OpenRad Services UK Ltd
% Eileen Heller
Final Reviewer
BeanStock Consulting
8885 Rio San Diego Dr. #237
San Diego, California 92108

April 24, 2024

Re: K240839
Trade/Device Name: OpenRad Cloud
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 27, 2024
Received: March 27, 2024

Dear Eileen Heller:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Radiological 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240839

Device Name
OpenRad Cloud

Indications for Use *(Describe)*
OpenRad Cloud PACS and Viewer is intended for use in the medical image analysis and diagnosis workflows of hospitals, imaging centres, radiologists, reading practices and any user who requires and is granted access to a patient image and associated demographic and report information, including Peer Review or Teleradiology providers. OpenRad Cloud PACS Viewer displays, modifies, and manages diagnostic quality DICOM images, including 3D visualisation 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 device is not intended for use with mobile displays. Review of images require an optimum display of images. Only use cleared monitors and printers for diagnosis review of images. Follow the maintenance and care instructions given in the manufacturer's documentation.

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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510k Summary

This summary of 510(k) safety and efficiency information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. SUBMITTER

OpenRad Services UK Ltd
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KT13 8DE

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Telephone: (+44) 7780 680864
Date Summary prepared: 19 April 2024

2. DEVICE

Device trade name: OpenRad Cloud
Device common name: Medical Image Processing Software System
Classification name: System, image processing, radiological
Device Regulation #: 21 CFR 892.2050
Regulatory Class: II
Product Code: LLZ

3. PREDICATE DEVICES:

Primary Predicate Device:
- Manufacturer: Biotronics3D,
- Trade name: 3Dnet Suite,
- Premarket Notification #: K063107
- Device Product Code & Regulation #: LLZ; 21 CFR 892.2050

Reference Predicate Device:
- Manufacturer: Dicom Grid, Inc., dba Ambra Health,
- Trade name: Ambra PACS including Ambra ProViewer
- Premarket Notification #: K202335
- Device Product Code & Regulation #: LLZ; 21 CFR 892.2050

4. DEVICE DESCRIPTION

The OpenRad Cloud is a software device for the display and evaluation of 2D/3D visualization of DICOM compliant medical image data, such as CT, MRI, Mammogram, and Ultrasound scans.

OpenRad Cloud principles of operation and its mode of action:

1. Receive/Send DICOM Studies;
2. Pre-process and archive in the correct folder;

3. Display study in the correct worklists for intended users;
4. Open the study for visualization together with any existing previous studies of the patient;
5. Produce, communicate and archive reports.

The system is a client-server based architecture.

OpenRad Cloud viewer requires a medical grade monitor for diagnostic reading of images, favouring the use of full radiology workstations.

The OpenRad Cloud Software provides several levels of functionality to the user:

- Basic analysis tools they use on a daily basis such as 2D review, orthogonal multiplanar reconstructions (MPR), oblique MPR, curved MPR, Slab MPR AvgIP, MIP, MinIP, measurements, annotations, reporting, distribution etc.
- Tools for in-depth analysis, such as segmentation, endoscopic view, color volume rendered slabs, grayscale volume rendered slabs, 3D volume review, path definition and boundary detection.
- Specialist tools and workflow enhancements for specific clinical applications which provide targeted workflows, custom UI, measurement and visualisation, including Virtual Colonoscopy, Vessel Analysis, Calcium Scoring, PET/CT, CT Lung Analysis, CT Dental and DCE-MRI Breast and Prostate.

The OpenRad Cloud Software product is based on the Biotronics3D 3Dnet product, developed and marketed by Biotronics3D. Biotronics3D was acquired by OpenRad, and 3Dnet will therefore be labelled and marketed in the US as OpenRad Cloud. The original product was previously approved as follows:

Manufacturer: Biotronics3D,
Trade name: 3Dnet Suite,
Premarket Notification #: K063107
Device Product Code & Regulation #: LLZ; 21 CFR 892.2050

5. INDICATIONS FOR USE

OpenRad Cloud PACS and Viewer is intended for use in the medical image analysis and diagnosis workflows of hospitals, imaging centres, radiologists, reading practices and any user who requires and is granted access to a patient image and associated demographic and report information, including Peer Review or Teleradiology providers. OpenRad Cloud PACS Viewer displays, modifies, and manages diagnostic quality DICOM images, including 3D visualisation 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 device is not intended for use with mobile displays. Review of images require an optimum display of images. Only use cleared monitors and printers for diagnosis review of images. Follow the maintenance and care instructions given in the manufacturer's documentation.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATE DEVICES

The OpenRad Cloud Software utilizes the same technological characteristics as the predicate devices Each provides multi-view user interfaces with combinations of 2D and 3D views correlated together for enhanced visualization. Each provides window/level adjustment of the views to enhance features, provide measurement tools for analysis of the observed structures, provide region of interest tools to isolate specific features and provide manual annotation tools to help indicate and describe findings. Each device supports the DICOM protocol for the communication of images with other medical devices. Image modalities are consistent for the display of 2D/3D visualisation of DICOM compliant medical image data, such as CT, MR, PT, US, CR, MG, NM, DX, OT, XA, XR, XC, RF, DR, DS, SR, OCT, PX, ECG, ES, IO modalities, and reporting.
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 Cloud hosting and thin-client provision 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.

