DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 5, 2017

Lifetrack Medical Systems, Inc.
% Mr. Keith Barritt
Attorney
Fish & Richardson
1425 K Street NW
WASHINGTON DC 20005

Re: K161341
Trade/Device Name: Lifesys™ PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 21, 2017
Received: March 22, 2017

Dear Mr. Barritt:

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)*
K161341

Device Name
LifeSys™ PACS

Indications for Use *(Describe)*
LifeSys™ PACS is a Picture Archive and Communications software product used to receive pertinent radiology patient information and DICOM images and allow easy generation of a Radiology Report for distribution over a network.

LifeSys™ PACS software is intended for use as a primary diagnostic and analysis tool for diagnostic images. LifeSys™ PACS is for hospitals, imaging centers, radiologists, radiology professional services providers and any user who requires and is granted access to patient image, demographic and report information.

The LifeSys™ PACS viewer displays images from CT, computed radiography, MRI, nuclear medicine, PET, ultrasound, x-ray angiography, and x-ray fluoroscopy.

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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Section 5: 510(k) Summary

Date Prepared: February 21, 2017

Submitter: Lifetrack Medical Systems, Inc.
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Trade Name: LifeSys™ PACS
Classification Name: System, Image Processing, Radiological
Common Name: Picture, archive and communications system (PACS)
Product Code: LLZ

Predicate Device:

Device Classification Name: System, Image Processing, Radiological
510(k) Number: K120995
Device Name: eRAD PACS and eRAD RIS/PACS
Original Applicant: eRAD, Inc., 9 Pilgrim Road, Greenville, SC 29607
Product Code: LLZ
Decision Date: December 3, 2012
Decision: Substantial equivalent (SE)
Type: Traditional

Device Description:

LifeSys™ PACS is a PACS software product that provides medical imaging departments of all types (Hospitals, Imaging Centers, and Clinics) with the capability to archive patient imaging studies and generate reports on said studies. LifeSys™ PACS is a single piece of software which includes the following functional modules: LifePACS™, which includes a Worklist, Tech Page, Image acquisition, receipt and archive, Report Editor, and tools for integration; and LifeView™, which includes a DICOM image viewer, rapid loading for fast and efficient reading and reporting and multiple monitor support.

Indications for Use:

LifeSys™ PACS is a Picture Archive and Communications software product used to receive pertinent radiology patient information and DICOM images and allow easy generation of a Radiology Report for distribution over a network.

LifeSys™ PACS software is intended for use as a primary diagnostic and analysis tool for diagnostic images. LifeSys™ PACS is for hospitals, imaging centers, radiologists, radiology professional services providers and any user who requires and is granted access to patient image, demographic and report information.

The LifeSys™ PACS viewer displays images from CT, computed radiography, MRI, nuclear medicine, PET, ultrasound, x-ray angiography, and x-ray fluoroscopy.

Technological Characteristics:

LifeSys™ PACS is a device that does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed.

The LifeSys™ PACS device labeling contains instructions for use and any warnings or cautions to provide for the safe and effective use of the device. Users of the device are responsible to imonsure that display quality, environmental lighting and other possible distractions are consistent with a clinical environment. The hardware components specified are all "off the shelf" computer components.

It is our conclusion that there is no software or hardware component in the LifeSys™ PACS device whose failure or latent design flaw would be expected to result in death or injury to a patient. The "level of concern" on the LifeSys™ PACS device is "moderate".

Substantial Equivalence:

The new device (LifeSys™ PACS) and predicate device (eRAD PACS and eRAD RIS/PACS) are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The new device does not raise any new potential safety risks and is equivalent in performance to the predicate device. The two devices are substantially equivalent in the areas of design, architecture, general function, application, and intended use.

Non-Clinical Testing:

Thorough non-clinical system verification and validation testing was conducted in accordance with applicable international standards and internal design requirement to verify that LifeSys™ PACS software product meets user needs and indications for use. The Verification & Validation Test Plan was designed to evaluate all input functions, output functions, and actions performed in each operational mode. LifeSys™ PACS software passed all in-house testing criteria.

Conclusion

The 510(k) Pre-Market Notification for LifeSys™ PACS contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. The subject device and predicate device are substantially equivalent in the areas of technical characteristics, general function, application, intended use, and does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices. LifeSys™ PACS is substantially equivalent with respect to safety and effectiveness to the predicate device.