centralized or Distributed Archive functionality
- Uses commercially available computers, servers, operating systems and network infrastructure, with expandable storage capability
- Single or Multi server options (i.e. Archive, Web Server and PACS application can reside on a single server computer)
- Pre-emptive downloading- perfecting of images in real time Web based solution
- Scalable from single practice to enterprise wide PACS
- High level of security
- DICOM, JPEG and JPEG 2000 compliant

Substantial Equivalence Comparisons to Predicate Device:

PACS and viewer

Features	Subject device: RADSpa™ PACS and Viewer	Predicate device: eRAD
Indications for use	RADSpa™ PACS is a flexible, standards-compliant, web-based, workflow management solution designed for centralized and distributed imaging environments. This device consolidates all radiology exam information including images and reports from multiple systems into a centrally managed work list, which can be accessible using any browser. RADSpa™ PACS provides complete PACS functionality used to receive and manage DICOM images and make the data available across a network. RADSpa™ viewer is used for diagnosis and Primary Image Interpretation of DICOM compliant image data derived from all modalities. This component is not intended for mobile devices.	eRAD PACS is a PACS and teleradiology system used to receive DICOM images, scheduling information and textual reports, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces. eRAD PACS is for hospitals, imaging centers, radiologist reading practices and any user who requires and is granted access to patient image, demographic and report information.

Computer platform minimum requirements	Dual core processor, 4GB RAM, 200 GB disk space, Gigabit Ethernet port,	Dual core processor, 4GB RAM, 200 GB disk space, Gigabit Ethernet port,
Computer operating system	Windows	RHEL
Distribution of images and data via internet and intranet	yes	Yes
Automatically receive DICOM images from any imaging acquisition device	yes	Yes
Web-delivered viewing software	yes	Yes
DICOM/HL7 interface capabilities	yes	Yes
Secure administration	yes	Yes
Cross sectional viewing	yes	Yes
Plain film studies	yes	Yes
Individual user templates	yes	Yes
Image review and manipulation tools	yes	Yes

Image measurement tools	yes	Yes
Image compression	yes	Yes
Modality support	All Modalities	All Modalities
Networking communication protocol	TCP/IP	TCP/IP
Standard interfaces	DICOM/ HL7/ HTTP/ HTTPS	DICOM/ HL7/ HTTP/ HTTPS
Image storage	Yes	Yes

RADSpa™ Viewer		
Receive, store, retrieve, display and process digital medical images	Yes	Yes
Display of clinical patient data when no access to work station	Yes ,Web based	Yes ,Web based
Multi Planar Reconstruction (MPR) and 3D image rendering	Yes	Yes
Maximum Intensity Projection (MIP)	Yes	Yes
Distance measurements	Yes	Yes
Standardized Uptake Value (SUV)	Yes	Yes
Zoom/pan	Yes	Yes
User authentication	Yes	Yes
Modalities	All	All
Operating platform	Windows 2000 onwards	Windows 2000 onwards
Hardware requirements	Operating System: Microsoft Windows ALL VERSIONS Processor speed: greater than 2GHz RAM: 4 GB Recommended viewing conditions	Processor speed: greater than 2GHz RAM: minimum is twice the size of the series loaded into the fusion frame Display controller:

	• Video RAM: minimum of 256MBs • Support for Direct X v9.0 drivers dated August, 2008 or more recently • Support for PixelShader 2.0 or later.	Video RAM: minimum of 256MBs Support for Direct X v9.0 drivers dated August, 2008 or more recently Support for PixelShader 2.0 or later. Operating system: Microsoft Windows ALL VERSIONS