Functionality	OpenRad	Biotronics3D Ltd.	Dicom Grid, Inc., dba Ambra Health
System	OpenRad Cloud Software	3Dnet Suite (K063107)	Ambra PACS including ProViewer (K202335)
Indication for use	OpenRad Cloud PACS and Viewer is intended for use in the medical image analysis and diagnosis workflows of hospitals, imaging centres, radiologists, reading practices and any user who requires and is granted access to a patient image and associated demographic and report information, including Peer Review or Teleradiology providers. OpenRad Cloud PACS Viewer displays, modifies, and manages diagnostic quality DICOM images, including 3D visualisation and reordering functionality. OpenRad Cloud PACS and Viewer is intended to be used by trained healthcare professionals and medical	The 3Dnet Suite is intended to be used by physicians for the display of 2D/3D visualization of DICOM compliant medical image data, such as CT, MRI, and Ultrasound scans. The 3Dnet Suite provides several levels of functionality to the user: - basic analysis tools they use on a daily basis such as 2D review, orthogonal multiplanar reconstructions (MPR), oblique MPR, curved MPR, Slab MPR AvgJP, MIP, MinlP, measurements, annotations, reporting, distribution etc. - tools for in-depth analysis, such as	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 i mage interpretations. Mammographic images may only be viewed using cleared monitors intended for

Functionality	OpenRad	Biotronics3D Ltd.	Dicom Grid, Inc., dba Ambra Health
	researchers, with knowledge on medical imaging and experience in digital imaging diagnosis and interpretation 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 device is not intended for use with mobile displays. Review of images require an optimum display of images. Only use cleared monitors and printers for diagnosis review of images. Follow the maintenance and care instructions given in the manufacturer's documentation.	segmentation, endoscopic review, color VR slab, grayscale VR slab, 3D volume review, path definition and boundary detection etc. - Specialist tools and workflow enhancements for specific clinical applications which provide target workflows, custom UI, targeted measurement and visualization, including colon screening which is indented for the screening of patients for colonic polyps, tumors and other lesions using tomographic colonography.	mammography display. Not intended for diagnostic use on mobile devices.
Functions	• Image input, storage, view, annotate • 2D/3D image viewing • Segmentation • Measurements • Data Analysis • Multi-Planar reformatting (MPR) • Volume rendering • Maximum Intensity Projection (MIP) • Image Editing • Printing	• 2D/3D image viewing • Segmentation • Measurements • Data Analysis • Multi-Planar reformatting (MPR) • Volume rendering • Maximum Intensity Projection (MIP) • Image Editing • Printing	Ambra ProViewer, a component of Ambra PACS, imports, displays, modifies, and manages diagnostic quality DICOM images, including 3D visualization and reordering.
Data Source	MR, CT, 3D US scanners	MR,CT,3D US scanners	MR, CT, 3D US scanners
Physical Characterization	• Operates on off- the-self hardware • Windows OS • DICOM compatible	• Operates on off- the-self hardware • Windows OS • DICOM compatible	• Operates on off- the-self hardware • Windows OS • DICOM compatible

Functionality	OpenRad	Biotronics3D Ltd.	Dicom Grid, Inc., dba Ambra Health

Technical Characteristics

Characteristic	OpenRad Cloud PACS	Biotronics3D Ltd.	Intelerad Ambra PACS including ProViewer	Difference?
Basic Tools				
Thin client/ Zero client	Y	Y	Y	These features were provided in Biotronics 3Dnet as a Windows application. These features are provided in both OpenRad Cloud and Ambra Viewer as Cloud applications.
Measurements and annotations	Y	Y	Y	
Dynamic hanging protocols	Y	Y	Y	
Comparative mode and sync navigation	Y	Y	Y	
Zoom, pan, invert, flip, cine mode, W/L	Y	Y	Y	
Reporting	Y	Y	Y	
CT Colonography	Y	Y	Y	
CTLung	Y	Y	Y	
CTVessel	Y	Y	Y	
CT Calcium Scoring	Y	Y	Y	
CTDental	Y	Y	Y	
BreastMRI	Y	Y	Y	
Mammography	Y	Y	Y	
X-ray Angiography (XA)	Y	Y	Y	
DCE-MRI	Y			Does not raise new questions of safety and effectiveness. Validated during performance testing
ADC Map	Y			ADC mapping is a minor visualisation tool common in DICOM viewers. Does not raise new questions of safety and effectiveness. Validated during performance testing
Spine Labelling	Y			This is a manual annotation tool, common in DICOM

				viewers, which users access and apply exactly as they do other annotation tools.
Prostate	Y			Viewer functionality. Does not raise new questions of safety and effectiveness. Validated during performance testing
Advanced and Specialist Visualisation Tools				
Multiplanar Reconstruction (MPR) (curved and oblique)	Y	Y	Y	These features were provided in Biotronics 3Dnet as a Windows application. These features are provided in both OpenRad Cloud and Ambra Viewer as Cloud applications.
PET / CT	Y	Y	Y	
3D Volume	Y	Y	Y	
Maximum Intensity Projection MIP	Y	Y	Y	
Slab MIP / Sliding Thin Slab (STS)	Y	Y	Y	
MeanMIP/AvgMIP, MinIP	Y	Y	Y	
Reorder Series	Y	Y	Y	

