August 14, 2026

Advahealth Solutions, LLC
% Meritxell Martinez
Senior Regulatory Affairs Specialist
Innolitics, LLC
1101 W. 34th St.
#550
AUSTIN TX 78705

Re: K262449
Trade/Device Name: AdvaView
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: July 16, 2026
Received: July 16, 2026

Dear Meritxell Martinez:

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 Lamb, PhD
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.	K262449

Please provide the device trade name(s).

AdvaView

Please provide your Indications for Use below.

AdvaView is a software application used for reference and diagnostic viewing and analysis of multi-modality medical imaging and non-imaging data (e.g., video information) with associated reports and information. AdvaView enables qualified healthcare professionals, including (but not limited to) physicians, surgeons, nurses, and administrators to receive and view patient images, documents, and data. AdvaView allows qualified users to perform simple and complex image manipulations (including window/level, markups, 3D visualization) and measurements.

Not intended for primary diagnosis of mammographic images.

Not intended for diagnostic use on mobile devices.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

1. Submitter Information

Company Name	AdvaHealth Solutions
Address	331 2nd Avenue Suite 400, Minneapolis, MN 55401 US
Company Contact	Imad Nijim, CEO
Email	imad.nijim@advahealthsolutions.com
Primary Correspondent	Meritxell Martinez, Innolitics
Email	fda@innolitics.com
Date Prepared	July 16th, 2026

2. Device Information

Trade Name	AdvaView
Common Name	DICOM Viewer
Product Code	LLZ
Regulation Number	892.2050
Classification Name	Picture archiving and communications system
Class	Class II
Panel	Radiology

3. Predicate Device Information

Predicate Device Name	FlexView Diagnostic
Manufacturer	AdvaHealth Solutions

510(k) Number	K233226
Product Code	LLZ
Regulation Number	892.2050
Classification Name	Picture archiving and communications system
Regulatory Class	Class II
Review Panel	Radiology

4. DEVICE DESCRIPTION

AdvaView is a medical image viewer which allows, reviewing, manipulating, and visualizing medical multi-modality image data in DICOM format and other data. AdvaView is a server-based solution that may integrate with healthcare facility software systems and display DICOM images. AdvaView enables healthcare professionals to access, manipulate, and measure DICOM images and collaborate using diagnostic-quality medical images without installing client software.

The AdvaView application has the following primary features and functions:

- Zero-footprint web browser-based
- Allows access to images for all participants in the healthcare process, including radiologists, technologists, physicians, nurses, and other patient care practitioners
- Contains functionality to view, annotate, and measure images
- Contains industry-standard tools for image manipulation, annotation, and measurements
- Advanced image manipulation functions like view synchronization across series, 3D visualization such as MIP and MPR
- Encrypted transmission of medical images through secured networks
- HIPAA-compliant data management, including centralized storage of user activities via audit trails

AdvaView is a configurable, software-only, web browser-based medical image viewer that displays and processes digital medical images and associated medical information to support clinical workflows.

AdvaView functions as a client application, enabling users to access, retrieve, and interact with imaging data through interfaces and APIs.

4.1. Key Marketing Claims

AdvaView is a zero-footprint web viewer for medical images. AdvaView allows easy access to image data through systems that implement the prescribed API Specifications.

5. INDICATIONS FOR USE

AdvaView is a software application used for reference and diagnostic viewing and analysis of multi-modality medical imaging and non-imaging data (e.g., video information) with associated reports and information. AdvaView enables qualified healthcare professionals, including (but not limited to) physicians, surgeons, nurses, and administrators to receive and view patient images, documents, and data. AdvaView allows qualified users to perform simple and complex image manipulations (including window/level, markups, 3D visualization) and measurements.

Not intended for primary diagnosis of mammographic images.

Not intended for diagnostic use on mobile devices.

