



October 30, 2024

Remedy Logic Inc.
% Yu Zhao
Principal Advisor
Bridging Consulting LLC
2108 N St., Suite N
Sacramento, CA 95816

Re: K241108

Trade/Device Name: RemedyLogic AI MRI Lumbar Spine Reader
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: September 30, 2024
Received: September 30, 2024

Dear Yu Zhao:

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.

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, 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

510(k) Number (if known)

K241108

Device Name

RemedyLogic AI MRI Lumbar Spine Reader

Indications for Use (Describe)

RemedyLogic AI MRI Lumbar Spine Reader (“RAI”) is an image post-processing and measurement software tool that provides quantitative spine measurements from previously-acquired DICOM lumbar spine Magnetic Resonance (MR) images for users’ review, analysis, and interpretation. It provides the following functionality to assist users in visualizing, measuring and documenting measurements:

- Feature segmentation;
- Feature measurement; and
- Exportation of measurement results in DICOM Structured Report and a downloadable .docx file for users to review and to use full or partial list of software-generated measurements to prepare their own radiology report.

RAI does not produce or recommend any type of medical diagnosis or treatment. Instead, it simply helps users to more easily identify and measure features in lumbar MR images and compile their own reports. The user is responsible for reviewing, verifying, and correcting, if necessary, the software-generated segmentations and measurements, leveraging useful software output and using their medical judgment and discretion to make diagnostic or treatment decisions.

The device is intended to be used only by radiologists, neuro- and spine-surgeons in hospitals and other medical institutions.

Only T2 MRI images in DICOM format, acquired from lumbar spine exams of patients aged 18 and older, are considered to be valid input. RAI does not support DICOM images of patients that are pregnant, undergo MRI scan with contrast media, or have post-operational complications, scoliosis, tumors, infections, and/or fractures.

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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510(k) Summary

1. Submitter

Remedy Logic Inc.

1177 Avenue of the Americas, 5th Floor

New York, NY 10036

USA

Contact Person: Andrej Rusakov

Date Prepared: March 30, 2024

2. Device

Name of Device: RemedyLogic AI MRI Lumbar Spine Reader

Common or Usual Name: RemedyLogic AI MRI Lumbar Spine Reader

Classification Name: Medical image management and processing system (21 CFR 892.2050)

Product Code: QIH

Regulatory Class: II

3. Predicate Devices

Device Name: CoLumbo

Manufacturer: Smart Soft Healthcare AD

Classification Panel: Radiology

Classification Name: Medical image management and processing system (21 CFR 892.2050)

Product Code: QIH

Device Class: Class II

510(k) Number: K220497 (cleared on June 23, 2022)

4. Device Description

The RemedyLogic AI MRI Lumbar Spine Reader (RAI) is an MR image post-processing and measurement software tool that provides quantitative spine measurements from previously acquired DICOM lumbar spine Magnetic Resonance (MR) images for qualified users' review, analysis, and interpretation. The qualified users (i.e., radiologists, spine- and neuro-surgeons) are physicians qualified to read and interpret spine MRI exams in a manner consistent with American College of Radiology (ACR) recommendations.

The RAI analyzes the user-uploaded lumbar spine images and provides the following functionalities to assist qualified users in visualizing images, and measuring images, and generating reports:

- Feature segmentation: the software automatically detects the borders of anatomical objects of interest and generates the corresponding contours for these objects.

- Feature measurement: the software automatically generates common measurements for segmented objects.
- Measurement export: a DICOM Structured Report or a .docx file containing the measurement results can be exported for users to review and to use the full or a partial list of the software-generated measurements to prepare their own radiology reports.

