Rology Inc.
℅ James Luker
VP of Regulatory Affairs
Innolitics, LLC
1101 West 34th Street, #550
AUSTIN TX 78705

September 20, 2023

Re: K231385
Trade/Device Name: Rology Teleradiology Platform (v.1.22.1103)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 11, 2023
Received: August 14, 2023

Dear James Luker:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

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)*
K231385

Device Name
Rology Teleradiology Platform

Indications for Use *(Describe)*

The Rology Teleradiology Platform is a Web-based software system used to receive, view and manipulate DICOM images, schedule, provide textual reports, organize, store, and make such information available.

When images are reviewed and used as an element of diagnosis, it is the responsibility of the qualified clinician to determine if the image quality is suitable for their clinical application.

The Rology Teleradiology Platform is intended to be used by clinicians qualified in the use of radiological images for interpretation/diagnosis.

Contraindications: Rology Teleradiology Platform is not intended for the acquisition of mammographic image data for primary diagnosis.

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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ROLOGY TELERADIOLOGY PLATFORM (K231385)

510(k) Summary

1. ADMINISTRATIVE INFORMATION

Submitter Name	Rology Inc.
Address	1202 NE McClain Road, Bldg 7, Bentonville, Arkansas, 72712, United States of America
Phone Number	302 561 9511
Fax Number	N/A
Company Representative	Amr Abodraiaa
Email	amr.abodraiaa@rology.net
Primary Contact	Jim Luker
Primary Contact Phone Number	321 205 3104
Primary Contact Email	JLuker@Innolitics.com
Date Summary Prepared	September 15, 2023

2. SUBJECT DEVICE INFORMATION

Trade Name	Rology Teleradiology Platform
510(k) #	K231385
Common Name	Medical image management and processing system
Product Code	LLZ
Regulation Number	892.2050

Classification Name	System, Image Processing, Radiological
Regulatory Class	Class 2
Review Panel	Radiology
Indications	The Rology Teleradiology Platform is a Web-based software system used to receive, view and manipulate DICOM images, schedule, provide textual reports, organize, store, and make such information available. When images are reviewed and used as an element of diagnosis, it is the responsibility of the qualified clinician to determine if the image quality is suitable for their clinical application. The Rology Teleradiology Platform is intended to be used by clinicians qualified in the use of radiological images for interpretation/diagnosis. Contraindications: Rology Teleradiology Platform is not intended for the acquisition of mammographic image data for primary diagnosis.

3. PREDICATE DEVICE INFORMATION

The Braid device (K200822) has been selected as the primary predicate device because it has equivalent intended use, indications and functions as compared to the Rology Teleradiology Platform. Both devices also have the following similar function:

- MIP/MPR Reconstruction

The following information relates to the predicate device:

Trade Name	Braid
510(k) Number	K200822
Common Name	Picture archiving and communications system
Product Code	LLZ
Regulation Number	892.2050

Classification Name	System, Image Processing, Radiological
Regulatory Class	Class 2
Review Panel	Radiology

4. REFERENCE DEVICE INFORMATION

The BOX DICOM Viewer (K151957) has been selected as a reference device to support the following functions which are not included in the Braid predicate device:

- Support for PET images
- Cobb Angle measurement

It is noted that the Braid device used the BOX DICOM Viewer as the predicate device in its 510(k) submission.

The following information relates to the reference device:

Trade Name	BOX DICOM Viewer
510(k) Number	K151957
Common Name	Picture archiving and communications system
Product Code	LLZ
Regulation Number	892.2050
Classification Name	System, Image Processing, Radiological
Regulatory Class	Class 2
Review Panel	Radiology

5. DEVICE DESCRIPTION

Rology Teleradiology Platform developed by Rology Inc. is a Software as a Medical Device (SaMD) system used to receive DICOM images, schedule information, and textual reports, organize and store them in an internal format, and make that information available across a network via web and customized user interfaces.

The Rology Teleradiology Platform is intended to be used by trained and qualified healthcare professionals, including radiologists, technologists, and medical professionals, in hospitals, clinics, and medical imaging centers, to aid the radiologists in reading, interpreting, and reporting. When images are reviewed and used as an element of diagnosis, it is the responsibility of the trained radiologist to determine if the image quality is suitable for their clinical application, so the radiologist retains the ultimate responsibility for making the final diagnosis decision.

Contraindications: Rology Teleradiology Platform is not intended for the acquisition of mammographic image data for primary diagnosis.

