July 21, 2026

ResolutionMD, Inc.
Sharon Cholowsky
Director Regulatory & Compliance
Suite 314, 1212 31 Ave. NE
Calgary, AB T2E 7S8
Canada

Re: K260500
Trade/Device Name: ResolutionMD
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: June 19, 2026
Received: June 22, 2026

Dear Sharon Cholowsky:

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,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260500

Please provide the device trade name(s).

ResolutionMD

Please provide your Indications for Use below.

The ResolutionMD solution is an enterprise imaging viewer that is used for the secure display, multiplanar reformatting and 3D visualization of medical image data and reports. It also provides for mobile access and real-time collaboration of clinical information.

The software is intended for use as a review and analysis tool by authorized healthcare professionals to drive clinical management. When interpreted by a physician, reviewed images may be used to aid in diagnosis. When used on a mobile device, ResolutionMD is not intended to replace full radiology workstations.

ResolutionMD displays both lossless and lossy compressed images. For lossy images, the healthcare professional 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 clearances, technical specifications, and quality control requirements for their use and maintenance. For mammography, mobile devices do not comply with the minimum display requirements; therefore mobile device usage for mammography is for reference and referral only.

Healthcare institutions may want to provide patients access to their clinical information. This access is for non-diagnostic informational purposes only.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

For 510(k) #: K260500 As per 21 CFR 807.92

Prepared on June 20, 2026

Contact Details

Applicant Name:	ResolutionMD, Inc.
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Applicant Contact:	Sharon Cholowsky
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Device Name

Device Trade Name:	ResolutionMD
Common Name:	Medical image management and processing system
Classification Name:	System, Image Processing, Radiological
Regulation Number:	892.2050
Product Code:	LLZ

Predicate Devices

510(k) #: K161130	Device Name: ResolutionMD	Product Code: LLZ
510(k) #: K172490	Device Name: eUnity	Product Code: LLZ

Device Description Summary

The ResolutionMD product is an enterprise imaging viewer software solution which enables users to access a centralized application running on a Linux or Windows server from an HTML5 web browser or HTML5 browser on a mobile device. The ResolutionMD application server interacts with a PACS or vendor-neutral archive (VNA) to enable users to search and view DICOM and non-DICOM clinical information.

ResolutionMD is a software application system which runs on general purpose computing hardware and operating systems software. It uses a client-server architecture whereby all processing takes place on the server. There is no local client software to install or download; the software is installed on a server.

Indications for Use

The ResolutionMD solution is an enterprise imaging viewer that is used for the secure display, multiplanar reformatting and 3D visualization of medical image data and reports. It also provides for mobile access and real-time collaboration of clinical information.

The software is intended for use as a review and analysis tool by authorized healthcare professionals to drive clinical management. When interpreted by a physician, reviewed images may be used to aid in diagnosis. When used on a mobile device, ResolutionMD is not intended to replace full radiology workstations.

ResolutionMD displays both lossless and lossy compressed images. For lossy images, the healthcare professional 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 clearances, technical specifications, and quality control requirements for their use and maintenance. For mammography, mobile devices do not comply with the minimum display requirements; therefore mobile device usage for mammography is for reference and referral only.

Healthcare institutions may want to provide patients access to their clinical information. This access is for non-diagnostic informational purposes only.

Indications for Use Comparison

The subject device indications for use (IFU) statement is similar to the predicate device statement. Phrases relating to mammography diagnostic use were modified, thereby adding support for diagnostic use of mammographic images, including digital breast tomography images. Additionally, some existing phrases were slightly modified for further clarity or standardization of terms.

The differences of the predicate and reference IFU statements and the subject device IFU statement do not present any new safety and effectiveness concerns because the new wording only adds further clarity and information to aid the healthcare professional and does not alter the clinical workflow of the device or how it will be used.