Functionality	**OpenRad Cloud PACS**	**Biotronics3D Ltd.**	**Intelerad Ambra PACS including ProViewer**	**Difference?**
User interaction/input	Y	Y	Y	No difference, These features were provided in Biotronics 3Dnet as a Windows application. These features are provided in both OpenRad Cloud and Ambra Viewer as Cloud applications.
Import / export images	Y	Y	Y	
Image search available	Y	Y	Y	
Image storage	Y	Y	Y	
Image annotation	Y	Y	Y	
DICOM 3.0 compatibility	Y	Y	Y	
Thumbnail viewing	Y	Y	Y	
Panning	Y	Y	Y	
Magnify glass	Y	Y	Y	
Fit image	Y	Y	Y	
Cloud hosting	Y	N	Y	Does not raise new questions of safety and effectiveness. Tested as part of software verification and validation

We conclude that the subject device, the OpenRad Cloud Software, is as safe and effective as the predicate devices and poses no new questions of safety and effectiveness.

7. PERFORMANCE DATA & CLINICAL EVALUATION

The OpenRad Cloud Software has been developed in a manner consistent with accepted standards for software development, including both unit and system integration testing protocols. The proposed use indications were evaluated through unit, system, and validation testing under established company

protocols for design specifications and requirements, subsequent risk management analysis, and final design review. The device performance as documented in the verification and validation report affirms design specifications are met and with a profile similar to the predicate device by clinical experts using the same methodology and datasets as the ones used for in-house tests. The evaluation outcome was based on their clinical experience and verifying the outputs against the known results of the datasets and the proposed transfer functions and parameters when used in other similar devices. Validated performance claims are associated with the intended use only, and clinical equivalence is aligned with that of the predicate device.

Non-clinical Testing

The OpenRad Cloud Software has been assessed and tested in-house and has passed all predetermined testing criteria. The Validation and Validation Plan and Clinical Evaluation Plan were designed to evaluate input functions, output functions, and actions performed by OpenRad Cloud Software, and followed the process documented in the respective plan.

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.

8. STANDARDS:

The following were used in the development of the OpenRad Cloud Software, in which the device meets the requirements set forth in the standards:

a. NEMA XR 22-2006 (R2020): “Quality Control Manual” Template for Manufacturers of Displays and Workstations Labeled for Final Interpretation in Full-field Digital Mammography

b. NEMA XR 23-2006 (R2020): “Quality Control Manual” Template for Manufacturers of Displays and Workstations Labeled for Final Interpretation in Full-field Digital Mammography

c. IEC 10918 First edition 1994-02-15: Information technology – Digital compression and coding of continuous-tone still images: Requirements and guidelines [Including: Technical Corrigendum 1 (2005)]

d. IEC 62562-2 Edition 1.0 2021-11: Medical electrical equipment – Medical image display systems – Part 2: Acceptance and constancy tests for medical image displays

e. Public law 104-191 Congress of the United States of America, Health Insurance Portability

f. 45 CFR Part 160 & 164 U.S. Department of Health & Human Services, Summary of the HIPAA Security Rule

g. 12-342 NEMA PS 3.1 - 3.20 2021e Digital Imaging and Communications in Medicine (DICOM) Set

h. 12-349 NEMA PS 3.1 - 3.20 2022d Digital Imaging and Communications in Medicine (DICOM) Set

i. ISO 14971:2019 IEC62304: 2015

j. 21 CFR Part 820 - Quality System Regulation

k. FDA-1997-D-0029 - General Principles of Software Validation

l. FDA-2011-D-0469 - Applying Human Factors and Usability Engineering to Medical Devices

m. FDA-2013-D-0616 - Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

n. FDA-2015-D-5105 - Postmarket Management of Cybersecurity in Medical Devices

o. FDA-2016-D-2483 Software as a Medical Device (SAMD): Clinical Evaluation

p. FDA-2020-D-0957 - FDA Guidance for Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS)

q. IEC 62304:2006/Amd 1:2015 - Medical device software – Software life cycle processes

r. IEC 62366-1:2015/Amd 1:2020 - Application of usability engineering to medical devices

s. ISO 13485:2016 - Quality Management Systems

t. ISO 14971:2019 - Medical devices – Application of risk management to medical devices

9. CONCLUSION

The OpenRad Cloud Software has similar indications for use and technological characteristics as the 3DNET SUITE and Ambra PACS including ProViewer.

OpenRad Cloud Software does not raise any new questions of safety or effectiveness and is equivalent in performance to existing, legally marketed devices. We conclude from these tests that OpenRad Cloud Software is substantially equivalent to the predicated devices.

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