July 31, 2026

Neurocareai, Inc. (Dba Savelife.Ai)
% Junaid Siddiq Kalia
Chief Executive Officer
1740 Lonesome Dove Dr.
PROSPER, TX 75078

Re: K260936
Trade/Device Name: RadioViewAI
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: June 23, 2026
Received: June 23, 2026

Dear Junaid Siddiq Kalia:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

, for

Jessica S. 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)*
K260936

Device Name
RadioViewAI

Indications for Use *(Describe)*
RadioViewAI is a web-based PACS and image management software, used for viewing and assessing multi modality DICOM images Ex: DX, DR, CR, CT, MR, US, RF, XA, XR, NM, PT, and 2D/3D mammography. It gathers digital images and information from a variety of sources adhering to DICOM standard, including PACS systems, digital and computed radiographic equipment, CT and MR scanners, ultrasound and RF machines, PET units, secondary capture tools and imaging gateways. RadioViewAI facilitates transmission, storage, processing and visualization of DICOM images and data within the system itself or over computer networks spanning different locations.

Lossy compressed mammographic images and digitized film screen images as received from hospitals must be reviewed for reference purposes only, not for primary diagnostic interpretation on the RadioViewAI. To ensure quality, DICOM images should only be viewed on a monitor that adheres to the technical specifications outlined by the FDA.

The software shall only be used by proficient and certified medical experts, including physicians, radiologists, and medical technicians.

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 of RadioViewAI
by
NEUROCAREAI INC (DBA SaveLife.AI)

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Contact Person: Junaid Kalia
Chief Executive Officer
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Date Prepared: March 19, 2026

Device Name and Classification

Name of Device: RadioViewAI 510k Number: K260936

Classification Name: Medical Image Management and Processing System

Common or Usual Name: System, Image Processing, Radiological
Classification Panel: Radiology

Regulation Number: 21 CFR 892.2050

Regulatory Class: Class II

Product Code: LLZ

Predicate Device:

Manufacturer	Device Name	Product Code	Application Number
CARPL.AI Inc.	CARPL	LLZ	K232891

Device Description:
RadioViewAI is a web-based PACS that provides comprehensive image viewing capabilities through a zero-footprint browser-based interface accessible via standard web browsers without requiring client-side software installation. The system operates on a secure cloud architecture where medical images and associated metadata are stored on cloud and accessed remotely by authorized users through encrypted web connections. The software receives medical images from Hospital PACS and other DICOM-compliant imaging modalities including DX, DR, CR, CT, MR, US, RF, XA, XR, NM, PT, and 2D/3D mammography, and provides secure, centralized storage while maintaining image integrity and associations with patient demographic and study information.

The web-based viewer provides standard image manipulation tools including window/level adjustment, zoom, pan, rotation, measurements, and annotations, enabling simultaneous display of multiple studies for comparison of current and prior examinations. The system is fully compliant with DICOM standards for image communication and storage, supporting DICOM services including retrieval, storage, transmission, and visualization of the DICOM images for radiologist's review and interpretation. The software integrates with hospital PACS systems through DICOM interfaces, providing worklist management and study routing capabilities, and supports radiologist reading workflows.

When assessing images for diagnostic purposes, it becomes the duty of the healthcare expert to ascertain whether the image quality is appropriate for clinical use. The system offers the choice to incorporate third-party AI models that have been cleared by the FDA. A regulatory compliance team ensures that only FDA-cleared third-party algorithms are made available within RadioViewAI. Each algorithm developer must prove regulatory clearances before their products can be incorporated with RadioViewAI. The solution solely aids in visualizing the outcomes of these third-party AI models without modifications. The safety and efficacy of the third-party model are governed by the regulatory approval granted to the original manufacturer of the said model.