	Subject Device	**Predicate Device**	**Reference Device for Mammo**
Feature	**ResolutionMD (This submission)**	**ResolutionMD (K161130)**	**eUnity (K172490)**
Model #	Model #: RESMD-D	Model #: RESMD-C	N/A
Class, Product Code	Class 2, LLZ	Same	Same
Intended Use	An enterprise imaging viewer that is used for the secure display, multiplanar reformatting and 3D visualization of medical image data and reports. It also provides for mobile access and real-time collaboration of clinical information. It is to be used as a review and analysis tool by authorized healthcare professionals to drive clinical management.	Same	Same
Pres. use or OTC	Prescription use	Same	Same
Intended Users	Healthcare professionals	Same	Same
Mammography support	Support for diagnostic use of mammographic (incl digital breast tomography) images	Support for non-diagnostic use of mammographic (incl digital breast tomography) images.	Same as subject device
Mammo mobile use	Mobile usage for mammography is for reference and referral only.	Same	Same
Indications for Use Statement	The ResolutionMD solution is an **enterprise imaging viewer** that is used for the **secure** display, multiplanar reformatting and 3D visualization of medical image data and reports. It also provides **for mobile access** and **real-time** collaboration of **clinical information**.	ResolutionMD software is an enterprise medical image viewer used with **off-the-shelf servers, web browsers**, and **specific mobile devices** for the 2D display, Multi-planar reformatting and 3D visualization of medical image data	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

	The software is intended for use as a review and analysis tool by **authorized** healthcare professionals to drive clinical management. When interpreted by a physician, reviewed images may be used to aid in diagnosis. When used on a mobile device, ResolutionMD is not intended to replace full radiology workstations. ResolutionMD **displays both lossless and lossy compressed images. For lossy images, the healthcare professional 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 clearances, technical specifications, and quality control requirements for their use and maintenance. For mammography, mobile devices do not comply with the minimum display requirements; therefore mobile device usage for mammography is for reference and referral only.** **Healthcare institutions may want to provide patients access to their clinical information. This access is for non-diagnostic informational purposes only.**	and reports. It provides collaboration **and integrated secure audio-video communication**, and displays **DICOM and non-DICOM medical images and reports**. ResolutionMD is intended for use as a **diagnostic**, review, and analysis tool by trained healthcare professionals to drive clinical management. When interpreted by a **trained** physician, reviewed images may be used to aid in diagnosis. When used on a mobile device, ResolutionMD is not intended to replace full radiology workstations. **ResolutionMD is not to be used for primary mammography diagnoses.**	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 only when a full workstation is not available. **Mobile usage for mammography is for reference and referral only.**

Technological Comparison

The subject device, ResolutionMD (model # RESMD-D), is a modification of the predicate device, ResolutionMD (model # RESMD-C), with improvements to various existing features, such as usability enhancements, performance improvements, integration improvements, updated software coding standards and supported software, etc. There were no changes to the client-server architecture, image display technology, reconstruction/projection algorithms, clinical workflow, mobile diagnostic use, etc.

These improvements do not alter the fundamental technology, do not introduce any new risks, and do not affect the safety/ effectiveness or the intended use of the device. No additional testing (outside of the standard verification and validation procedures) was needed to confirm the safety and effectiveness of these changes.

	Subject Device	**Predicate Device**
Feature	**ResolutionMD (This submission)**	**ResolutionMD (K161130)**
Model #	Model #: RESMD-D	Model #: RESMD-C
Product type	Stand-alone software device (SaMD). Does not include AI/ML.	Same

