PMX Inc.
% Rory Carrillo
Regulatory Consultant
Cosm
45 Bartlett St.
San Francisco, California 94110

June 17, 202

Re: K233331
Trade/Device Name: MediOMx
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 29, 2023
Received: May 13, 2024

Dear Rory Carrillo:

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
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic 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)*
K233331

Device Name
MediOMx

Indications for Use *(Describe)*
MediOMx is a software-based viewer intended to be used with off-the-shelf hardware for the display of DICOM data to aid in diagnosis for healthcare professionals. It performs operations relating to the transfer, storage, and display of image data. MediOMx allows users to perform image manipulations, including window/level, pan, zoom, and rotation. MediOMx provides 2D display, Multi-planar Reformatting of medical image data. MediOMx is not intended for primary mammography interpretation.

Mobile usage is for reference and referral only.

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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"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."

510(k) Summary

1. General Information

510(k) Sponsor	PMX Inc,
Address	50 N Brockway St, Suite 3-3 Palatine, IL 60067
Correspondence Person	Rory A. Carrillo Regulatory Consultant Cosm
Contact Information	Email: rory@cosmhq.com Phone: 415-580-0916
Date Prepared	September 29, 2023

2. Proposed Device

Proprietary Name	MediOMx
Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Regulation Name	Medical image management and processing system
Product Code	LLZ
Regulatory Class	II

3. Predicate Device

Proprietary Name	MD.ai Viewer
Premarket Notification	K223425
Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Regulation Name	Medical image management and processing system
Product Code	LLZ
Regulatory Class	II

4. Device Description

MediOMx is a software-based medical image viewer used with web browsers for the 2D visualization of DICOM and non-DICOM medical images. MediOMx is intended for storage, display, manipulation, 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
- 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 (e.g.pan, zoom, rotate, window level)
- Metadata information and orientation labels display
- Advanced image manipulation functions like view synchronization across series, 3D visualization like MIP and MPR
- Encrypted transmission of medical images through secured networks
- Encrypted storage of medical images
- HIPAA-compliant data management, including centralized storage of user activity via audit trails.
- Management of users, roles, and permissions
- It supports optional integration with FDA-cleared 3rd party AI models. It sends the input study to the 3rd party AI model, receives the AI output and displays outputs of the 3rd party AI model "as-is" in MediOMx for visualization by the Radiologist to assist in diagnosing the study. Outputs are displayed in accordance with the 3rd party provider's regulatory clearance. The original image is always accessible

MediOMx consists of a cloud-based application that displays and processes 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. MediOMx 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 MediOMx which can be shared and enables collaboration with other users. The data connection and imaging data processing is handled by the MediOMx backend module which supports the standardized transmission protocol as defined in the DICOM standard. Users interact with

MediOMx through a standard web browser, thus providing access to full quality images from anywhere and supporting a greater efficiency for care. MediOMx 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 a proper network, MediOMx 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. MediOMx provides end-users with the ability for industry standard features such as Window/ Level, Image Flip and Rotate. Images are initially displayed in the 2D view mode, but with the ability to toggle into advanced viewing mode of MPR for relevant exam types. It supports processing and displaying Multiplanar Reconstruction (MPR). MediOMx provides an image rendering mechanism that preloads lower resolution images during image scrolling to improve interactivity and performance for users operang 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. MediOMx tracks user activity via audit trails and stores the audit data on the centralized server.

5. Indications For Use

MediOMx is a software-based viewer intended to be used with off-the-shelf hardware for the display of DICOM data to aid in diagnosis for healthcare professionals. It performs operations relating to the transfer, storage, and display of image data. MediOMx allows users to perform image manipulations, including window/level, pan, zoom, and rotation. MediOMx provides 2D display, Multi-planar Reformatting of medical image data. MediOMx is not intended for primary mammography interpretation

Mobile usage is for reference and referral only.

6. Substantial Equivalence

	Proposed Device MediOMx	**Predicate Device:** *MD.ai Viewer* (K223425)	**Substantially Equivalent**
Indications for Use	MediOMx is a software-based viewer intended to be used with off-the-shelf hardware for the display of DICOM data to aid in diagnosis for healthcare professionals. It performs operations relating to the transfer, storage, and display of image data. MediOMx allows users to	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	Yes

	Proposed Device MediOMx	Predicate Device: *MD.ai Viewer* (K223425)	Substantially Equivalent
	perform image manipulations, including window/level, pan, zoom, and rotation. MediOMx provides 2D display, Multi-planar Reformatting of medical image data. MediOMx is not intended for primary mammography interpretation Mobile usage is for reference and referral only.	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.	

Feature/ Function	Proposed Device MediOMx	Predicate Device: *MD.ai Viewer* (K223425)	Substantially Equivalent
User Install Requirements	Thin Client - no install, runs within browser	Thin Client - no install, runs within browser	Yes
Communication	DICOM, non-DICOM	DICOM, non-DICOM	Yes
Modalities	CT, MR, X-ray, US	CR, CT, DX, IVOCT, MR, MG, NM, OCT, OT, PT, RF, SC, US, XA	Yes
Window Level, Rotate/Pan/Zoom, Reset, Presets, Invert	Yes	Yes	Yes
Multi-study viewing, Image Export, Image Sharing compliant	Yes	Yes	Yes
Metadata Display/Hide	Yes	Yes	Yes
Orientation Labels	Yes	Yes	Yes
Keyboard Shortcuts	No	Yes	Yes

Feature/ Function	Proposed Device MediOMx	Predicate Device: *MD.ai Viewer* (K223425)	Substantially Equivalent
Measurements, Annotations	No	Yes	Yes
Full Screen Mode	Yes	Yes	Yes
Multi-monitor, Layouts	No	Yes	Yes
Linking Series	No	Yes	Yes
Image Scrolling, Linked Scrolling, Reference Lines	Yes	Yes	Yes
GSPS, KIN	No	No	Yes
Multiplanar reformat (MPR)	Yes	Yes	Yes
Maximum Intensity Projection (MIP)	Yes	Yes	Yes
Oblique, Volume Rendering, Opacity Presets, Scalpel tool, bone removal	No	No	Yes
Sharpen, blur, emboss, edge filters	No	Yes	Yes
Histogram Equalization filter	No	Yes	Yes

The subject device and predicate device have substantially equivalent indications for use and technological characteristics. The minor differences do not raise questions of safety or effectiveness as the underlying technology is similar and risks associated with these differences are mitigated with similar general and special controls.

7. Performance Data

Safety and performance of the PMX MediOMx device has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification,validation,standalone and clinical performance testing. Additionally, the software validation activities were performed in accordance with *IEC 62304:2006/A1:2016 Medical device software – Software life cycle processes,* in addition to the FDA Guidance documents, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* and *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"*.

8. Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing, the MediOMx raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, effectiveness, and performance.