The RAI software does not interface directly with any MR scanner or data collection equipment. Rather, a qualified user must upload a previously acquired MR study in DICOM format into the RAI software via their Picture Archiving and Communication System (PACS). The PACS serves as the RAI user interface. After less than two minutes of processing, the RAI software automatically generates and uploads back to PACS the DICOM with segmentations of regions of interest along with corresponding measurements. These measurements are also presented in a DICOM Structured Report and a downloadable .docx file, which is accessible for download from the PACS from PACS system. The user reviews the software-generated measurement list, studies the software-annotated images and/or the original unannotated images when necessary, and reviews other pertinent medical information about the patient. The user can manually segment anatomical objects and mark their own measurements using the DICOM viewer tools. The user can also edit measurements in the downloaded .docx file. The user then writes their own radiology report, incorporating some or all verified or corrected measurements, with diagnosis and/or treatment recommendations.

The purpose of the RAI software is to save time by automating tedious, time-consuming, and potentially error-prone manual tasks. The software does not perform any functions that could not be accomplished by a qualified user. The outputs of the software, i.e. feature segmentations and quantitative measurements, are reviewed, analyzed, confirmed or corrected by the user before any such content is included in the user's final report.

The RAI consists of a cloud-based machine learning (ML) analytical algorithm deployed on a GPU cloud service and an API to integrate directly with the client's PACS system.

5. Indications for Use

RemedyLogic AI MRI Lumbar Spine Reader ("RAI") is an image post-processing and measurement software tool that provides quantitative spine measurements from previously-acquired DICOM lumbar spine Magnetic Resonance (MR) images for users' review, analysis, and interpretation. It provides the following functionality to assist users in visualizing, measuring and documenting measurements:

- Feature segmentation;
- Feature measurement; and
- Exportation of measurement results in a DICOM Structured Report and a downloadable .docx file for users to review and to use full or partial list of software-generated measurements to prepare their own radiology report.

RAI does not produce or recommend any type of medical diagnosis or treatment. Instead, it simply helps users to more easily identify and measure features in lumbar MR images and compile their own reports. The user is responsible for reviewing, verifying and correcting, if necessary, the software-generated segmentations and measurements, leveraging useful software output and using their medical judgment and discretion to make diagnostic or treatment decisions.

The device is intended to be used only by radiologists, neuro- and spine-surgeons in hospitals and other medical institutions.

Only T2 MRI images in DICOM format, acquired from lumbar spine exams of patients aged 18 and older, are considered to be valid input. RAI does not support DICOM images of patients that are pregnant,

undergo MRI scan with contrast media, or have post-operational complications, scoliosis, tumors, infections, and/or fractures.

6. Comparison of the Technological Characteristics with the Predicate Devices

In comparison to the Predicate Device and the Reference Devices, the Subject Device provides comparable outputs in terms of segmentation, measurement and reporting. A tabular high-level comparison of the Subject Device and the Predicate Device is provided in the table below.

Comparison of Technological Characteristics with Predicate Device

	Predicate Device CoLumbo (K220497)	Subject Device RAI
Intended User	Radiologist and neuro- and spine- surgeons	Radiologist and neuro- and spine- surgeons
Intended Patient Population	Patients aged 18 years or older, undergoing clinical lumbar spine MR exams. CoLumbo does not support DICOM images of patients that are pregnant, undergo MRI scan with contrast media, or have post-operational complications, scoliosis, tumors, infections, fractures.	Patients aged 18 years or older, undergoing clinical lumbar spine MR exams. RAI does not support DICOM images of patients that are pregnant, undergo MRI scan with contrast media, or have post-operational complications, scoliosis, tumors, infections, fractures.
Supported Body Part	Lumbar spine	Lumbar spine
Segmentation	Software automatically generates segmentations of anatomical features of interest	Software automatically generates segmentations of anatomical features of interest
Measurement	Software automatically generates measurements of interest	Software automatically generates measurements of interest
Threshold-Based Out-of-Range Measurements	Software automatically highlights and reports out-of-range measurements based on predetermined thresholds	Software does not automatically highlight or report any out-of-range measurements
Reporting	Exportation of measurement results to a written report for user's review, revise and approval	Exportation of measurement results in both a DICOM Structured Report and a .docx file for users to review and to use full or partial list of software- generated measurements to prepare their own radiology report.
SaMD	Yes	Yes
Algorithm	Deep Convolutional Image-to-Image Neural Network	Convolutional Neural Network
Supported Modality	MR	MR

The Subject Device is substantially equivalent in comparison to the Predicate Device. The information regarding the Subject Device does not raise new questions about safety and effectiveness and demonstrates that RAI is at least as safe and effective as the legally marketed devices.