Rology Teleradiology Platform is designed to integrate with current medical systems through standard medical protocols:

- DICOM: for exchanging medical imaging.
- HL7/FHIR: for exchanging electronic health records

The Rology Teleradiology Platform is to be used to view DICOM-compliant studies, which are stored in the cloud using to AWS's S3 service and is intended for professional use only as a viewing tool for medical image studies. The Rology Teleradiology Platform is comprised of the following modules/functions:

- **Acquiring studies** by the Rology Connect module which allows for the automatic acquisition of images from DICOM-compliant devices. It receives, anonymizes, compresses, and uploads the studies to the platform using AWS's S3 service. A third-party DICOM device sends the images to the Rology DICOM node, which will extract DICOM data and upload the images to cloud servers.
- **Scheduling and organizing studies** after being uploaded by the Workflow Manager.
- **View DICOM-compliant studies** using the DICOM Viewer software which will fetch images and data from backend servers, to allow users to view those images on their personal computers, to diagnose, manipulate, and interpret the studies.
  - **Report textual/transmission** to the healthcare facility using the Reporting Tool which is part of the DICOM Viewer, to Incorporate non-image data, such as scanned documents, using consumer industry standard formats like PDF (Portable Document Format). The report will be sent securely to the healthcare facility for review/acceptance.

The features and functions of Rology DICOM Viewer module, which includes Viewer technology and features include:

General Functions:

- Receive DICOM images from the acquisition device
- Textual reports, and transmit the reports securely to the hospital
- Store images in a secure cloud environment

Basic Imaging functions:

- Grayscale Image Rendering
- Localizer Lines
- Localizer Point
- Distance Markers
- Study Data Overlays
- Stack Navigation Tool
- Window/Level Tool
- Zoom Tool
- Panning Tool
- Clockwise/Counterclockwise Rotation
- Color Inversion
- Area Measurement Annotation
- Angle Measurement Annotation
- Added keyboard shortcuts for some tools
- Orientation Markers

Advanced imaging functions

- Multi-Planar Reconstruction (MPR)
- Maximum Intensity Projection (MIP)

The Rology DICOM Viewer module is the only 'module' of the system that is believed to meet the definition of being a regulated medical device. The other modules of the Rology Teleradiology Platform are included to provide a complete understanding of the software system and its interactions with the intended user(s).

6. DEVICE COMPARISON TABLE

The subject and predicate device have equivalent technological characteristics. Additional technological characteristics are supported by a reference device. A comparison is provided in the table below.

Feature/Function	**Subject Device: Rology Teleradiology Platform**	**Predicate Device: Braid (K200822)**	**Reference Device: BOX DICOM Viewer (K151957)**	**Comments**
Applicant	Rology, Inc.	Braid.Health	BOX, Inc	N/A
Device Name	Rology Teleradiology Platform	Braid	BOX DICOM Viewer	N/A
Product Code	LLZ	LLZ	LLZ	Same
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050	Same
Intended Use/Indications for Use	The Rology Teleradiology Platform is a Web-based software system used to receive, view and manipulate DICOM images, schedule, provide textual reports, organize, store, and make such information available. When images are reviewed and used	Braid is a software teleradiology system used to receive DICOM images, scheduling information and textual reports, organize and store them in an internal format, and to make that information available across a network via	The BOX DICOM Viewer is a software Teleradiology system used to receive DICOM images, scheduling information and textual	The proposed indications for the Rology Teleradiology Platform are equivalent to Braid predicate device with the exception of support for PET images and Cobb Angle calculation. Both of these

Feature/Function	Subject Device: Rology Teleradiology Platform	Predicate Device: Braid (K200822)	Reference Device: BOX DICOM Viewer (K151957)	Comments
	as an element of diagnosis, it is the responsibility of the qualified clinician to determine if the image quality is suitable for their clinical application. The Rology Teleradiology Platform is intended to be used by clinicians qualified in the use of radiological images for interpretation/diagnosis. Contraindications: Rology Teleradiology Platform is not intended for the acquisition of mammographic image data for primary diagnosis.	web. Braid is used by hospitals, clinics, imaging centers, and radiologist reading practices. Braid can optionally be used for mobile diagnostic use for review and analysis of CR, DX, CT, and MR images and medical reports. Braid mobile diagnostic use is not intended to replace full diagnostic workstations and should only be used when there is no access to a workstation. Braid mobile diagnostic use is not intended for the display of mammography images for diagnosis. When images are	reports, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces. The BOX DICOM Viewer is used by hospitals, imaging centers, radiologist reading practice. Contraindications: The BOX DICOM Viewer is	functions are present in the BOX DICOM Viewer reference device. Additionally, the Rology Teleradiology Platform has the same intended use as both the predicate and reference device. All three devices are intended to be used to receive DICOM images, schedule information and textual reports, organize and store them in an internal format, and to make that information available