RadioViewAI integrated FDA-cleared algorithms list is exclusively managed by NEUROCAREAI, customers do not have the ability technically or administratively to add or modify which FDA-cleared AI algorithms are integrated with RadioViewAI. Only FDA-cleared algorithms which have passed rigorous integration testing, regulatory and quality standards review by NEUROCAREAI to guarantee functionality, safety and security are made available in RadioViewAI.

The system implements role-based access control with user authentication, and employs encryption for data transmission and storage in compliance with HIPAA security and privacy requirements. The software can be deployed on cloud via PACS to PACS connection or on-premises ConnectAI app over standard TCP/IP networks with appropriate bandwidth for image transmission. User access is supported through modern web browsers (Chrome, Firefox, Safari, Edge) on desktop or laptop devices. The system maintains full compliance with DICOM standards, and supports all standard DICOM image formats and modalities for comprehensive medical imaging workflow management.

RadioViewAI simply presents the simple AI response output, and the initial anonymized image remains consistently available. The duty of evaluating the AI output, validating the results, and conducting the diagnosis lies with competent medical professionals. RadioViewAI current list of integrated FDA cleared AI Models:

Device Name	FDA 510(K)-Number	Company Name
Hyper Insight - ICH	K240353	Sk, Inc. (PurpleAI)
NeuroICH	K241719	NEUROCAREAI INC (SaveLife.AI)

Intended Use:
RadioViewAI is a web-based PACS and image management software intended for the display, transmission, storage, and review of multi-modality DICOM images. The software enables trained healthcare professionals such as physicians, radiologists, and certified medical technicians to view and assess medical images within the clinical workflow through web based PACS viewer. All images should be viewed on monitors that meet FDA-recommended technical specifications for diagnostic purposes. RadioViewAI is not intended to replace dedicated diagnostic workstations.

Indications for Use:
RadioViewAI is a web-based PACS and image management software, used for viewing and assessing multi modality DICOM images Ex: DX, DR, CR, CT, MR, US, RF, XA, XR, NM, PT, and 2D/3D mammography. It gathers digital images and information from a variety of sources adhering to DICOM standard, including PACS systems, digital and computed radiographic equipment, CT and MR scanners, ultrasound and RF machines, PET units, secondary capture tools and imaging gateways. RadioViewAI facilitates transmission, storage, processing and visualization of DICOM images and data within the system itself or over computer networks spanning different locations.

Lossy compressed mammographic images and digitized film screen images as received from hospitals must be reviewed for reference purposes only, not for primary diagnostic interpretation on the RadioViewAI. To ensure quality, DICOM images should only be viewed on a monitor that adheres to the technical specifications outlined by the FDA.

The software shall only be used by proficient and certified medical experts, including physicians, radiologists, and medical technicians.

RadioViewAI incorporates the following:

1. RadioViewAI supports two integration options for receiving imaging data from hospital PACS systems:
    - **Direct PACS to PACS Connection:** In this configuration, the hospital PACS or DICOM server is configured to send imaging data directly to the NEUROCAREAI Orthanc server hosted on the HITRUST certified cloud. This direct connection enables seamless transfer of DICOM studies from the hospital infrastructure to the RadioViewAI cloud environment without requiring any on-premise intermediary application.
    - **ConnectAI App On-Premise Integration:** In this configuration, the ConnectAI application is installed on-premise at the hospital facility. The hospital PACS or

DICOM server is configured to send imaging data directly to the ConnectAI app and securely routes it to the main Orthanc server on the HITRUST certified cloud

In both integration options, the database syncs itself with the cloud Orthanc server and pushes the data as soon as received by the hospital PACS/DICOM server.

