Intelerad Medical Systems, Inc.
℅ Mr. Carl Alletto
Consultant
OTech, Inc.
215 E. University Drive, Suite B
DENTON TX 76209

April 2, 2020

Re: K192176
Trade/Device Name: IntelePACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: February 12, 2020
Received: February 14, 2020

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); 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192176

Device Name
IntelePACS

Indications for Use *(Describe)*

IntelePACS is a software application that receives digital images and data from various sources (such as, CT scanners, MR scanners, ultrasound systems, R/F units, computer and direct radiographic devices, secondary capture devices, scanners, imaging gateways, or other imaging sources). Images and data can be communicated, processed, manipulated, enhanced, stored, and displayed within the system and/or across computer networks at distributed locations. Post-processing of the images can be performed using Multi Planar Reconstruction (MPR). 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.
When used with a mobile device, IntelePACS is suitable for diagnostic image review only on tested devices as specified in Intelerad product documentation. IntelePACS is not intended for primary diagnostic image review on mobile devices. Mobile usage for Mammography is for reference and referral only.

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.

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510(k) Summary

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

I. SUBMITTER

Intelerad Medical Systems Incorporated
800, Boul. De Maisonneuve Est.
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Montreal, Canada H2L 4L8
Email: luce.caron@intelerad.com

Contact Person: Ms. Luce Caron, Quality Management Systems Manager
Date Prepared: March 25, 2020

II. DEVICE

Name of Device: IntelePACS
Common or Usual Name: Picture Archiving Communications System
Classification Name: system, image processing, radiological (21 CFR 892.2050)
Regulatory Class: II
Product Code: LLZ

III. PREDICATE DEVICES

Primary Predicate Device

IntelePACS, (K150707) v4.9.1 by Intelerad Medical Systems, Inc. CFR 892.2050, Product Code LLZ.

Reference Predicate Device

eUnity, (K172490) by Client Outlook Inc. CFR892.2050, Product code: LLZ

IV. DEVICE DESCRIPTION

IntelePACS, (version 5), is based upon the predicate device IntelePACS, version 4.9.1 (K150707). Both the subject device and the predicate are from Intelerad Medical Systems Inc. IntelePACS is comprised of software modules that provide image capture, storage, distribution, enhancement, manipulation, and networking of medical images at distributed locations. In cases where DICOM images are not directly available to IntelePACS, the system can acquire medical images using a DICOM image gateway, which generates DICOM-type files. For example, film digitizers obtain images from original film and convert them to meet DICOM standards. Stored files are transmitted using a network and can be viewed or manipulated using InteleViewer viewing software.

The main components are:

- InteleViewer is an image viewing system, providing access to the tools required for reviewing images and searching to find studies and reports. InteleViewer features DICOM support, including DICOM Query/Retrieve, Store, and Print. The software module includes a thumbnail display, real-time cine playback, linked stacking, MPR, annotations and measurements, etc. The web-enabled InteleViewer software uses JPEG 2000 compression and an advanced streaming protocol to provide lossless or lossy image viewing and manipulation. The user can examine multiple studies simultaneously and define customized image layouts. With a mouse click, the User can stack, rotate, zoom, take measurements, and view reports.
- InteleConnect Enhanced Viewer (used on Mobile Devices) is a web-based portal for medical images review that can be used on the desktop and on mobile devices without requiring software installation. This is a new module which is not in the Primary Predicate but is available in the Reference Predicate device.

  InteleConnect EV is designed to run in modern web browsers, including Chrome, Firefox and Safari, mobile browsers running on IOS and Android devices, as well as Microsoft Edge and, with some limitations, Internet Explorer 11. It is also accessible on mobile devices such as iPhones and iPads. The mobile version of InteleConnect

EV was not designed as a native application but rather as another, self-contained web application, re-using much of the same front-end infrastructure as the desktop version.

- InteleBrowser which is a web-based administrative interface for IntelePACS, and allows the facility System Administrator to customize and configure the facility radiological workflow and corporate branding. The System Administrator can administer hundreds or thousands of IntelePACS users by taking advantage of the user management and access granting tools.