Feature/Function	Subject Device: Rology Teleradiology Platform	Predicate Device: Braid (K200822)	Reference Device: BOX DICOM Viewer (K151957)	Comments
		reviewed and use as an element of diagnosis, it is the responsibility of the trained physician to determine if the image quality is suitable for their clinical application. Contraindications: Braid is not intended for the acquisition of mammographic image data and is meant to be used by qualified medical personnel only who are qualified to create and diagnose radiological image data.	not intended for the acquisition of mammographic image data and is meant to be used by qualified medical personnel only who are qualified to create and diagnose radiological image data.	across a network via web.
Intended user	Radiologists & Qualified medical personnel	Radiologists & Qualified medical personnel	Radiologists & Qualified medical personnel	Same

Feature/Function	**Subject Device: Rology Teleradiology Platform**	**Predicate Device: Braid (K200822)**	**Reference Device: BOX DICOM Viewer (K151957)**	**Comments**
Acquisition devices	CR, DX, CT, MR, US, PET	CR, DX, CT, MR	CT, MR, US, PET	Rology Teleradiology Platform supports PET and US images as does the BOX DICOM Viewer reference device.
Communication	DICOM	DICOM	DICOM	Same
Network Access	Web browser	Web browser	Web browser	Same
Web Browser Software	Google Chrome	Google Chrome, Safari	Google Chrome for all features. Microsoft Internet Explorer & Mozilla Firefox for features except the DICOM Viewer.	Equivalent – each product supports the Google Chrome internet browser.

Feature/Function	**Subject Device: Rology Teleradiology Platform**	**Predicate Device: Braid (K200822)**	**Reference Device: BOX DICOM Viewer (K151957)**	**Comments**
Mobile Platforms	None	iPhones, iPads	None	The Rology Teleradiology Platform does not support mobile platforms. This is equivalent to the reference device. The lack of support for mobile platforms does not add different questions related to safety or effectiveness.
User Interface/Input	Mouse and keyboard	Mouse keyboard, and Touchscreens	Mouse and keyboard	Equivalent input type. The Rology Teleradiology Platform does not support touchscreen use. This is equivalent to the reference device. The lack of

Feature/Function	Subject Device: Rology Teleradiology Platform	Predicate Device: Braid (K200822)	Reference Device: BOX DICOM Viewer (K151957)	Comments
				support for touchscreen use does not add different questions related to safety or effectiveness.
Drag and Drop Import	No	Yes	Yes	The subject device does not have this feature, but the absence of this feature does not raise questions of safety and effectiveness or affect the intended use of the device.
Image Storage	Yes	Yes	Yes	Same
Textual Reports	Yes	Yes	No	Same as the predicate device
Database software	MongoDB	CouchDB, IndexedDB, LevelDB	MySQL	MongoDB is an alternative to CouchDB, IndexedDB, LevelDB, and

Feature/Function	Subject Device: Rology Teleradiology Platform	Predicate Device: Braid (K200822)	Reference Device: BOX DICOM Viewer (K151957)	Comments
				MySQL database software, which can provide the same functionalities.
Grayscale Image Rendering	Yes	Yes	Yes	Same
RGB Image Rendering	No	No	Yes	Same as the predicate device
Distance Markers	Yes	Yes	Yes	Same
Study Data Overlays	Yes	Yes	Yes	Same
Stack Navigation Tool	Yes	Yes	Yes	Same
Window Level	Yes	Yes	Yes	Same
Zoom in on the Image	Yes	Yes	Yes	Same
Panning	Yes	Yes	Yes	Same
Invert image	Yes	Yes	Yes	Same
Text Annotation	Yes	Yes	Yes	Same

Feature/Function	Subject Device: Rology Teleradiology Platform	Predicate Device: Braid (K200822)	Reference Device: BOX DICOM Viewer (K151957)	Comments
MIP/MPR Reconstruction	Yes	Yes	No	Same as the predicate device
Area Measurement Annotation	Yes	Yes	Yes	Same
Angle Measurement Annotation	Yes	Yes	Yes	Same
User Interface text styles, colors, fonts, and icons.	None	None	BOX Styles	Same as the predicate device
WebGL Rendering Optimizations	Yes	Yes	Yes	Hardware acceleration is used. WebGL (Web Graphics Library) is a JavaScript API for rendering interactive 3D computer graphics and 2D graphics within any compatible web browser without the use of plug-ins. The user