2. It has a dataset manager i.e., study list/worklist, which includes all the studies that are uploaded to the system. The worklist provides search and filter capabilities to manage patient studies efficiently.
3. It has a radiology workflow management that allows administrators to manage user roles. Radiologists can then view the study images, diagnose them, and complete their reading workflow through the RadioViewAI web viewer.
4. Radiologists use it to view the DICOM images for diagnosis and assessment. The PACS viewer application offers standard PACS functionality provided by the OHIF (Open Health Imaging Foundation) viewer framework. The viewer supports DICOM images from Digital X-Ray (DX), Digital Radiography (DR), Computerized Radiography (CR), Ultrasound (US), Computed Tomography (CT), Magnetic Resonance (MR), Nuclear Medicine (NM), Digital Mammography (MG), Positron Emission Tomography (PT), Radiographic imaging (XR), Radio Fluoroscopy (RF), and X-Ray Angiography (XA).
5. It only incorporates algorithms that have received FDA clearance. A regulatory compliance team at NEUROCAREAI ensures that only FDA-cleared third-party algorithms are made available within RadioViewAI. Each algorithm developer must demonstrate regulatory clearances before their products can be incorporated. NEUROCAREAI verifies the 510(k) clearance status against the FDA database before proceeding with integration.
6. Where enabled, the system optionally forwards eligible DICOM studies to external FDA-cleared third-party AI models. The AI Model Service transmits DICOM instances to the external AI model. The external AI model processes the received DICOM instances in accordance with its FDA-cleared intended use and returns its output to the RadioViewAI environment.
7. It can provide priority status indicators for the studies in the worklist based on the outputs provided by the third-party AI models that have been cleared for this intended use.
8. For models cleared to assist the radiologist, it displays the output of the third-party AI model in the Viewer for visualization by the Radiologist to assist in diagnosing the study. RadioViewAI does not modify AI-generated DICOM objects prior to display.
9. The OHIF Viewer integrated into the RadioViewAI platform is a zero-footprint, browser-based DICOM viewer. It supports key image visualization features including window/level adjustments, zoom, pan, rotation, stack scrolling, series comparison, and layout customization. Additional tools include distance and angle measurements, region-of-interest (ROI) annotations, overlay display controls, and metadata panels displaying patient and study information derived from DICOM headers.
10. RadioViewAI provides a list of annotation and measurement tools that the user can use to annotate a case and carry out measurements. The following tools are provided:
    - Length: The user can use this to measure the distance between two points on the image, which is expressed in mm/cm. The user places the cursor over the starting point and drags to draw a segment with visible measurement.
    - Annotate: Users can mark a region of interest on the image. After the user finishes the marking, a label can be added to the annotated area for documentation.

- Angle: Angle tool can be used when a user wants to measure the angle between two lines. The user draws the first arm of the angle and releases it, and similarly draws the second arm, after which the value is displayed in degrees.
- Bidirectional: It is a tool to measure a region of interest's length and width. The user annotates a suspected lesion; using this tool the user can obtain the length and width of the marked ROI. The values are displayed in mm.
- Ellipse: This tool helps users mark a region of interest on an image in a defined elliptical border. The user draws an ellipse by dragging the mouse cursor on the ROI and releasing it to complete the shape.
- Rectangle: Similar functions to Ellipse. The only difference is the shape of the ROI, which appears as a rectangle.
- Freehand/Close Polygon: This is used for giving a freehand shape to a region of interest. The user clicks to create nodes around the ROI and completes the shape.
- Eraser: The user can click on a marked annotation and erase it.
- Reset: This button restores the study image to its original state.

There are no significant differences with the predicate device CARPL, that raise new questions of safety or effectiveness.

Features compared	**Subject Device (RadioViewAI)**	**Predicate Device (CARPL) K232891**
Manufacturer	NEUROCAREAI INC.	CARPL.AI Inc.
Common Name	Medical image management and processing system	Medical image management and processing system
Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological
Classification	Class II	Class II
Regulation Number	21 CFR 892.2050	21 CFR 892.2050
Product Code	LLZ	LLZ
Indications For Use	RadioViewAI is a web-based PACS and image management software, used for viewing and assessing multi modality DICOM images Ex: DX, DR, CR, CT, MR, US, RF, XA, XR, NM, PT, and 2D/3D mammography. It gathers digital images and information from a variety of sources adhering to DICOM standard, including PACS systems, digital and computed radiographic equipment, CT and MR scanners, ultrasound	CARPL, a web-based PACS and radiology workflow management device, used for viewing and assessing DICOM images Ex: DX, DR, CR, CT, MR, US, RF and 2D/3D mammography. It gathers digital images and information from a variety of sources that adhere to the DICOM standard. These sources encompass a range of devices, including digital and computed radiographic equipment, CT and MR scanners, ultrasound and RF machines, PET units, secondary capture tools, imaging gateways.