V. INDICATIONS FOR USE

IntelePACS is a software application that receives digital images and data from various sources (such as CT scanners, MR scanners, ultrasound systems, R/F units, computer and direct radiographic devices, secondary capture devices, scanners, imaging gateways, or other imaging sources). Images and data can be communicated, processed, manipulated, enhanced, stored, and displayed within the system and/or across computer networks at distributed locations. Post-processing of the images can be performed using Multi Planar Reconstruction (MPR). 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.

When used with a mobile device, IntelePACS is suitable for diagnostic image review only on tested devices as specified in Intelerad product documentation. IntelePACS is not intended for primary diagnostic image review on mobile devices. Mobile usage for Mammography is for reference and referral only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The subject device and primary predicate are both PACS, 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 is the next version of the primary predicate device and they are substantially equivalent in the areas of general function, application, and intended use. The subject device is adding a mobile viewing function which was not available on the primary predicate but is available on the reference predicate.

Any differences between the subject device and the predicates and the new device has no impact on safety or efficacy of the new device and does not raise any new potential or increased safety risks and is equivalent in performance to existing legally marketed devices.

Item	Functionality	INTELEPACS, v 5 Subject Device	INTELEPACS, v4.9.1 Primary Predicate K150707	eUNITY, Reference Predicate K172490	Difference?
1	Intended use	Acquire, view, edit, and store radiographic images	Similar	Similar	No difference
2	Intended user	radiologist	radiologist	radiologist	No difference
3	Network	10/100/100 Ethernet	10/100/100 Ethernet	10/100/100 Ethernet	No difference
4	User interaction/input	Mouse, keyboard, or touch monitor	Mouse, keyboard, or touch monitor	Mouse, keyboard, or touch monitor	No difference
5	Import / export images	Yes	Yes	Yes	No difference

6	Image search available	Yes	Yes	Yes	No difference
7	Image storage	Yes	Yes	Yes	No difference
8	Image viewing	Yes	Yes	Yes	No difference
9	Image measurement	Yes	Yes	Yes	No difference
10	Image annotation	Yes	Yes	Yes	No difference
11	DICOM 3.0 compatibility	Yes	Yes	Yes	No difference
12	Thumbnail viewing	Yes	Yes	Yes	No difference
13	Panning	Yes	Yes	Yes	No difference
14	Magnify glass	Yes	Yes	Yes	No difference
15	Fit image	Yes	Yes	Yes	No difference
16	Resident workflow module	Yes	No	Unknown	Yes, there is a difference.
17	Image Ingestion Failure Notification	Yes	No	Unknown	Yes, there is a difference.
18	Bi-directional notes integration for HL7 (Sending notes between systems)	Yes	No	Unknown	Yes, there is a difference.
19	Email alert for TAT breach	Yes	No	Unknown	Yes, there is a difference.
20	Cloud archive on AWS (Cloud storage of images)	Yes	No	Unknown	Yes, there is a difference.
21	Peer review - retrospective reviews	Yes	No	Unknown	Yes, there is a difference.
22	Proxied DICOM query/retrieve for InteleViewer/InteleConnect/InteleBrowser	Yes	No	Unknown	Yes, there is a difference.
23	InteleViewer Tool Customization (Mouse)	Yes	No	Unknown	Yes, there is a difference.
24	Bridge Reporting Workflow Gap - Proxy Signing	Yes	No	Unknown	Yes, there is a difference.
25	Bridge Reporting Workflow Gap - Transcription Edits	Yes	No	Unknown	Yes, there is a difference.
26	Study Tagging	Yes	No	Unknown	Yes, there is a difference.
27	Support for DICOM 6000 Image Overlays in (InteleConnect) Enhanced Viewer	Yes	No	Unknown	Yes, there is a difference.
28	View Reports in (InteleConnect) Enhanced Viewer	Yes	No	Unknown	Yes, there is a difference.
29	Mobile Version of (InteleConnect) Enhanced Viewer	Yes	No	Yes	Yes, there is a difference.

