



MSKai
Wade Lloyd
Chief Operating Officer
6075 Poplar
Suite 221
Memphis, TN 38119

December 16, 2024

Re: K240793
Trade/Device Name: MSKai
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: November 10, 2024
Received: November 15, 2024

Dear Wade Lloyd:

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,



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

Indications for Use

Submission Number (if known)

K240793

Device Name

MSKai

Indications for Use (Describe)

MSKai is an image identification, post-processing, measurement, and reporting software tool that provides qualitative viewing and quantitative spine measurements from previously-acquired T2 weighted DICOM lumbar spine Magnetic Resonance Imaging (MRI) images for users' review, evaluation and analysis. It provides the following functionality to assist users in identifying, observing, measuring and reporting measurements:

- Anatomy segmentation;
- Anatomy labeling;
- Anatomy measurement; and
- Export of measurement results to a qualitative and quantitative report for user's evaluation, amendment and authorization

MSKai does not serve as a diagnostic device by providing or recommending any type of medical diagnosis or treatment. MSKai simply provides users the ability to access objective and repeatable identification, segmentation, measurement and reported measurements of the Lumbar spine. The user is responsible for the indications of preferences and settings, confirming the software-generated measurements, and reviewing, confirming and approving draft reports based on their medical training.

The device is intended to be used only by physicians, radiologist, hospitals and other medical institutions. Only T2 weighted DICOM images of MRI acquired from lumbar spine exams of patients aged 18 and above are acceptable input. MSKai does not support DICOM images of patients that are pregnant, have post-operational complications, tumors, infections, or complex hardware.

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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MSKai
510k Summary

1. Submitter

MSKai
6075 POPLAR SUITE 221
Memphis TN 38119
United States
Phone: (901) 498-6655
Contact Person: Dr. Lloyd Wade, Ph.D.
Position: Chief Operating Officer

2. Device

Common or Usual Name: MSKai
Classification Name: Automated Radiological Image Processing Software
Regulatory Class: 892.2050
Product Code: QIH

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)

Device Name: AI-Rad Companion Brain MR
Manufacturer: Siemens Healthcare GmbH
Classification Name: Medical image management and processing system (21 CFR 892.2050)
Secondary Classification Name: Magnetic resonance diagnostic device
Classification Product Code: LLZ Subsequent
Product Code: LNH Classification Panel: Radiology
Device Class: Class II 510(k)
Number: K193290 cleared July 5, 2019

Device Name: AI-Rad Companion (Cardiovascular)
Manufacturer: Siemens Medical Solutions USA, Inc.
Classification Name: Computed tomography x-ray system
Regulation Number: 21 CFR 892.1750
Classification Product Code: JAK
Subsequent Product Code: LLZ
Classification Panel: Radiology Device Class: Class II

4. Device Description

MSKai is a medical device (software) for inspecting and evaluating T2-weighted magnetic resonance imaging (MRI) of the lumbar spine. The software is an imaging interpretation tool that assists radiologists and neuro/ortho spine surgeons (“users”) to identify and measure lumbar spine features in medical images and document their interpretations in a report. The segmentation and measurements are classified using “alerts” based on rule-based algorithms. The user also identifies and classifies any other observations that the software may not annotate.

The purpose of MSKai is to provide information regarding common spine measurements confirmed by the user. Every feature segmented, labeled, and measured by the software, based on the user-defined settings, must be reviewed and affirmed by the radiologist before the measurements of these features can be stored and reported. The software initiates adjustable measurements resulting from semi-automatic segmentation. If the user rejects a measurement the corresponding segmentation is rejected too. Segmentations are not intended to be a final output but serve the purpose of interpretation and calculating measurements. The device outputs are intended to be a starting point for a clinical workflow and should not be interpreted or used as a diagnosis. The user is responsible for confirming segmentation and all measurement outputs. The output is an aid to the clinical workflow of measuring patient anatomy and should not be misused as a diagnosis tool.

User-confirmed/defined settings control the sensitivity of the software for labelling measurements in an image. The user (not the software) controls identifying out-of-range measurements, and, in every case once an out-of-range measurement is identified, the user must confirm or reject its presence.

The software facilitates this process by labeling and mask segmenting around features of the relevant anatomy and displaying measurements based on these masks. The user maintains control of the process by inspecting the segmentation, measurements and labels upon which the measurements are based. The user may also examine other features of the imaging not annotated by the software to form a complete impression and diagnostic judgment of the overall state of disease, disorder, or trauma.