6. PREDICATE DEVICE COMPARISON

6.1. Summary of Technological Characteristics Comparison

AdvaView is a modification of the predicate device, FlexView Diagnostic (K233226), submitted under the Special 510(k) pathway. The subject and predicate devices have the same intended use and the same fundamental scientific technology: both are web browser-based, multi-modality medical image viewers that load, display, manipulate, annotate, and measure DICOM images and associated data, and both rely on an existing PACS as the source of imaging studies. Both provide the same core review capabilities, including window/level adjustment,

image view controls (rotate, pan, and zoom), measurement functions, text annotations, report generation, and DICOM windowing, and both support the same imaging modalities (US, CT, MRI, and X-Ray).

The principal technological difference between the two devices is a change in deployment architecture. FlexView Diagnostic was deployed as a hosted, multi-tenant platform that operated self-managed backend infrastructure. AdvaView has been re-implemented as a client-side, zero-footprint viewer that runs within the web browser and integrates with external systems for image storage, configuration, authentication, and supporting services through defined RESTful API interfaces. Consistent with this architecture, functions that were previously performed by the self-operated backend (e.g., patient-data storage and confidentiality, service availability, in-transit encryption, and user authentication and access control) are delegated to the system integrator and the third-party PACS. This is a change in how the software is deployed and integrated rather than a change in the methods by which images are rendered, manipulated, or measured. The fundamental scientific technology of the viewer is unchanged.

AdvaView also adds a set of viewer features that extend the functionality of the predicate. These fall into four categories:

- Image display and projection functions, including Maximum, Minimum, and Average Intensity Projection modes, a viewport scale overlay, and scrollbar.
- Region-of-interest and measurement tools, including ellipse, rectangle, circle, and freehand ROI tools; spline and livewire contour tools; and Cobb angle, spine-labeling, and cardiothoracic ratio (CTR) tools.
- Annotation and workspace customization, including a pencil annotation tool, an annotation show/hide toggle, hanging-protocol configuration, multiple-monitor support, and configurable thumbnail location, radial menu, toolbars, viewport labels, and mouse bindings.
- Input-handling robustness, through validation of DICOM input received from external systems.

These differences between the subject and predicate devices do not alter the intended use and do not raise new questions of safety or effectiveness.

7. Discussion of Performance Testing

7.1. Software Verification and Validation

Software verification and validation testing were conducted on the AdvaView system and documentation was provided as recommended by FDA's 2023 Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions."

The software verification and validation testing verified that the design requirements were successfully met. The intended use and user needs were successfully validated.

7.1.1. Measurement Accuracy

Verification of AdvaView included manual testing of the accuracy of the measurement tools using phantom (calibrated and un-calibrated) DICOM images.

Measurement accuracy testing involved evaluating the difference (i.e., delta) between the expected length and the measurement entered by the user. Delta results were calibrated to +/- 1 units, which is equivalent to +/- 1 units relative to the acquisition size and display resolution. This calibration ensured consistent accuracy across different zoom levels.

Acceptance criteria for this test included statistical analyses such as mean, standard deviation, standard error and a one tailed t-test. Verification testing for all measurement tools passed the predetermined acceptance criteria.

7.2. Conclusion

AdvaView is a modification of AdvaHealth Solutions' own legally marketed device, FlexView Diagnostic (K233226), submitted under the Special 510(k) pathway. AdvaView retains the same intended use and the same fundamental scientific technology as the predicate: both are zero-footprint, web browser-based, multi-modality medical image viewers that load, display, manipulate, annotate, and measure DICOM images and associated data, and both rely on an existing PACS as the source of imaging studies.

The modifications comprise a change in deployment architecture together with a set of additional viewer features. Each modification was evaluated under the manufacturer's design control procedures using well-established methods, and the associated risk analysis,

verification, and validation activities demonstrate that the changes were adequately verified and validated. No clinical testing was necessary to support the modifications. The results confirm that the modifications do not alter the intended use and do not raise new questions of safety or effectiveness relative to the predicate.

Based on the risk analysis, the verification and validation results, and the technological characteristics comparison presented above, AdvaView is substantially equivalent to FlexView Diagnostic (K233226).