LEAD Technologies Inc.
% Mr. Carl Alletto
Consultant
OTech Inc.
8317 Belew Drive
McKINNEY TX 75071

November 12, 2021

Re: K212984
Trade/Device Name: MiPACS HTML5 Web Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 5, 2021
Received: September 17, 2021

Dear Mr. Alletto:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212984

Device Name
MiPACS HTML5 Web Viewer

Indications for Use *(Describe)*

MiPACS HTML5 Web Viewer, is a software device, that enables Users to view and manipulate medical images. Patient images/studies can be accessed by Users locally within the system or across a wide-area network at distributed locations. The MiPACS HTML5 Web Viewer requires no installation on the client's behalf and is compatible with any HTML5-compliant web browser (e.g. Google Chrome, Microsoft Internet Explorer 10, Microsoft Edge, Mozilla Firefox, MacOS). Only preprocessed DICOM for presentation images can be interpreted for primary image diagnosis in mammography. Mammographic images with lossy, compression and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA.
MiPACS HTML5 Web Viewer, is not intended for diagnostic image review on 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

Submission number: K212984

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

Mr. William Little, FDA Project Manager
Medicor Imaging, a division of LEAD Technologies Inc.
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Date Prepared: November 3, 2021

II. DEVICE

Name of Device: MiPACS HTML5 Web Viewer
Regulation Name: Medical Image Management and Processing System
Classification Name: system, image processing, radiological (21 CFR 892.2050)
Regulatory Class: II
Product Code: LLZ

III. PREDICATE DEVICES

The predicate device is: InstaRISPACS / InstaZFP / InstaMobi V5.0 (K182572), Class II, regulation number; 892.2050, product code LLZ.

IV. DEVICE DESCRIPTION

MiPACS HTML5 is a medical software with a Moderate level of concern.

MiPACS HTML5 Web Viewer uses web-based technology and a secure operating system. This means that virtually any computer at any location can use an Internet browser to access the device and RIS systems. Whether on-site or from another location, physicians and trained professionals can manage, edit, view and move diagnostic exams quickly and efficiently. As part of the MiPACS HTML5 Web Viewer support, Medicor Imaging, performs virtually all the system maintenance.

The MiPACS HTML5 Web Viewer is an implementation of an IHE (Integrating the Healthcare Enterprise) compliant Image Archive and Report Repository. This includes the capabilities:

- To store and retrieve various kinds of DICOM Objects such as:
  - Images from multiple modalities,
  - Grayscale Presentation States [GSPS], which specifies the presentations of images as gray scaling, zoom, text and graphical annotations,
  - Key Objects [KO], which specifies a particular selection of images for a specified reason and with an attached note,
  - Structured Reports [SR].

The MiPACS HTML5 Web Viewer, is a server application. Its Web-based User Interface is intended for system configuration and monitoring by system administrators.

Key Feature List

- Web-based technology for access from anywhere
- Integration with any modality, RIS, HIS or EMR, desktop Integration, and custom integration
- Turnkey installations including all PACS professional services

- Off-site disaster recovery service
- Automatic management reports
- Detailed HIPAA log of PACS transactions
- Diagnostic viewer

The MiPACS HTML5 Web Viewer device does not intend to replace the skills and judgment of a qualified physician/radiologist and must be used only by people who are properly trained in the system's functions and capabilities.

The User must be aware of the accuracy and precision limitations of the data displayed, printed or exported from The MiPACS HTML5 Web Viewer. The quality of the data depends on the information received, user interaction, and the features in the display device and printer, among others.

Warning: When an app viewer is being used, the medical images are only for consultation; and must not be viewed for diagnostic purpose.

V. INDICATIONS FOR USE

The MiPACS HTML5 Web Viewer is a software device that enables Users to view and manipulate medical images. Patient images/studies can be accessed by Users locally within the system or across a wide-area network at distributed locations. The MiPACS HTML5 Web Viewer requires no installation on the client's behalf and is compatible with any HTML5-compliant web browser (e.g., Google Chrome, Microsoft Internet Explorer 10, Microsoft Edge, Mozilla Firefox, MacOS). Only preprocessed DICOM for presentation images can be interpreted for primary image diagnosis in mammography. Mammographic images with lossy, compression and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA. The MiPACS HTML5 Web Viewer, is not intended for diagnostic image review on mobile devices.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The subject and predicate devices are both web-based viewers which are indicated for medical image management, review, and data distribution. Both systems have been developed to replace traditional film handling in radiology. The subject device and the predicate device are substantially equivalent in the areas of general function, application, and intended use.

Any differences between the subject and predicate devices have no negative impact on the device safety or efficacy and do not raise any new potential or increased safety risks and are equivalent in performance to existing legally marketed devices.

