March 31, 2026

Mediott, Inc.
% Abe Takehiko
C.E.O
18-2 Shitamachi, Akagi Kagura Sacas
Shinjuku-Ku, TOKYO 162-0803
JAPAN

Re: K253029
Trade/Device Name: RW-1
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: February 13, 2026
Received: February 13, 2026

Dear Abe Takehiko:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

FDA Digitally signed by GABRIELA M. RODAL -S for

Lu Jiang Ph.D.
Assistant Director
Diagnostic X-Ray Systems 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)*
K253029

Device Name
RW-1

Indications for Use *(Describe)*
This software is a medical device intended for the visualization of various intensity modulation including FFT filter. It receives, stores, processes, and displays sequential DICOM images primarily obtained through low-dose chest fluoroscopy (e.g., RF and AX modalities) .
This software is not intended to be used for primary diagnosis. Reference images such as scintigraphy or CT scans may be displayed for supplementary purposes. This software is intended for use in adult patients 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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K253029

510(k) Summary

Date of Preparation: September 20th, 2025

Applicant

Company name : Mediott Inc.
Address: 18-2 Shitamachi, Akagi Kagura Sacas, Shunjuku-ku, Tokyo, 162-0803, Japan

Contact

Contact Person: Takehiko Abe
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Fax: None
e-mail: abe@radwisp.com

Name of Device

Product Name: RW-1
Classification Name: System, Image Processing, Radiological
Regulation Name: Medical image management and processing system
Regulation Number: 21 CFR 892.2050
Regulatory Class: Class II
Product Code: LLZ
Panel: Radiology

Predicate Device

Product Name: KONICAMINOLTA DI-X1
Classification Name: System, Image Processing, Radiological
Regulation Name: Medical image management and processing system
Regulation Number: 21 CFR 892.2050
Regulatory Class: Class II
Product Code: LLZ
Panel: Radiology
501(k) Number: K212685
Applicant: Konica Minolta, Inc.

Device Description

The subject device is the software device that receives, stores, processes, and displays sequential DICOM images including the intensity modulation primarily obtained through chest fluoroscopy (e.g., RF and AX modalities). The software is compatible with external systems such as hospital PACS via DICOM-compliant communication protocols.

The device incorporates a intensity modulation mode image including fast Fourier transform

(FFT) , which extracts time-varying components corresponding to lower and higher frequency band pass filter in chest XP dynamics. When appropriate image acquisition conditions are met (e.g., fixed exposure, no post-processing, sufficient number of frames), the software generates differential projection images:

- RDP (Lower frequency band pass filter modulated projection in chest XP dynamic imaging)
- BDP (Higher frequency band pass filter modulated projection in chest XP dynamic imaging

Additionally, the software can compute time-compressed summary images (e.g., MEDP, MIDP, MBDP), which provide intuitive visualization of regional changes, similar to maximum intensity projection techniques used in CT imaging. The device operates as a standalone application, with all processing and visualization of the intensity modulation integrated into a single software package.

Indications for Use

This software is a medical device intended for the visualization of various intensity modulation including FFT filter. It receives, stores, processes, and displays sequential DICOM images primarily obtained through low-dose chest fluoroscopy (e.g., RF and AX modalities) .

This software is not intended to be used for primary diagnosis. Reference images such as scintigraphy or CT scans may be displayed for supplementary purposes. This software is intended for use in adult patients only.

Technological Characteristics

The subject device and the predicate device are both software-based medical imaging systems that receive, process, display, and transmit X-ray digital images.

While there are differences in the number of image processing modes, display functions, measurement tools, and system configuration, the subject device retains the core capabilities necessary for its intended use.

These differences represent either reductions in functionality or architectural simplifications. They do not raise new questions of safety or effectiveness.

	Subject Device	**Predicate Device**
Device Name	RW-1	KONICAMINOLTA DI-X1
510(k) number	This submission	K212685
Indications for Use	This software is a software device that receives, stores, processes, and displays sequential DICOM images including the intensity modulation	KONICAMINOLTA DI-X1 is a software device that receives digital x-ray images and data from various sources (i.e. R/F Units, digital radiographic

	primarily obtained through chest fluoroscopy (e.g., RF and AX modalities). This software is not intended to be used for primary diagnosis. Reference images such as scintigraphy or CT scans may be displayed for supplementary purposes.	devices or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and/or across computer networks at distributed locations. It is not intended for use in diagnostic review for mammography
Input Image	● DICOM 3.0 ● DICOM Modality (RF, DX, CR, AX)	● DICOM 3.0 ● DICOM Modality (RF, DX, CR)
I/O Data	● DICOM Storage	● DICOM Storage
Image Processing	● RDP (PL-MODE) ● BDP (PH-MODE)	● REGIUS ● FE-MODE ● DM-MODE ● BS-MODE ● PL-MODE ● Pk to Pk ● PH-MODE ● PH2-MODE ● LM-MODE
Display Functions	● Adjustment of density and gradation, Rotation, Scaling, Panning ● Screen display (listing, viewer) ● Image display (Cine, Comparison) ● Graph display (Time-series comparison)	● Adjustment of density and gradation, Rotation and reversal, Scaling, Panning ● Screen display (listing, viewer) ● Image display (Cine, Comparison, Annotation, Overlay) ● Graph display (Time-series comparison)
Measurement Functions	● Area	● Distance ● Angle ● Area ● CTR (Only the image of the front of ● the chest)
Client	● RW-1 client (Standalone application)	● DI-X1 client ● DI-X1 Server client ● PC client (WEB reference)

Performance (Non-Clinical) Testing

Non-clinical performance testing was conducted as part of the comprehensive system-level verification and validation (V&V) activities for the subject device. These tests were designed to confirm that the implemented software algorithms operate reliably and consistently under representative conditions. The primary focus was on ensuring functional correctness, repeatability, and robustness of the device functions, consistent with industry standards for

software-based medical devices. Statistical exhaustiveness was not required due to the deterministic nature of the implemented algorithms.

No separate standalone bench tests were performed beyond these system-level V&V activities, as the system-level testing was considered sufficient to evaluate all performance-critical features under anticipated use conditions. This approach aligns with standard practices for medical software, where system-level integration tests typically serve as the main source of performance evidence.

Cybersecurity requirements were addressed per FDA guidance document, Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions.

This mode image is designed to enhance visuality under specific conditions. While previous literature suggests some possibility of clinical relevance, the representation of this mode in this case marely illustrates its image under certain conditions and does not establish its clinical significance. Collectively, these results support the conclusion that the subject device performs as intended and is substantially equivalent to the predicate device with respect to safety and effectiveness

Conclusion

Based on the comparison of technological characteristics and intended use, as well as non-clinical performance testing, it is concluded that the subject device is substantially equivalent to the predicate device. The observed differences do not raise new questions of safety or effectiveness and reflect reductions in scope or architectural simplification.