RADSpa™ MPR / MIP/3D

Features	Subject : RADSpa™ MPR / MIP/3D	Predicate Device: Resolution MD™2.1
Intended use/ indications for use	RADSpa™ MPR/MIP/3D components are used for post-processing and is designed to assist radiologists in the diagnostic analysis, visualization, and quantification of CT and MR images. This device supports enhanced visualization and analysis techniques such as multi-planar and oblique reformats, maximum intensity projections, image averaging, subtraction and blinking of images acquired at different time points. RADSpa™ MPR/MIP/3D is also used to perform post-processing analysis digital images from CT and MR. The software analysis tools may be applied to image subtractions, reformatted images, multi-planar reformats and maximum intensity projections. The	The ResolutionMD™ 2.1 is a software-based Picture Archiving and Communication System (PACS) used with general-purpose computing hardware for the display and 3D visualization of medical image data. It provides for communication, storage, reformatting, rendering, and display of DICOM 3.0 compliant image data derived from various; sources including CT and MRI. The ResolutionMD™ 2:1 device incorporates a Calcium Scoring module which is used to identify and quantify calcified plaque within the coronary arteries. This protocol is performed on non contrast enhanced cardiac CT

	software package includes tools to allow the radiologist to manipulate and fly-through images for enhanced visualization. RADSpa™ MPR/MIP/3Dis not intended for mobile devices.	data sets. It also includes the Coronary Artery Analysis protocol which is used to visually identify and measure stenosis in the coronary arteries. This protocol is performed on contrast-enhanced cardiac CTA data sets. The ResolutionMD™2.1 software is intended for use as a diagnostic, review, and analysis tool by trained professionals such as physicians, technologists, and nurses. When interpreted by a trained physician, reviewed images may be used as an element for diagnosis. It is the user's responsibility to ensure that the software is installed on appropriate hardware and that image quality is suitable for the clinical application. Calgary Scientific recommends that users of the ResolutionMD™2.1

		software consult the appropriate American College of Radiology Practice Guidelines pertaining to the anatomy and pathology being studied. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

2D Features		
Cross sectional imaging presents a wide array of image manipulation possibilities. Being able to reconstruct multiple planes from a single CT or MR dataset provides the reporting physician the ability to view anatomical structures from different aspects. Maximum Image Projection views for better evaluation of vascular structures. The WL settings are carried over to the MPR or MIP from the 2D display or the user can apply presets to the reconstructed images.	yes	Yes
All features of 2D	yes	Yes
Slab MPR (Up To 393.8 mm) with Custom entry: The data set is rendered with a user defined slab thickness for rapid and flexible reporting of large datasets. As part of the workflow all views automatically adjust to the newly applied thickness. Users see this rendering in real time, with server-grade performance.	yes	Yes
MIP, minIP, Average Slab Rendering: Allows the users to adjust the settings for various rendering displays to see different anatomy and pathology.	yes	Yes
Orthogonal and Oblique MPR: User can change the origin and orientation of the displayed MPR slices by manipulating Image Cursor tool. This feature allows you to inspect any region of interest using the three-sided oblique MPR view.	yes	Yes
MIP - Using maximum intensity projection (MIP) for re-sampling basically gives the maximum	yes	Yes

extent of high attenuation objects within the slab from the current viewing direction. Another advantage of MIP re-sampling is an increase of spatial orientation since dense side objects may become visible.		
MinMIP - Analogously the minimum intensity re-sampling method (MinMIP) is intended to emphasize structures of low attenuation.	yes	Yes
RaySum - Averaging the voxels projected to one pixel in image space naturally results in blurred images. Especially tiny structures tend to fade out as well as calcified parts may decrease attenuation. However especially for data sets with low signal noise ratio this kind of re-sampling improves the image quality.	yes	Yes
CPR: Curved planar reformations are two-dimensional images that may be used to trace the course of an anatomic structure through the entire data set. Curved planar reformations can delineate a curved path and display the whole course of an anatomy in a single cross- section image according to a manually drawn curved line.	yes	Yes
3D Features :		
2D Features included Collaboration, Pan, Window Width/Level, Linear measurement, Zoom, WL Presets Text Annotation, Keyboard Shortcuts, Screenshot, Reset To Original View Settings	yes	Yes
3D visualization template: Predefined visualization templates are designed to point out object of interest such as bones, vessels, skin, lungs, etc. precise tools for adjusting visualization templates, creating new templates and saving them for further use.	yes	Yes

