Dicom Grid, Inc., dba Ambra Health
% Rafael Aguila
Responsible Third-Party Official
Accelerated Device Approval Services, LLC
6800 S.W. 40th Street, Suite 403
LUDLUM FL 33155

September 4, 2020

Re: K202335
Trade/Device Name: Ambra PACS including Ambra ProViewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 14, 2020
Received: August 17, 2020

Dear Rafael Aguila:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202335

Device Name
Ambra PACS including Ambra Pro Viewer

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.

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New York, NY 10038
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510(k) Summary

K202335

This 510(k) summary of safety and effectiveness information for the Ambra ProViewer is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

May 13, 2020

Submitter Information:

DICOM Grid Inc., dba Ambra Health
199 Water Street, 34th Floor
New York, NY 10038
888-587-2280

Company Contact:

Patrice Nedelec
Director of Compliance and Regulatory Affairs
pnedelec@ambrahealth.com

Device:

Trade Name: Ambra PACS including Ambra ProViewer
Common Name: Picture Archive and Communication System
Classification: II
Product Code: LLZ
Classification Name – Picture Archive and Communication System (21 CFR 892.2050)

Primary Predicate Device:

Trade Name: Ambra PACS
Manufacturer: DICOM GRID Inc., dba Ambra Health
Common Name: Picture Archive and Communication System
Predicate Device Premarket Notification #: K152977
Predicate Device Regulation number: 21 CFR 892.2050
Predicate Classification and Product Code: Class II, LLZ

Reference Predicate Device:

Trade Name: Osirix MD
Manufacturer: PIXMEO SARL
Common Name: Picture Archive and Communication System
Predicate Device Premarket Notification #: K101342
Predicate Device Regulation number: 21 CFR 892.2050

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Predicate Classification and Product Code: Class II, LLZ

Device Description:

Ambra ProViewer, a component of Ambra PACS, displays, modifies, and manages diagnostic quality DICOM images, including 3D visualization and reordering functionality. It is designed to target standards-compliant, cross-platform web browsers with an underlying architecture built on top of ReactJS and Material-UI, as well as WebGL2 for advanced visualization tools. The Ambra ProViewer is designed to utilize modern web application APIs.

Ambra PACS is considered a 'Continuous Use' device. This device is compliant with HIPAA/HITECH, Safe Harbor, 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.

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.

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Not intended for diagnostic use on mobile devices.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**:**

The Ambra ProViewer is a substantially equivalent viewer in the intended use and technology to the predicate Ambra Viewer (K152977). 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 advanced visualization and reordering functionality. These advanced features are substantially equivalent to the PIXMEO

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SARL Osirix MD system marketed under (K101342). These features have been demonstrated to be substantially equivalent through direct comparison testing utilizing the same reference DICOM images.

Summary of Supporting Data:

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

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." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could indirectly result in minor injury or or delayed information or through the action of a care provider.

Risk Analysis demonstrating acceptable risk including cybersecurity risks has been provided.

Conclusion

Based upon design, functional testing, and non-clinical results. The Ambra ProViewer performs similarly to the Ambra PACS Viewer, and the Pixmeo SARL Osirix MD viewer that is currently marketed for the same intended use.