7. Performance Data

7.1. Biocompatibility Testing

Not applicable.

7.2. Electrical Safety and Electromagnetic Compatibility (EMC)

Not applicable.

7.3. Animal Study

Not applicable.

7.4. Voluntary Conformance Standards

RAI has been tested to meet the requirements of conformity to multiple industry standards. Non-clinical performance testing demonstrated that RAI complies with the following voluntary FDA recognized Consensus Standards listed in the table below.

Voluntary Conformance Standards

Recognition #	Standard
13-79	IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION, Medical device software — Software life cycle processes
5-125	ISO 14971 Third Edition 2019-12, Medical devices — Application of risk management to medical devices
5-129	IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION, Medical devices — Part 1: Application of usability engineering to medical devices
5-134	ISO 15223-1 Fourth edition 2021-07, Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
12-349	NEMA PS 3.1 – 3.20 2022d, Digital Imaging and Communications in Medicine (DICOM) Set

7.5. Nonclinical Tests

Remedy Logic has performed software design verification testing and a standalone performance assessment study, in accordance with the FDA guidance, *General Principles of Software Validation; Final Guidance for Industry and FDA Staff*, issued on January 11, 2002. All software requirements and risk analysis have been successfully verified and traced. The performance data demonstrates continued conformance with special controls for medical devices containing software.

Software documentation for Basic Documentation level, per FDA *Guidance for Industry and Food and Drug Administration Staff, Content of Premarket Submissions for Device Software Functions*, issued on June 14, 2023, were provided.

Remedy Logic conforms to the cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed or transferred from a medical device to an external recipient, per FDA *Guidance for Industry and Food and Drug Administration Staff, Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*, issued on September 27, 2023, as well as FDA *Guidance for Industry and Food and Drug Administration Staff, Postmarket Management of Cybersecurity in Medical Devices*, issued on December 28, 2016. The vulnerability assessment and penetration testing demonstrated satisfactory security performance.

The nonclinical test data demonstrated conformance with special controls and substantial equivalence to predicate devices' performance.

Standalone Software Performance Study

To validate the RAI software from a clinical perspective, a clinical data based standalone software

performance study was conducted in the U.S. The standalone software performance study included 200 MR image studies for 200 patients of different ages and racial groups, collected from three (3) geographically diverse sites across the U.S. The standalone software performance study compared the RAI software outputs to the ground truth defined by five (5) radiologists on segmentations and measurements.

Study Subjects

	Number of subjects	Percent of total
Total number of subjects	200	100%
Gender, Male	92	46%
Gender, Female	108	54%
Age, 18 - 21	43	21.5%
Age, 22 - 50	89	44.5%
Age, 51 - 100	68	34%
Racial, Caucasian	107	53.5%
Racial, Black/African American	16	8%
Racial, Hispanic	58	29%
Racial, Asian or other	19	9.5%

Imaging Systems

The 200 MR studies were acquired on MRI imaging systems made by five (5) manufacturers.