VII. PERFORMANCE DATA

Nonclinical Testing:

The IntelePACS system has been assessed and tested at the factory and has passed all predetermined testing criteria. The Validation Test Plan was designed to evaluate input functions,

output functions, and actions performed by IntelePACS, and followed the process documented in the System 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:

In the overall effort to characterize the suitability of the Enhanced Viewer for diagnostic use in non-mammography applications, we have followed the FDA guidelines for Display Devices for Diagnostic Radiology. The following mobile devices have been tested:

- iPad Pro 2017,
- iPhone 8,
- iPhone XS and
- iPad Air (2019)

Based on the guidance provided in "Assessment of display performance for medical imaging systems: Executive summary of AAPM TG18 report and AAPM report 270 - Display Quality Assurance", we have analyzed the test results as follows:

- Spatial Resolution: Devices tested provide high resolution displays with high pixels per inch counts, with pixel pitch well below 250 μm. The guidance provided in AAPM report 270 states that for LCD and OLED panels, which typically provide some black material between the pixel structure, it is recommended to ensure that they use a digital interface and to inspect to see if the pixel structure is not visible at typical viewing distance. All devices tested, satisfy this criterion.
- Pixel Defects - Devices were visually inspected for any pixel defects and none were detected.
- Artifacts – A test lab evaluated for image artifacts such as ghosting and/or image sticking from displaying a fixed test pattern for a period of time. At the end of the test, a visual observation was performed and confirmed that no such occurrence of either artifact, for all devices tested.
- Temporal Response – A test lab measured the rise and fall time constants for 5–95% and 40–60% luminance transitions. All devices tested present a reasonable response time in the 40-60% luminance transitions, namely around 30ms or better.
- Luminance - Maximum luminance is well above 350 cd/m^2 for all devices tested.
- Conformance to DICOM GSDF - All devices tested only conform to DICOM GSDF within 20% over subsets of the JND range. While some mobile devices performed better than others, any one of the mobile devices did not fully satisfy the criteria. Multiple mitigations have been established for the user to make an appropriate assessment as to the suitability of their device and lighting conditions given the possible limitations.
- Color Tracking - All values for ΔD65(u',v') are within acceptable range for all devices tested.
- Mitigations and Instructions for Use - In order to mitigate the potential risks due to device calibration limitations, the following has been implemented, as based on the recommendations of AAPM report No.260 Considerations for the Use of Handheld Image Viewers:
    - Devices not explicitly tested, display a "Not for diagnostic use" permanent label. Mammography is excluded for any device and hence the label "Not for diagnostic use" persists when a mammography study is displayed, regardless of the device used.
    - A screen and reading environment quality check built into the device. The User is presented with two standard patterns, along with instructions to identify specific parts of the pattern. If the User cannot identify these areas of the pattern, the "Not for diagnostic use" label will continue to be displayed. The result of the test

is persisted for the rest of the day; however, the user will be prompted to validate again when using on a future date.

Based on the performance as documented in the V&V Testing, IntelePACS was found to have a safe and effectiveness profile that is similar to the predicate device.

The following Standards were used to develop IntelePACS, and the device has met all the requirements listed in the Standards except for inapplicable requirements (which are listed in the various test reports):

- ANSI AAMI IEC 62304:2006. Medical device software - Software life cycle processes. FDA Recognized Standard #13-32.
- NEMA PS 3.1 - 3.20 (2016). Digital Imaging and Communications in Medicine (DICOM) Set DICOM Standard. FDA Recognized Standard #12-300.
- JPEG Standard IEC/ISO10918-1 First edition 1994-02-15, Information technology - Digital compression and coding of continuous-tone still images: Requirements and guidelines [Including: Technical Corrigendum 1 (2005)]. FDA Recognized Standard #12-261.
- ISO 14971:2007/(R)2010 (Corrected 4 October 2007), Medical devices - Applications of risk management to medical devices. FDA Recognized Standard #05-40.
- FDA - Display Devices for Diagnostic Radiology: Guidance for Industry and Food and Drug Administration Staff.

VIII. CONCLUSIONS

The 510(k) Pre-Market Notification for IntelePACS, contains adequate information, data, and nonclinical test results to enable FDA - CDRH to determine substantial equivalence to the predicate device. The new device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use does 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.

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