	and RF machines, PET units, secondary capture tools and imaging gateways. RadioViewAI facilitates transmission, storage, processing and visualization of DICOM images and data within the system itself or over computer networks spanning different locations. Lossy compressed mammographic images and digitized film screen images as received from hospitals must be reviewed for reference purposes only, not for primary diagnostic interpretation on the RadioViewAI. To ensure quality, DICOM images should only be viewed on a monitor that adheres to the technical specifications outlined by the FDA. The software shall only be used by proficient and certified medical experts, including physicians, radiologists, and medical technicians.	CARPL enables the storage, transmission, processing, and visualization of images and data within the system itself or over computer networks spanning different locations. Only pre-processed DICOM images specifically intended for presentation are suitable for primary image diagnosis in mammography. Lossy compressed Mammographic images and digitized film screen images must not be reviewed for primary image interpretation on the CARPL. To ensure accurate interpretation, mammographic images should only be evaluated on a monitor that adheres to the technical specifications outlined by the FDA. This system is designed exclusively for use by proficient and certified medical experts, including physicians, radiologists, and medical technicians.
Modalities	DX, DR, CR, CT, MR, US, RF, XA, XR, NM, PT, and 2D/3D Mammography	DX, DR, CR, CT, MR, US, RF and 2D/3D Mammography
Web Browser Software	Google Chrome, Mozilla Firefox, Safari, and Edge	Google Chrome, Mozilla, and Edge
Resolution	32 bit Color Display & 1920x1080	32 bit Color Display & 1920x1080
Image Storage	YES	YES
Software Environment	ConnectAI App: Windows 11 or higher; Cloud: HITRUST certified environment; Viewer: Zero-footprint web application	OS: Windows 10 or higher
Main Functions	• Log In • Worklist – Search Filter • Worklist – Open image • Worklist – Study List • Worklist – Series • Viewer – View exam	• Log In • Worklist – Search Filter • Worklist – Open image • Worklist – Study List • Worklist – Report • Worklist – Series

	• Viewer – Control View window • Viewer – View mode (real resolution) • Viewer – Stacking • Viewer – Changing the layout • Viewer – Comparative study • Viewer – Preset filter • Viewer – Zoom • Viewer – Panning • Viewer – Invert Image • Viewer – Rotation • Viewer – Reference line • Viewer – Measure • Viewer – Inverting image color • Viewer – Cine • Viewer – Overlaying • Viewer – Window/Level	• Viewer – View exam • Viewer – Control View window • Viewer – View mode (real resolution) • Viewer – Highlight • Viewer – Stacking • Viewer – Changing the layout • Viewer – Comparative study • Viewer – Preset filter • Viewer – Zoom • Viewer – Panning • Viewer – Invert Image • Viewer – Rotation • MIP/MPR Reconstruction • Viewer – Reference line • Viewer – Sharpening • Viewer – Measure • Viewer – Inverting image color • Viewer – Cine • Viewer – Overlaying
Optional Integration of FDA-cleared 3rd party AI models	YES - Optional integration of FDA-cleared third-party AI models (visualization only; no modification of outputs).	YES - Optional integration of FDA-cleared third-party AI models (visualization only; no modification of outputs).
Device Components	• ConnectAI app installed on-premise for DICOM routing • Cloud-based PACS storage (HITRUST certified) • Zero-footprint web based PACS viewer (OHIF) • Admin panel managed by NEUROCAREAI • Role-based access and secure encrypted communication • Optional integration layer for FDA-cleared third-party AI algorithms	• CARPL Gateway installed on-site for DICOM routing • CARPL Viewer with MPR/MIP tools • Workflow manager (study assignments, collaboration) • Optional integration layer for FDA-cleared third-party AI algorithms
Operation Features	• Web environment-based PACS • Viewing and handling DICOM medical images • Review study located on cloud • View multiple AI model output • Role-based access control	• Web environment-based PACS • Viewing and handling DICOM medical images • Review and report study located on a server • View multiple AI model output