Manufacturer	Model name	Tesla	Number of MRIs	Percent
GE Medical Systems	GENESIS SIGNA	1.5	5	2.5%
	SIGNA Creator	1.5	1	0.5%
	SIGNA EXCITE	1.5	10	5%
	Signa HDxt	1.5	21	10.5%

Philips	Prodiva CS	1.5	5	2.5%
Philips Medical Systems	Achieva	1.5	1	0.5%
	Ingenia	1.5	11	5.5%
	Panorama 0.23 T Power	0.23	21	10.5%
SIEMENS	Espreo	1.5	25	12.5%
	MAGNETOM Altea	1.5	21	10.5%
	Skyra	3	21	10.5%
	Symphony	1.5	7	3.5%
TOSHIBA MEC	MRT200PP2	1.5	51	25.5%

Ground Truth

The ground truths for the segmentation of anatomical structures and the measurements were independently established by five (5) U.S. radiologists without using the RAI software.

For the segmentation, each radiologist used a specialized pixel labeling tool to independently label the pixels of the tissues at the predetermined levels of the preselected axial and sagittal slices. The per-pixel majority opinion of the five (5) radiologists established the ground truth for each anatomical structure. Specially, if at least 3 of the 5 radiologists labeled a pixel as belonging to a particular anatomical structure, the pixel was included. Otherwise, the pixel was excluded.

For the measurement, each radiologist used a commercial software tool to produce a standard set of areal, angular and linear measurements. The ground truth was established by taking the mean of the five (5) radiologists' measurements.

Acceptance Criteria and Study Results

Primary Endpoints:

- For 4 measurements, the maximum Mean Absolute Error (MAE) as defined as the upper limit of the 95% confidence interval for MAE is below a predetermined allowable error limit (MAE limit) for each measurement listed below.

Measurement	MAE limit
Dural Sac Area (Axial)	20 mm ²
Spinal Canal Area (Axial)	30 mm ²

Lordotic Angle (Sagittal)	6 °
Vertebral Body Slippage (Sagittal)	2 mm

Secondary Endpoints:

- For segmentations of 14 anatomical structures: the minimum Mean Dice Coefficient, defined as the lower limit of the 95% confidence interval for MDC, is above a predetermined allowable limit (MDC Limit) for each segmentation listed below.

Anatomical structure	MDC limit
Artery (Axial)	0.8
Disc (Axial)	0.7
Disc (Sagittal)	0.7
Disc Material Outside IV Space (Axial)	0.7
Dural Sac (Axial)	0.8
Kidney (Axial)	0.8
Ligamentum Flavum (Axial)	0.7
Muscle (Axial)	0.8
Sacrum (Sagittal)	0.8
Spinal Canal (Axial)	0.8
Spinal Canal (Sagittal)	0.8
Vein (Axial)	0.8
Vertebral Arch (Axial)	0.8
Vertebral Body (Sagittal)	0.8

- For 10 measurements: the maximum Mean Absolute Error (MAE) as defined as the upper limit of the 95% confidence interval for MAE is below a predetermined allowable error limit (MAE limit) for each measurement listed below.

Measurement	MAE limit
Anterior Disc Height (Sagittal)	2 mm
Anterior Vertebral Body Height (Sagittal)	2 mm
Dural Sac Anterior-Posterior Diameter (Axial)	2 mm
Dural Sac Transverse Diameter (Axial)	2 mm
Middle Disc Height (Sagittal)	2 mm
Middle Vertebral Body Height (Sagittal)	2 mm
Posterior Disc Height (Sagittal)	2 mm
Posterior Vertebral Body Height (Sagittal)	2 mm
Spinal Canal Anterior-Posterior Diameter (Axial)	2 mm

Spinal Canal Transverse Diameter (Axial)	2 mm
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Primary Endpoints Results:

Measurement	Mean Absolute Error (MAE)	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound	MAE Limit	Success
Dural Sac Area (Axial)	17.2 mm ²	16.5 mm ²	17.9 mm ²	20 mm ²	Yes
Spinal Canal Area (Axial)	23.3 mm ²	22.3 mm ²	24.3 mm ²	30 mm ²	Yes
Lordotic Angle (Sagittal)	3.4 °	2,9 °	3,9 °	6 °	Yes
Vertebral Body Slippage (Sagittal)	0.6 mm	0,5 mm	0,8 mm	2 mm	Yes