3D Tools: Trimming: Trimming the image enables you to expose your region of interest or remove certain parts of the image. Since the region of interest can be Considerable smaller then original image.	yes	Yes
Thin Slab/Oblique Trim: Trim Mode is very efficient and easy to use, but it can only trim rectangle/orthogonal regions. Thin Slab tool enables you to display only the region between two parallel planes orientated in any direction – this region is called Thin Slab.	yes	Yes
Sculpting: To remove an arbitrary region from a 3D image, use the Sculpting tool. Sculpting tool enables you to define a region on the 3D window and remove all the data that lies within boundaries of that region.	yes	Yes
3D Flythrough: current position of the camera and the target at which the camera is looking at. User can drag the camera and the target to a new position.	yes	Yes

Intended use:21 CFR 807.92 (a)(5)

RADSpa™ components are intended to be used in hospitals, imaging centers, radiologist reading practices and by any user who requires and is granted access to view patient's images, demographic and report information.

RADSpa™ PACS and Viewer

RADSpa™ PACS is a flexible, standards-compliant, web-based, workflow management solution designed for centralized and distributed imaging environments. This device consolidates all radiology exam information including images and reports from multiple systems into a centrally managed work list, which can be accessible using any browser. RADSpa™ PACS provides complete PACS functionality used to receive and manage DICOM images and make the data available across a network. RADSpa™ viewer is used for diagnosis and Primary Image Interpretation of DICOM compliant image data derived from all modalities. This component is not intended for mobile devices.

RADSpa™ MPR/MIP/3D

RADSpa™ MPR/MIP/3D components are used for post-processing and is designed to assist radiologists in the diagnostic analysis, visualization, and quantification of CT and MR images. This device supports enhanced visualization and analysis techniques such as multi-planar and oblique reformats, maximum intensity projections, image averaging, subtraction and blinking of images acquired at different time points.

RADSpa™ MPR/MIP/3D is also used to perform post-processing analysis digital images from CT and MR. The software analysis tools may be applied to image subtractions, reformatted images, multi-planar reformats and maximum intensity projections. The software package includes tools to allow the radiologist to manipulate and fly-through images for enhanced visualization.

RADSpa™ MPR/MIP/3Dis not intended for mobile devices.

Technological characteristics: 21 CFR 807.92 (a)(6)

The device does not contact the patient, nor does it control any life sustaining devices. A specialised physician interprets the images and information being displayed and printed.

Conclusion: 21 CFR 807.92 (b)

The 510(k) Pre-Market Notification for RADSpa™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. The subject device has been and will be developed in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the "Level of Concern for potential hazards has been classified as "minor".

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

June 20, 2014

TELERAD TECH Private Limited
% Manoj Zacharias
President
Liberty Management Group Ltd.
2871 Coastal Drive
AURORA IL 60503

Re: K141329
Trade/Device Name: RADSpa™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 23, 2014
Received: May 21, 2014

Dear Mr. Zacharias:

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

Janine M. Morris
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)*
K141329

Device Name
RADSpa™

Indications for Use *(Describe)*
RADSpa™ components are intended to be used in hospitals, imaging centers, radiologist reading practices and by any user who requires and is granted access to view patient's images, demographic and report information.

RADSpa™ PACS and Viewer

RADSpa™ PACS is a flexible, standards-compliant, web-based, workflow management solution designed for centralized and distributed imaging environments. This device consolidates all radiology exam information including images and reports from multiple systems into a centrally managed work list, which can be accessible using any browser. RADSpa™ PACS provides complete PACS functionality used to receive and manage DICOM images and make the data available across a network. RADSpa™ viewer is used for diagnosis and Primary Image Interpretation of DICOM compliant image data derived from all modalities. This component is not intended for mobile devices.

RADSpa™ MPR/MIP/3D

RADSpa™ MPR/MIP/3D components are used for post-processing and is designed to assist radiologists in the diagnostic analysis, visualization, and quantification of CT and MR images. This device supports enhanced visualization and analysis techniques such as multi-planar and oblique reformats, maximum intensity projections, image averaging, subtraction and blinking of images acquired at different time points.
RADSpa™ MPR/MIP/3D is also used to perform post-processing analysis digital images from CT and MR. The software analysis tools may be applied to image subtractions, reformatted images, multi-planar reformats and maximum intensity projections. The software package includes tools to allow the radiologist to manipulate and fly-through images for enhanced visualization.
RADSpa™ MPR/MIP/3D is not intended for mobile devices.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."