MDAI Inc.
℅ Leon Chen
CEO
110 Wall Street
NEW YORK NY 10005

Re: K223425 February 10, 2023
Trade/Device Name: MD.ai Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 9, 2022
Received: November 14, 2022

Dear Leon Chen:

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223425

Device Name
MD.ai Viewer

Indications for Use *(Describe)*
MD.ai Viewer is a software-based viewer intended to be used with off-the-shelf hardware for the display of DICOM and non-DICOM medical images and other healthcare data to aid in diagnosis for healthcare professionals. It performs operations relating to the transfer, storage, display, and measurement of image data.

MD.ai Viewer allows users to perform image manipulations, including window/level, rotation, measurement and markup. MD.ai Viewer provides 2D display, Multi-Planar Reformatting and 3D visualization of medical image data.

Mobile usage is for reference and referral only.

MD.ai Viewer is not intended for primary mammography interpretation.

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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K223425

Administrative Information

Submitter:	MDAI Inc
Submission Type:	Traditional 510(k), New device
Address:	110 Wall Street Suite 6-028, NY, NY 10005
Phone Number:	917-725-1883
Contact Person/Company Representative	Leon Chen CEO, MDAI Inc
Email:	fda@md.ai

Device Information

Trade Name	MD.ai Viewer
Common Name	Medical image viewing and analysis software
Product Code	LLZ
Regulation Number	892.2050
Regulatory Class	Class 2
Regulatory Name	System, Image Processing, Radiological
Review Panel	Radiology

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Predicate Device Information

Predicate Device Name	eUnity
Predicate Device K Number	K172490
Product Code	LLZ
Regulation Number	892.2050
Regulatory Class	Class 2
Regulatory Name	System, Image Processing, Radiological
Review Panel	Radiology

To our knowledge the predicate device has not been subject to a design related recall.

Reference Device

Reference Device Name	Ambra PACS including Ambra ProViewer
Predicate Device K Number	K202335
Product Code	LLZ
Regulation Number	892.2050
Regulatory Class	Class 2
Regulatory Name	System, Image Processing, Radiological
Review Panel	Radiology

Device Description

MD.ai Viewer is a software-based medical image viewer used with off-the-shelf workstation and web browsers for the 2D & 3D visualization of DICOM and non-DICOM medical images. MD.ai Viewer is intended for storage, display, manipulation, measurement and processing of radiological data, including images, reports and other clinical information. It has the following primary features and functions

- Zero-footprint HTML5 medical image upload, transfer and display of medical images between facilities

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- Easy access to images for all participants in the healthcare process, including radiologists, technologists, physicians, nurses and other patient care practitioners
- Serve as information and data management system for for DICOM and non-DICOM medical images
- Tools for image manipulation, annotation and measurement.
- Metadata information and orientation labels display
- Advanced image manipulation functions like view synchronization across series, 3D visualization like MIP and MPR
- Advanced image processing filters like histogram equalization (CLAHE) filter to aid in visualization of pathological features in the images
- Encrypted transmission of medical images through secured networks
- Encrypted storage of medical images
- HIPAA-compliant data management, including centralized storage of user activities via audit trails.
- Management of users, roles, and permissions

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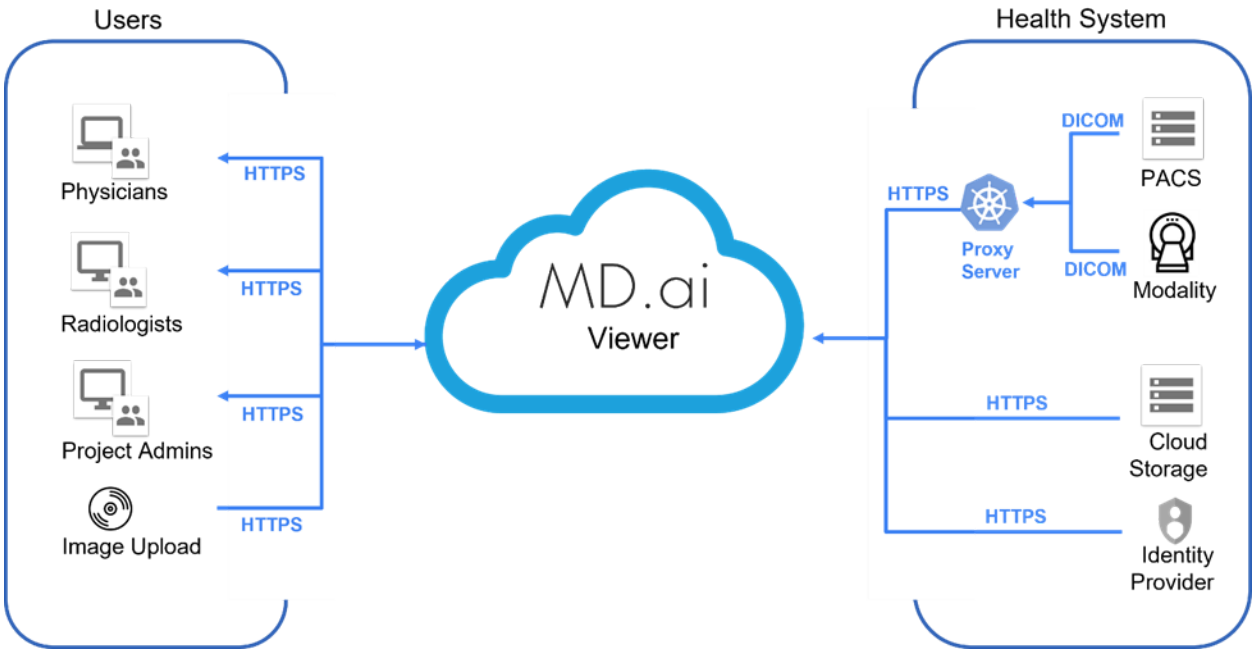