The technological principle for both the subject and predicate devices is the same in terms of prescription use, support of various modalities, resolution, image storage, use of the DICOM standard, and operation features. Most of the features, specifications, and functions of both the subject and predicate devices, like indications for use, software web browser, software intended environment, study viewer, and study worklist are similar.

RadioViewAI provides the feature of optional integration with external FDA-cleared third-party AI models like the predicate device CARPL does. The integration with the FDA-cleared third-party AI models is optional based on the user's discretion, and always in accordance with the third-party manufacturer's regulatory clearance. RadioViewAI integrated FDA-cleared algorithms list is exclusively managed by NEUROCAREAI. Customers do not have the ability technically or administratively to add or modify which FDA-cleared AI algorithms are integrated with RadioViewAI. Only FDA-cleared algorithms which have passed rigorous integration testing, regulatory and quality standards review by NEUROCAREAI to guarantee functionality, safety and security are made available in RadioViewAI. Hence, the difference in the list of offered AI algorithms does not affect the product effectiveness and safety.

Both devices provide similar basic image manipulation tools like window/level adjustment, zoom, pan, rotation, measurements, and annotations, enabling simultaneous display of multiple studies for comparison of current and prior examinations. The minor differences in the capability of tools provided does not raise any new questions of safety and effectiveness. Both devices have the capability to integrate and display outputs from external AI algorithms. Neither device performs diagnostic analysis, or alters medical images. Both devices are intended to be used by certified medical experts including physicians, radiologists and medical technicians who are experts in the independent diagnostic review and interpretation of medical images.

Any differences between the subject and predicate devices are limited to backend architectural implementation, including microservice-based synchronization workflows and cloud scalability mechanisms. These differences do not affect intended use, core technological principles, safety, or effectiveness and do not introduce new potential risks.

PERFORMANCE DATA

Non-clinical testing:

RadioViewAI has been tested and has passed all predetermined testing criteria. The Validation Testing protocol was designed to evaluate output functions and actions performed by NEUROCAREAI INC. and followed the process documented in the Software Validation Testing Protocol. 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.

Based on the performance as documented in the Validation Testing, RadioViewAI was found to have a safe and effectiveness profile that is substantially equivalent to the predicate device.

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

Standard	FDA Recognition #	Title
IEC 62304:2006+A1:2015	13-79	Medical device software – Software life cycle processes
ISO 14971:2019	4-392	Medical devices – Application of risk management to medical devices
ISO/TR 24971:2020	N/A (Technical Report)	Guidance on the application of ISO 14971
ISO/TR 80002-1:2009	N/A (Technical Report)	Guidance on the application of ISO 14971 to medical device software
IEC 62366-1:2015+A1:2020	5-166	Application of usability engineering to medical devices
ISO 13485:2016	1-69	Quality management systems – Requirements for regulatory purposes
Nema PS 3.1-3.20 2024e	12-363	Digital Imaging and Communications in Medicine (DICOM) set

CONCLUSION

The information presented in the 510(k) for RadioViewAI contains adequate information, data, and nonclinical (validation) test results to demonstrate substantial equivalence to the predicate device. RadioViewAI was shown to be substantially equivalent to the predicate device CARPL (K232891) in the areas of technical characteristics, general function, application, and intended use and does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.