Feature/Function	Subject Device: Rology Teleradiology Platform	Predicate Device: Braid (K200822)	Reference Device: BOX DICOM Viewer (K151957)	Comments
				of this technology raises no new questions of safety and effectiveness and is supported by performance testing.
Support for high-resolution Retina displays	Full pixel density on all displays	Full pixel density on all displays	Full pixel density on all displays	Same
Keyboard shortcuts	Yes	Yes	Yes	Same
Localizer Lines	Yes	Yes	Yes	Same
Localizer Point	Yes	Yes	Yes	Same
Color Inversion	Yes	Yes	Yes	Same
Orientation Markers	Yes	Yes	Yes	Same
Clockwise/Counterclockwise Rotation	Yes	Unknown	Yes	Equivalent to the reference device
Search	Yes	Unknown	Yes	Equivalent to the reference device

Feature/Function	Subject Device: Rology Teleradiology Platform	Predicate Device: Braid (K200822)	Reference Device: BOX DICOM Viewer (K151957)	Comments
Cobb Angle Measurement Annotation	Yes	Unknown	Yes	Equivalent to the reference device
Thumbnail viewing	Yes	Unknown	Yes	Equivalent to the reference device
Automatic Upload	Yes	No	No	The addition of this feature raises no new questions of safety and effectiveness and is supported by performance testing
Worklist	Yes	Unknown	Yes	Equivalent to the reference device
Download Report	Yes	Unknown	Unknown	The addition of this feature raises no new questions of safety and effectiveness and is supported by performance testing

Feature/Function	Subject Device: Rology Teleradiology Platform	Predicate Device: Braid (K200822)	Reference Device: BOX DICOM Viewer (K151957)	Comments
Recheck	Yes	No	No	The addition of this feature raises no new questions of safety and effectiveness and is supported by performance testing
Pick up studies	Yes	No	No	The addition of this feature raises no new questions of safety and effectiveness and is supported by performance testing
Side-by-side Comparison	Yes	Unknown	Unknown	The addition of this feature raises no new questions of safety and effectiveness and is supported by performance testing

Feature/Function	Subject Device: Rology Teleradiology Platform	Predicate Device: Braid (K200822)	Reference Device: BOX DICOM Viewer (K151957)	Comments
Play	Yes	Unknown	Unknown	The addition of this feature raises no new questions of safety and effectiveness and is supported by performance testing.

7. PERFORMANCE TESTING

7.1.1. Performance Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The Rology Teleradiology Platform was considered a 'moderate level of concern'.

The performance testing (design verification and design validation) verified that the design requirements were successfully met.

Performance testing included the following tests and results:

Performance Test	Result
User Interface/Input	Pass
Drag and Drop Import	Pass
Image Storage	Pass

Performance Test	Result
Textual Reports	Pass
Database software	Pass
Grayscale Image Rendering	Pass
RGB Image Rendering	Pass
Distance Markers	Pass
Study Data Overlays	Pass
Stack Navigation Tool	Pass
Window Level	Pass
Zoom in on the Image	Pass
Panning	Pass
Invert image	Pass
Text Annotation	Pass
MIP/MPR Reconstruction	Pass
Area Measurement Annotation	Pass
Angle Measurement Annotation	Pass
User Interface text styles, colors, fonts, and icons.	Pass
WebGL Rendering Optimizations	Pass
Support for high-resolution Retina displays	Pass
Keyboard shortcuts	Pass
Localizer Lines	Pass

Performance Test	Result
Localizer Point	Pass
Color Inversion	Pass
Orientation Markers	Pass
Clockwise/Counterclockwise Rotation	Pass
Search	Pass
Cobb Angle Measurement Annotation	Pass
Thumbnail viewing	Pass
Automatic Upload	Pass
Worklist	Pass
Download Report	Pass
Recheck	Pass
Pick up studies	Pass
Side-by-side Comparison	Pass

The Intended use and user needs were successfully validated using appropriate validation partners representing the intended users of the Rology Teleradiology Platform.

As the intended use, functionality and performance of the Rology Teleradiology Platform and predicate device are equivalent, the result of the performance testing is evidence that the Rology Teleradiology Platform performs in an equivalent manner to the Braid device. Additional features which are not found in the predicate device, such as Cobb angle measurement and support of PET/US images, are common features for DICOM viewers under regulation 892.2050 and product code LLZ. These functionalities are supported by the inclusion of the BOX reference device in this submission.

7.1.2. Clinical Performance Testing

No clinical performance testing was performed for the Rology Teleradiology Platform in support of this submission.

8. CONCLUSION

The Rology Teleradiology Platform has the same intended use as the predicate Braid (K200822). The Rology Teleradiology Platform has equivalent technological characteristics and performance characteristics as compared to the Braid device. The BOX DICOM Viewer (K1519570 was included as a reference device to support the inclusion of the PET and Ultrasound (US) image modalities as well as the Cobb Angle measurement. These functions are not included in the Braid device. Based on device comparisons and the acceptable results of the performance testing, it is determined that the Rology Teleradiology Platform is substantially equivalent to its predicate device.