DICOM modalities support	CT, MR, CR, DX, ES, KO, NM, OP, PT, SC, US, XA, RF, MG IO, XC, SR, RTIMAGE, OPT, ECG	CT, MR, CR, DX, ES, KO, NM, OP, PT, SC, US, XA, RF, MG
Non-DICOM support	JPG, TIFF, AVI, MP4 and other non-DICOM data	Same
Software Architecture	Client/server. No user installation of client.	Same
Server platform	Microsoft Windows OS or Red Hat Linux OS. General purpose computing hardware.	Same
Client platform - Desktop/laptop	HTML5 web browser on desktop operating systems.	HTML5 or Flex web browser on desktop operating systems.
Client platform - Mobile device	HTML5 browser on iOS and Android mobile devices. Optionally using a shell iOS/Android app that uses the HTML5 client.	Native iOS app and native Android app. HTML5 browser on iOS mobile devices.
Mobile diagnostic use	Diagnostic use on validated iOS and Android mobile devices. Mobile usage for mammography is for reference/referral only.	Same
Secure data access	Data maintained on server-side; no data stored on client. Encryption, authentication, audit logs, etc.	Same
Compression	Lossless and lossy JPEG image compression. Image is initially displayed with no compression (100% quality). Interactive slider provides ability to increase/decrease quality.	Lossless and lossy JPEG image compression. Image is initially displayed at 80% quality. Interactive slider provides ability to increase/decrease quality.
Search interface	Ability to search for patient studies in PACS and archives through a variety of configurable methods, based on several criteria. Also can visually see the timeline of patient imaging.	Ability to search for patient studies in PACS and archives through a variety of configurable methods, based on several criteria.
2D viewing	2D image viewer displaying DICOM images, reports, and non-DICOM data.	Same
MIP, MPR, cMPR viewing	MIP, MPR, and curvedMPR reconstructions and projections	Same
3D viewing	3D volume rendering	Same
Metadata display	Display of patient/study information, including a more visible patient banner. Optionally toggle display off, for confidentiality.	Display of patient/study information. Optionally toggle display off, for confidentiality.
Interactive user controls	Window/level, rotate, pan, zoom, presets, reset, hotkeys, slice scrolling, 3D lens.	Same
Measurement & Markup tools	Tools include freehand, text, point, linear, ROI, volume, angle, calipers, 3D segmentation, ECG.	Tools include freehand, text, point, linear, ROI, volume, angle, calipers, 3D segmentation.
Multi-study layouts	Multi-study intelligent layouts with reference lines and linked scrolling. Includes multi-monitor support.	Multi-study intelligent layouts with reference lines and linked scrolling.
Significant findings	GSPS/CSPS, key image objects (KO), and KIN display and navigation.	Same
Collaboration	Real-time shared image viewing session with other invited users, including a text chat.	Real-time shared image viewing session with other invited users, including an audio-visual component.
Printing and sharing	Image/Report printing and downloading; DICOM secondary capture	Same

Non-Clinical and Clinical Tests Summary

The ResolutionMD device was verified at the unit, integration, and system levels, including feature testing, regression testing, and deployment/upgrade testing, with both manual and automated testing across various configurations, browsers, monitors, and mobile devices. The testing included a number of different areas, including elements of safety, performance, security, and usability requirements. Validation testing was also completed by clinical experts and end users, based on various typical workflows, including mobile diagnostic use for image types other than mammography.

Testing for mammography diagnostic use demonstrated that ResolutionMD maintained appropriate DICOM compliance, image rendering behavior, spatial resolution performance, and overall image quality for mammography and DBT usage when using appropriate viewing hardware.

The software development process complies with IEC 62304 “Medical Device Software – Software Life Cycle” and IEC 62366-1 “Medical devices Usability Engineering” standards. The software design and testing complies with appropriate technical standards, such as the NEMA PS 3.1 – 3.20 DICOM standard, ISO 10918-1 JPEG standard, and Annex D Handheld Display Devices of IEC 62563-1 “Medical image display systems” standard.

Verification and validation testing confirmed the device meets performance, safety, usability and security requirements. The testing and results did not raise new questions of safety and effectiveness from those associated with the predicate device and demonstrated that the ResolutionMD device performs substantially equivalent to the predicate device.

No additional clinical studies were needed to support the changes that are part of this submission. Ongoing clinical evidence for the device is regularly gathered through post-market surveillance, including literature review and data analysis, as well as an in-depth review of information through clinical evaluation.

Conclusions

Based on the above considerations, ResolutionMD, Inc. believes that the ResolutionMD software is substantially equivalent to the predicate device and is as safe and effective as the predicate for its intended use.