Radical Imaging, LLC
℅ Meritxell Martinez
Regulatory Consultant
Innolitics, LLC
1101 West 34th St #550
Austin, TX 78705

Re: K233226

January 17, 2024

Trade/Device Name: FlexView Diagnostic (v1.1.20)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 28, 2023
Received: December 22, 2023

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 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

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.

Submission Number *(if known)*

K233226

Device Name

FlexView Diagnostic (v1.2.7)

Indications for Use *(Describe)*

FlexView Diagnostic 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. FlexView Diagnostic enables qualified healthcare professionals, including (but not limited to) physicians, surgeons, nurses, and administrators to receive and view patient images, documents and data. FlexView Diagnostic 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.

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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1. CONTACT INFORMATION

Company Name	Radical Imaging LLC
Address	179 Great Road #233, Stow, MA 01775
Phone Number	978-853-9281
Fax Number	N/A
Company Contact	Rob Lewis, CEO and Founder
Email	rob.lewis@radicalimaging.com
Primary Correspondent	Meritxell Martinez, Innolitics
Email	mmartinez@innolitics.com
Date Prepared	January 12th, 2024

2. DEVICE INFORMATION

Trade Name	FlexView Diagnostic
Common Name	DICOM Viewer
Product Code	LLZ
Regulation Number	892.2050
Class	Class II
Panel	Radiology

3. PREDICATE DEVICE INFORMATION

Predicate Device Name	ZeeroMED View
Predicate Device 510(k) Number	K200546
Product Code	LLZ

Regulation Number	892.2050
Class	Class II
Panel	Radiology

4. DEVICE DESCRIPTION

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

The FlexView Diagnostic application has the following primary features and functions:

- Zero-footprint Web browser based
- Medical image upload, transfer and display of medical images between facilities
- Allows access to images for all participants in the healthcare process, including radiologists, technologists, physicians, nurses and other patient care practitioners
- Serves as an information and data management system for DICOM and non-DICOM medical images
- 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 like MIP and MPR
- Encrypted transmission of medical images through secured networks
- HIPAA-compliant data management, including centralized storage of user activities via audit trails

FlexView Diagnostic 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 with which users interact when viewing the imaging data and other 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.

FlexView Diagnostic can connect and access the medical images across different sources in a health system: such as an existing PACS, cloud storage or local server-based storage. The data connection and imaging data processing is handled by the FlexView backend module which supports the standardized transmission protocol as defined in the DICOM standard.

Users interact with FlexView Diagnostic through a standard web browser, thus providing access to full quality images from anywhere with an Internet access. FlexView Diagnostic utilizes authorization and authentication mechanisms to ensure that only authorized users can access the imaging data. The system extends beyond the hospital and its internal network. With proper authorization, FlexView Diagnostic 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 opinions.

4.1. Key Marketing Claims

FlexView Diagnostic is a zero-footprint web viewer platform for medical images. FlexView Diagnostic allows easy access to cloud-stored image files. FlexView Diagnostic supports images that are compliant with the DICOMweb standard.

5. INDICATIONS FOR USE

FlexView Diagnostic 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. FlexView Diagnostic enables qualified healthcare professionals, including (but not limited to) physicians, surgeons, nurses, and administrators to receive and view patient images, documents and data. FlexView Diagnostic 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

Feature	**FlexView Diagnostic**	**ZeeroMED View (K200546)**	**Comments**
Intended Use	FlexView Diagnostic is a software application used for reference and diagnostic viewing and analysis of multi-modality medical imaging and non-imaging data (e.g., video	ZeeroMED View software is intended for use as a diagnostic and analysis tool for diagnostic images for	FlexView and the predicate device (ZeeroMED View) have similar indications for use, as they are both indicated to view, display and manage

Feature	FlexView Diagnostic	ZeeroMED View (K200546)	Comments
	information) with associated reports and information. FlexView enables qualified healthcare professionals, including (but not limited to) physicians, surgeons, nurses, and administrators to receive and view patient images, documents and data. FlexView 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.	hospitals, imaging centers, radiologists, reading practices and any user who requires and is granted access to patient image, demographic and report information. ZeeroMED View displays and manages diagnostic quality DICOM images. ZeeroMED View is not intended for diagnostic use with mammography images. Usage for mammography is for reference and referral only. ZeeroMED View is not intended for diagnostic use on mobile devices.	patient images. Both devices are indicated for prescription-use in patients who've had non-mammographic medical images taken. FlexView and ZeeroMED View share the same intended use to be used as diagnostic and analysis tools for viewing and manipulating medical images. Both devices are also intended for use in hospitals, imaging centers, radiology practices, and reading practices. Neither FlexView nor ZeeroMED View is intended for primary diagnosis of mammographic images, nor for diagnostic use on mobile devices.
Mammographic Use	No	No	Same
DICOM Image Loading and Visualization	Yes	Yes	Same
Can Search Patient Study Data	Yes	Yes	Same
User Authentication	Yes	Yes	Same
Window/ Level Adjustments	Yes	Yes	Same
Control the Image View: Rotate, Pan, and Zoom	Yes	Yes	Same
Image Display Operations	Flip horizontal, vertical Rotate left, right Reset Magnification Scroll Layout 1x1 -3x3 Thumbnails left, right, top,	Flip horizontal, vertical Rotate left, right Reset Magnification Scroll Layout 1x1 -3x3 Thumbnails left, right, top,	PET Fusion is imaging not supported in FlexView version v1.2.7. However, this difference does not raise any concerns. All of FlexView's other image display operations (i.e., those listed in table) are