Feature/Functions		**Subject Device – MiPACS HTML5 Web Viewer**	**Predicate InstaRISPACS/ InstaZFP/ InstaMobi K182572**
System	Indications for Use	Medical image management and processing system	Medical image management and processing system
	Processor	8 core Xeon Processor (or more)	Core i7 / Quad Core Xeon

510(k) Summary

Submission number: K212984

Feature/Functions		Subject Device – MiPACS HTML5 Web Viewer	Predicate InstaRISPACS/ InstaZFP/ InstaMobi K182572
Workstation Client Hardware (recommended)	Operating System	Any Operating System (Windows, MacOS, Linux, Firefox)	Windows 8.1 (64 bit)
	Display	Medical Grade Monitor is recommended. Resolution depends on the modality type.	Medical Grade Monitor is recommended. Resolution depends on the modality type.
	RAM	Minimum 8GB RAM	Minimum 8GB RAM
	Hard Disk	500 GB minimum	750GB minimum
Server features	System Architecture	Web based	Web based
	Hardware	Vendor Agnostic	Vendor Agnostic
	Security	Log-on user ID & password	Log-on user ID & password
	Remote monitoring	Yes	Yes
	Database	SQL Server	MySQLv5.7
Viewer Features:	Image Viewing Layout	Customer Layout or Std. formats (up to 4*4)	Std. formats (up to 4*4)
	WW/WL	Yes	Yes
	Zoom in/Zoom out	yes	yes
	Hounsfield Measurement	Yes	Yes
	Linear and angle measurements	Yes	Yes
	Series Comparison	Yes	Yes
	Scout line display	Yes	Yes
	MPR/MIP capabilities	Yes	Yes
	Stack mode	Yes	Yes
	Gray scale invert	Yes	Yes
	Filters	Yes	Yes
	Rotate	Yes	Yes
	Key Image selection	Yes	Yes
	DICOM Print	Yes	Yes
	Windows print	Yes	Yes
	Query/Retrieve	Yes	Yes
	Image compression	Lossless streaming	Lossless streaming

Feature/Functions		Subject Device – MiPACS HTML5 Web Viewer	Predicate InstaRISPACS/ InstaZFP/ InstaMobi K182572
	Selection tools	Thumbnails	Thumbnails
Other features	Link to Hospital Information System (HIS)	Yes	Yes
	HIPAA	Compliant	Compliant
Configurations	PACS Server	Yes	Yes
	Radiology Workstation	Yes	Yes
	Basic Image Viewer	Yes	Yes

VII. PERFORMANCE DATA

Clinical testing is not necessary to show substantial equivalence for the subject device. Successful Bench Testing should be sufficient in demonstrating substantial equivalence.

Nonclinical Testing:

The MiPACS HTML5 Web Viewer has been assessed and tested at the company's facility and has passed all predetermined testing criteria. The Validation Test Plan was designed to evaluate output functions, and actions performed by Medicor Imaging, and followed the process documented in the Validation Test Plan.

Nonclinical testing results are provided in the 510(k). Validation testing indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met.

Summary:

Based on the performance as documented in the Validation Testing, MiPACS HTML5 Web Viewer was found to have a safe and effectiveness profile that is similar to the predicate device.

The following Standards were used to develop the MiPACS HTML5 Web Viewer, and the device has met all the requirements listed in the Standards except for inapplicable requirements:

Title of Standard	Date Of Recognition	Specialty Task Group Area	FDA Recognition Number	Standard Developing Organization	Standard Designation Number and Date
Digital Imaging and Communications in Medicine (DICOM) Set	06/27/2016	Radiology	12-300	NEMA	PS 3.1 - 3.20 (2016)
Analysis techniques for system reliability - Procedure for failure mode and	01/14/2019	Radiology	5-120	IEC	60812 Edition 3.0 2018-08,

Title of Standard	Date Of Recognition	Specialty Task Group Area	FDA Recognition Number	Standard Developing Organization	Standard Designation Number and Date
effects analysis (FMEA)					
Medical device software - Software life cycle processes [Including Amendment 1 (2016)]	01/14/2019	Software/ Informatics	13-79	ANSI AAMI IEC	62304:2006/A 1:2016

- FDA Guidance on Cyber Security: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Document Issued on: October 2, 2014
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005

VIII. CONCLUSIONS

The 510(k) Pre-Market Notification for the MiPACS HTML5 Web Viewer contains adequate information, data, and nonclinical test results 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, and intended use. The MiPACS HTML5 Web Viewer do not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Nonclinical tests demonstrate that the device is as safe, as effective, and performs comparably to the predicate devices.