MD.ai Viewer consists of configurable software-only modules that display and process digital medical images, and associated medical information to aid in the day-to-day operations and workflow of clinicians and healthcare practitioners. The web browser based medical image viewer serves as the frontend module which users interact with in viewing the imaging data. The backend module handles the connection and processing of data from a variety of sources within the health system, in view of preparing visualizations to be rendered by the viewer.

MD.ai Viewer can connect and access the medical images across different sources in a health system: an existing PACS or VNA, cloud storage or local server-based storage. Users can also upload images securely into MD.ai Viewer which can be shared and enables collaboration with other users. The data connection and imaging data processing is handled by MD.ai Viewer backend module which supports the standardized transmission protocol as defined in the DICOM standard. In situation where secure network link is not available between health system and MD.ai cloud instance, the MD.ai Viewer proxy server can provide a secure and encrypted transfer of imaging data.

Users interact with MD.ai Viewer through a standard web browser, thus providing access to full quality images from anywhere and supporting a greater efficiency for care. MD.ai Viewer utilizes authorization and authentication mechanisms that enforces authorized users to access the

imaging data. The system extends beyond the hospital and its internal network. With proper authorization, MD.ai Viewer can be accessed by clinical users outside of the hospital network. This way referring physicians can easily call up the imaging data of their patients or external expert accessing the imaging data for additional opinion.

MD.ai Viewer provides end-users with the ability for industry standard features such as Window/ Level, Image Flip and Rotate, Invert, Hanging Protocol, Image Measurements, and Keyboard/Mouse shortcuts. Images are initially displayed in the 2D view mode, but with the ability to toggle into advanced viewing mode of 3D/MPR for relevant exam type. It supports processing and displaying Multiplanar Reconstruction (MPR) and different intensity rendering modes based on user-defined slab thickness. It also provides image processing filters like histogram equalization (CLAHE) filter to better visualize pathological features when displaying low contrast images from some modality devices.

MD.ai Viewer provides an image rendering mechanism that preloads lower resolution images during image scrolling to improve interactivity and performance for users operating in lower network bandwidth while the full quality image is loaded in the background.

The use of a secure data transmission protocol and data encryption ensure high data security for data management via the Internet. MD.ai Viewer tracks user activity via audit trails and stores the audit data on the centralized server

Subject Device Indications for Use

MD.ai Viewer is a software-based viewer intended to be used with off-the-shelf hardware for the display of DICOM and non-DICOM medical images and other healthcare data to aid in diagnosis for healthcare professionals. It performs operations relating to the transfer, storage, display, and measurement of image data.

MD.ai Viewer allows users to perform image manipulations, including window/level, rotation, measurement and markup. MD.ai Viewer provides 2D display, Multi-Planar Reformatting and 3D visualization of medical image data.

Mobile usage is for reference and referral only.

MD.ai Viewer is not intended for primary mammography interpretation.

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Subject Device Contraindications for Use

MD.ai Viewer is not indicated for interpreting mammography.

Substantial Equivalence Discussion

Predicate Device Indications for Use

eUnity is a software application that displays medical image data and associated clinical reports to aid in diagnosis for healthcare professionals. It performs operations relating to the transfer, storage, display, and measurement of image data.

eUnity allows users to perform image manipulations, including window/level, rotation, measurement and markup. eUnity provides 2D display, Multi-Planar Reformatting and 3D visualization of medical image data, and mobile access to images.

eUnity displays both lossless and lossy compressed images. For lossy images, the medical professional user must determine if the level of loss is acceptable for their purposes. Display monitors or mobile devices used for reading medical images for diagnostic purposes must comply with applicable regulatory approvals and with quality control requirements for their use and maintenance. For mobile diagnostic usage when a full workstation is not available.

Mobile usage for mammography is for reference and referral only.

