DICOM Grid dba Ambra Health
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

June 7, 2023

Re: K231360
Trade/Device Name: Ambra PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 10, 2023
Received: May 10, 2023

Dear Prithul Bom:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Imaging Devices
and Electronic Products
OHT8: Office of 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)*
K231360

Device Name
Ambra PACS

Indications for Use *(Describe)*
Ambra PACS software is intended for use as a primary diagnostic and analysis tool for diagnostic images for hospitals, imaging centers, radiologists, reading practices and any user who requires and is granted access to Patient image, demographic and report information.

Ambra Pro Viewer, a component of Ambra PACS, displays, modifies and manages diagnostic quality DICOM images including 3D visualization and reordering functionality.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretations. Mammographic images may only be viewed using cleared monitors intended for mammography Display.

Not intended for diagnostic use 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.

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."

An Intelerad Company

450 Park Avenue South
New York, NY 10016
USA
intelerad.com
T 514-931-6222

Ambra Health 510(k) – Ambra PACS

510(k) Summary

K231360

450 Park Avenue South
New York, NY 10016
USA
intelerad.com
T 514-931-6222

510(k) Summary

K231360

This 510(k) summary of safety and effectiveness information for the Ambra PACS is provided as required by section 807.92(c).

Date Prepared:

March 8, 2023

Submitter Information:

DICOM Grid Inc., dba Ambra Health
450 Park Avenue South
New York, NY 10016
USA
intelerad.com
514-931-6222

Company Contact:

Ashley Brown
Regulatory Compliance Manager
regulatory@intelerad.com

Device:

Trade Name: Ambra PACS
Regulation Name: Medical image management and processing system
Classification: II
Product Code: LLZ
Device Classification Name: System, image processing, radiological (21 CFR 892.2050)

Predicate Device:

Trade Name: Ambra PACS with ProViewer
Manufacturer: DICOM GRID Inc., dba Ambra Health
Regulation Name: Picture Archive and Communication System
Predicate Device Premarket Notification #: K202335
Predicate Device Regulation number: 21 CFR 892.2050
Predicate Classification and Product Code: Class II, LLZ

AMBRA
An Intelerad Company

450 Park Avenue South
New York, NY 10016
USA
intelerad.com
T 514-931-6222

Device Description:

Ambra PACS software is intended for use as a primary diagnostic and analysis tool for diagnostic images and reporting for hospitals, imaging centers, radiologists, reading practices and any user who requires and is granted access to patient image, demographic and supplementary information.

Ambra PACS is considered a 'Continuous Use' device. This device is compliant with HIPAA and 21 CFR Part 11 regulations regarding patient privacy (such as restricting access to particular studies, logging access to data), data integrity, patient safety and best software development and validation practices.

Ambra PACS provides common diagnostic and analytic radiology functionality. Specifically, Ambra PACS enables:

- Real-time viewing and management of DICOM images for diagnostic, clinical, research and education purposes;
- Ingestion and normalization of DICOM content for review and archiving;
- Electronic distribution and secure storage of images;
- Off-site viewing and reporting (distance education, tele-diagnosis).

Ambra ProViewer, a component of Ambra PACS, displays, modifies, and manages diagnostic quality DICOM images, including 3D visualization and reordering functionality. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretations. Mammographic images may only be viewed using cleared monitors intended for mammography display.

Intended Use/Indications for Use:

Ambra PACS software is intended for use as a primary diagnostic and analysis tool for diagnostic images for hospitals, imaging centers, radiologists, reading practices and any user who requires and is granted access to patient image, demographic and report information.

Ambra ProViewer, a component of Ambra PACS, displays, modifies, and manages diagnostic quality DICOM images, including 3D visualization and reordering functionality.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretations. Mammographic images may only be viewed using cleared monitors intended for mammography display.

Not intended for diagnostic use on mobile devices.

An Intelerad Company

450 Park Avenue South
New York, NY 10016
USA
intelerad.com
T 514-931-6222

Comparison to Predicate Device:

The Ambra PACS with ProViewer is substantially equivalent in the intended use and technology to the predicate Ambra PACS with ProViewer (K202335). Display and management of diagnostic quality DICOM images is the technological principal for both the subject and predicate devices.

The primary difference when compared to the predicate is the change of programming language from Java to C++ for the Transcoding component of Ambra PACS. The primary function of Transcoding is to convert the supported DICOM compression formats into a web-viewer readable format.

The subject Ambra PACS device has been demonstrated to be substantially equivalent through verification and validation testing using the same protocol and acceptance criteria as the predicate Ambra PACS with ProViewer (K202335).

Table 1 below shows a feature comparison to the predicate device.

AMBRA
An Intelerad Company

450 Park Avenue South
New York, NY 10016
USA
intelerad.com
T 514-931-6222

Table 1 - Additional elements to consider demonstrating Substantial Equivalence

Category	Ambra PACS (Proposed)	Ambra PACS (Predicate) K202335
Product Code	LLZ	LLZ
Indications for Use	Ambra PACS software is intended for use as a primary diagnostic and analysis tool for diagnostic images for hospitals, imaging centers, radiologists, reading practices and any user who requires and is granted access to patient image, demographic and report information. Ambra ProViewer, a component of Ambra PACS, displays, modifies, and manages diagnostic quality DICOM images, including 3D visualization and reordering functionality. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretations. Mammographic images may only be viewed using cleared monitors intended for mammography display. The Ambra PACS and Ambra ProViewer are not intended for diagnostic use on mobile devices.	Ambra PACS software is intended for use as a primary diagnostic and analysis tool for diagnostic images for hospitals, imaging centers, radiologists, reading practices and any user who requires and is granted access to patient image, demographic and report information. Ambra ProViewer, a component of Ambra PACS, displays, modifies, and manages diagnostic quality DICOM images, including 3D visualization and reordering functionality. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretations. Mammographic images may only be viewed using cleared monitors intended for mammography display. The Ambra PACS and Ambra ProViewer are not intended for diagnostic use on mobile devices.
Software-only system	Yes	Yes

AMBRA
An Intelerad Company

450 Park Avenue South
New York, NY 10016
USA
intelerad.com
T 514-931-6222

User Patient database	Postgres - cloud	Postgres - cloud
Coding Language for Transcoding Component	C++, with built in http server	Java, Scala, Spring
Imaging review capability	Yes	Yes
Image annotation and measurement capability	Yes	Yes
Browser-based application	Yes	Yes
User Interface Design	Browser based	Browser based
Secure Login	Yes	Yes
Interface with Electronic Medical Records (EMR)	Yes	Yes
Connection of the imaging instruments via DICOM and/or non-DICOM methods	Yes	Yes

Summary of Supporting Data:

Ambra Health has provided a summary validation testing of DICOM images to demonstrate substantially equivalent performance of the measurement and visualization tools in the Ambra ProViewer.

Non-Clinical Performance Data

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

An Intelerad Company

450 Park Avenue South
New York, NY 10016
USA
intelerad.com
T 514-931-6222

Verification and validation testing was performed against functional, design, measurement, and deployment requirements, to confirm the product continues to meet the software requirements defined by the manufacturer. Simulated use testing was conducted to confirm that the device can achieve its intended use.

All verification and validation acceptance criteria were met.

Conclusion

Based upon design, functional testing, and non-clinical results, the Ambra PACS performs similarly to the predicate device, Ambra PACS (which includes Ambra ProViewer) (K202335), that is currently marketed for the same intended use. The conclusions drawn from the nonclinical tests discussed above demonstrate that the device is as safe, as effective, and performs as well or better than the predicate device, as required by 807.92(b)(3).