Secondary Endpoints Results:

Anatomical Structure Segmentation	Mean Dice Coefficient (MDC)	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound	MDC Limit	Success
Artery (Axial)	0.866	0.861	0.871	0.8	Yes
Disc (Axial)	0.806	0.796	0.815	0.7	Yes
Disc (Sagittal)	0.914	0.910	0.918	0.7	Yes
Disc Material Outside IV Space (Axial)	0.803	0.793	0.812	0.7	Yes
Dural Sac (Axial)	0.926	0.924	0.929	0.8	Yes
Kidney (Axial)	0.879	0.872	0.886	0.8	Yes
Ligamentum Flavum (Axial)	0.740	0.736	0.744	0.7	Yes
Muscle (Axial)	0.946	0.945	0.947	0.8	Yes
Sacrum (Sagittal)	0.925	0.923	0.928	0.8	Yes
Spinal Canal (Axial)	0.942	0.941	0.944	0.8	Yes
Spinal Canal (Sagittal)	0.871	0.865	0.877	0.8	Yes
Vein (Axial)	0.821	0.815	0.827	0.8	Yes
Vertebral Arch	0.846	0.843	0.850	0.8	Yes

(Axial)					
Vertebral Body (Sagittal)	0.900	0.894	0.905	0.8	Yes

Measurement	Mean Absolute Error (MAE)	95% confidence interval Lower bound	95% confidence interval Upper bound	MAE limit	Success
Anterior Disc Height (Sagittal)	1.3 mm	1.18 mm	1.32 mm	2 mm	Yes
Anterior Vertebral Body Height (Sagittal)	1.6 mm	1.48 mm	1.81 mm	2 mm	Yes
Dural Sac Anterior-Posterior Diameter (Axial)	1.49 mm	1.46 mm	1.52 mm	2 mm	Yes
Dural Sac Transverse Diameter (Axial)	1.15 mm	1.09 mm	1.22 mm	2 mm	Yes
Middle Disc Height (Sagittal)	1 mm	0.95 mm	1.04 mm	2 mm	Yes
Middle Vertebral Body Height (Sagittal)	1.3 mm	1.21 mm	1.33 mm	2 mm	Yes
Posterior Disc Height (Sagittal)	1 mm	0.95 mm	1.07 mm	2 mm	Yes
Posterior Vertebral Body Height (Sagittal)	1.6 mm	1.44 mm	1.72 mm	2 mm	Yes
Spinal Canal Anterior-Posterior Diameter (Axial)	0.81 mm	1.78 mm	0.83 mm	2 mm	Yes
Spinal Canal Transverse Diameter (Axial)	1.74 mm	1.64 mm	1.85 mm	2 mm	Yes

The RAI software was shown to produce segmentations and measurements accurate to within a prospectively-defined margin of error around the Ground Truth. This accuracy was preserved for all critical subgroups, including MRI scanner manufacturer, patient age, gender and race, except for the dural sac area measurement from MR studies conducted using Philips MR equipment and for patients in over 51 year-old age group.

Training, Testing and Validation Data Independence:

The RAI software machine learning algorithm training and testing data used during the algorithm development, as well as validation data used in the U.S. standalone software performance assessment study were all independent data sets.

7.6.Clinical Validation Study

No human clinical study was conducted to support the pre-market clearance.

8. Conclusions

The RemedyLogic AI MRI Lumbar Spine Reader (“RAI”) software is as safe and effective as the predicate device. The subject device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences between subject and predicate device in indications do not alter the intended use of the device and do not raise new or different questions regarding its safety and effectiveness when used as labeled.

The software verification and validation testing data, including the standalone software performance assessment study data, support the safety of the devices and demonstrate that the RAI software performs as intended in the specified use conditions.

Therefore, the RAI software is substantially equivalent.