1.1. Subject Device Indications for Use

MD.ai Viewer is a software-based viewer intended to be used with off-the-shelf hardware for the display of DICOM and non-DICOM medical images and other healthcare data to aid in diagnosis for healthcare professionals. It performs operations relating to the transfer, storage, display, and measurement of image data.

MD.ai Viewer allows users to perform image manipulations, including window/level, rotation, measurement and markup. MD.ai Viewer provides 2D display, Multi-Planar Reformatting and 3D visualization of medical image data.

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Mobile usage is for reference and referral only. MD.ai Viewer is not intended for primary mammography interpretation.

1.2. Indications for Use Equivalence Discussion

The Predicate Device (eUnity) and Subject Device (MD.ai Viewer) are both software-based viewer designed to receive, display, and measure image data and indicated for use to aid in diagnosis for trained healthcare professionals.

Both devices shared common technological characteristics. Both are intended as a zero-download, zero-footprint browser-based viewer. By leveraging the industry standard browser-based technology, both devices enable image data display with off-the-shelf hardware.

Both devices are capable of displaying image data in DICOM format from imaging modalities that are standard in the provision of care as well as non-DICOM image data captured in widely used JPEG or PNG format.

Further comparison between the two devices as performed in Device Comparison Table.

The indications for use of the Predicate Device and Subject Device are substantially equivalent.

Device Comparison Table

Characteristic	**Subject Device:MD.ai Cloud Platform**	**Primary Predicate:Client Outlook eUnity**	**Comment**
User Install Requirements	Thin Client - no install, runs within browser	Thin Client - no install, runs within browser	Equivalent
Communication	DICOM, non-DICOM	DICOM, non-DICOM, IHE	The Subject Device supports the DICOM communication protocol used within the IHE framework. Similar to the Predicate Device, it fulfills the role of Image Display described in the IHE Radiology Integration Profile.
Modalities	CR, CT, DX, IVOCT, MR, MG, NM, OCT, OT, PT, RF, SC, US, XA	CR, CT, DX, ECG, MR, MG, NM, OP, PR, PT, RF, SC, SR, US, XA, XL	Key modalities used in provision of care are supported.

Window Level, Rotate/Pan/Zoom, Reset, Presets, Invert	Yes	Yes	Equivalent
Multi-study viewing, Image Export, Image Sharing compliant	Yes	Yes	Equivalent
Metadata Display/Hide	Yes	Yes	Equivalent
Orientation Labels, Keyboard Shortcuts	Yes	Yes	Equivalent
Measurements, Annotations	Yes	Yes	Equivalent
Full Screen Mode, Multi-monitor, Layouts	Yes	Yes	Equivalent
Linking Series, Image Scrolling, Linked Scrolling, Reference Lines	Yes	Yes	Equivalent
GSPS, KIN	No	Yes	Subject Device manages the presentation state as an internal record that allows Intended users to interact with the presentation state within the device. The Subject Device currently does not support the export of presentation state in GSPS and KIN. The difference does not impact the equivalence for the Predicate and Subject Device.
Multiplanar reformat (MPR)	Yes	Yes	Equivalent
Maximum Intensity Projection (MIP)	Yes	Yes	Equivalent
Oblique, Volume Rendering, Opacity Presets, Scalpel tool, bone removal	No	Yes	The Predicate Device provides additional capabilities in 3D advanced visualization which the Subject Device does not have. The difference does not impact the equivalence for the Predicate and Subject Device.
Sharpen, blur, emboss, edge filters	Yes	No	These filters are part of the image manipulation tool included in the Subject Device which the users could use when displaying the image data. The difference does not impact the equivalence for the Predicate and Subject Device.

Histogram Equalization filter	Yes	No	These filters are part of the image manipulation tool included in the Subject Device which the intended users could use when displaying the image data. The difference does not impact the equivalence for the Predicate and Subject Device.
Data Encryption	HTTPS	HTTPS	Equivalent
Data Security	Stored on server	Stored on server	Equivalent
Access Control	Built-in access control or parent application access control	Built-in access control or parent application control	Equivalent

Non-Clinical Performance Testing

The MD.ai Viewer was subjected to non-clinical performance testing which verified that the design requirements were successfully met. Intended use and user needs were successfully validated. The measurement features of MD.ai Viewer were validated using Digital Reference Objects and comparison with the reference device - K202335.

As the intended use, functionality and performance of the subject MD.ai Viewer and predicate eUnity device are equivalent, the result of the non-clinical performance testing is evidence that the MD.ai Viewer performs in an equivalent manner to the eUnity device.

Clinical Performance Data Equivalence Discussion

No clinical performance data were performed for this submission.

Animal Studies Data

No animal studies were performed for this submission.

Conclusion

Based on the comparisons and analyses detailed above in this summary, we believe that the information and performance test reports of the MD.ai Viewer provided in this Traditional

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510(k) submission are sufficient to demonstrate the safety and effectiveness as compared to the eUnity (K172490) predicate device.