Feature	FlexView Diagnostic	ZeeroMED View (K200546)	Comments
	bottom Volumetric rendering	bottom PET fusion Volumetric rendering	also supported by the predicate device.
Measurement Functions Included	Yes	Yes	Same
Text Annotations	Yes	Yes	Same
Report Generation	Yes	Yes	Same
Print Reports	PDF	PDF	Same
Export	Yes	Yes	Same
Share Function	No	Yes	Share Function not included in FlexView version v1.2.7. However, this does not raise any different questions on safety of effectiveness of the device.
DICOM Windowing	Yes	Yes	Same
Imaging Modalities Included: US, CT, MRI, X-Ray	Yes	Yes	Same
Communications	DICOM	DICOM	Same
Operating Systems Supported	Mac, Windows	Mac, Windows, Linux	The subject device supports the same operating systems as the predicate device (Mac and Windows), with the exception of Linux. However, this does not raise any different questions on safety of effectiveness of the device.
Web Browsers Supported	Chrome, Edge, Safari	Chrome, Edge, Firefox	The subject device supports the same web browsers as the predicate device, except for Firefox. In addition, the subject device also supports Safari. This difference in supported web browsers does

Feature	FlexView Diagnostic	ZeeroMED View (K200546)	Comments
			not raise any new questions of safety and effectiveness, and has been verified through testing.
Mobile Device Support	No	No	Same
Store, Display, and Transfer Medical Images	Yes	Yes	Same
Connects to Existing PACS	Yes	Yes	Same

6.1. Summary of Technological Characteristics Comparison

FlexView Diagnostic and ZeeroMED View share equivalent intended use and functionality, as well as similar web technologies. Both systems allow access, upload, and display of DICOM images and metadata, and provide tools and resources for physicians to review studies. Additionally, both systems are hosted on web servers and are equipped with security features and user authentication.

Both devices offer similar features such as window/level adjustments, image view controls (rotate, pan, and zoom), measurement functions, text annotations, report generation and DICOM windowing.

Additionally, both devices can connect to existing PACS systems and store, display, and transfer medical images. Both devices also support the same imaging modalities, including US, CT, MRI, and X-Ray.

There are several minor differences in technological characteristics between the two devices:

- The predicate device has a "Share Function," which enables remote, real-time collaboration among multiple users. This feature is not currently supported by the subject device.
- The predicate device supports Mac, Windows, and Linux operating systems, while the subject device only supports Mac and Windows.
- The predicate device supports Chrome, Edge, and Firefox browsers, while the subject device supports Chrome, Edge, and Safari.

The lack of features (e.g., share function, Linux OS compatibility, and Firefox compatibility) in the subject device that are found in the predicate device is not a concern relating to safety or effectiveness, as these are not required to meet the device's intended use. Similarly, the presence of additional features (e.g., compatibility with additional internet browsers) in the subject device that are not found in the predicate device does not raise any new questions of safety and effectiveness and have been properly verified through testing.

7. DISCUSSION OF NON-CLINICAL TESTING

FlexView Diagnostic was subjected to the following non-clinical testing.

7.1. Software Verification and Validation

Software verification and validation testing were conducted on the FlexView Diagnostic 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.

As the intended use, indications, functionality and performance of FlexView Diagnostic and the ZeeroMED View are equivalent, the result of the non-clinical performance testing is evidence that the subject device performs in an equivalent manner to the predicate device.

7.2. Measurement Accuracy

Verification of FlexView Diagnostic included manual testing of the accuracy of the measurement tools (length, bidirectional and angle measurements) 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.

7.3. Conclusion

The subject device shares similar technological characteristics, intended use, and functionality with the predicate device. There are no differences between the devices that raise new questions of safety and effectiveness.

Furthermore, non-clinical performance test data and software verification and validation demonstrate that FlexView Diagnostic performs comparably to the predicate device in terms of safety and effectiveness.

Based on the device comparisons and the acceptable testing results, it is determined that FlexView Diagnostic is substantially equivalent to the predicate device.