5. Indications for Use

MSKai is an image identification, post-processing, measurement, and reporting software tool that provides qualitative viewing and quantitative spine measurements from previously-acquired T2 weighted DICOM lumbar spine Magnetic Resonance Imaging (MRI) images for users' review, evaluation and analysis. It provides the following functionality to assist users in identifying, observing, measuring and reporting measurements:

- Anatomy segmentation;
- Anatomy labeling;

- Anatomy measurement; and
- Export of measurement results to a qualitative and quantitative report for user's evaluation, amendment and authorization

MSKai does not serve as a diagnostic device by providing or recommending any type of medical diagnosis or treatment. MSKai simply provides users the ability to access objective and repeatable identification, segmentation, measurement and reported measurements of the Lumbar spine. The user is responsible for the indications of preferences and settings, confirming the software-generated measurements, and reviewing, confirming and approving draft reports based on their medical training.

The device is intended to be used only by physicians, radiologist, hospitals and other medical institutions. Only T2 weighted DICOM images of MRI acquired from lumbar spine exams of patients aged 18 and above are acceptable input. MSKai does not support DICOM images of patients that are pregnant, have post-operational complications, tumors, infections, or complex hardware.

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 Technology Characteristics with Predicate Device			
	Predicate Device	Subject Device	Remarks Discussion
	Columbo (K220497)	MSKai	
Intended User	· Radiologist · Neurosurgeons and Ortho/Spine Surgeons	· Radiologist · Neurosurgeons and Ortho/Spine Surgeons	Largely Similar
Intended Patient Population	Not subject to restrictions other than above the age of 18, not pregnant, without postoperative complication, scoliosis, tumors, infections, fractures	Not subject to restrictions other than above the age of 18, not pregnant, without postoperative complication, tumors, infections, complex hardware	
Supported Body Part	Lumbar Spine	Lumbar Spine	· Similar to Predicate Device and Reference Device 2 · Different from Reference Device 1
Segmentation	Yes, Segmentation and Quantitative Analysis	Yes, Segmentation and Quantitative Analysis	Same
Measurement	Yes, Quantitative comparison of structure with normative data or user set thresholds	Yes, Quantitative comparison of structure with normative data.	Same
Reporting	Yes, Exploration of results with the findings for further reporting.	Yes, Exploration of results with the findings for further reporting.	Same. Reports radiologists of physicians evaluate, authorized and modify reports
SaMD	Yes	Yes	Same
Algorithm	Deep Convolutional Image to Image Neural Network	Mask Region-based Convolutional Neural Network	Similar
Supported Modality	MR	MR	Same as Predicate device, similar to reference devices.

Comparison of Technology Characteristics with Reference Device (1)			
	Predicate Device	Subject Device	Remarks Discussion
	AI-Rad Companion Brain MR (K193290)	MSKai	
Intended User	Radiologist	Radiologist Neurosurgeons and Ortho/Spine Surgeons	Largely Similar
Intended Patient Population	Patient population above the age of 22 years old.	Not subject to restrictions other than above the age of 18, not pregnant, without postoperative complication, tumors, infections, complex hardware	Largely Similar
Supported Body Part	Brain	Lumbar Spine	Similar to Predicate Device and Reference Device 2 Different from Reference Device 1
Segmentation	Yes, Segmentation and Quantitative Analysis	Yes, Segmentation and Quantitative Analysis	Same
Measurement	Yes, Quantitative comparison of structure with normative data or user set thresholds.	Yes, Quantitative comparison of structure with normative data.	Same.
Reporting	Yes, Exploration of results with the findings for further reporting.	Yes, Exploration of results with the findings for further reporting.	Same. Reports radiologists of physicians evaluate, authorized and modify reports
SaMD	Yes	Yes	Same
Algorithm	Unclear	Mask Region-based Convolutional Neural Network	Similar
Supported Modality	CT	MR	Same as Predicate device, similar to reference devices.

Comparison of Technology Characteristics with Reference Device (2)			
	Predicate Device	Subject Device	Remarks Discussion
	AI-Rad Companion Musculoskeletal (K193267)	MSKai	
Intended User	· Radiologist · Primary Care Physicians · Specialty/Urgent Care Physicians	· Radiologist · Neurosurgeons and Ortho/Spine Surgeons	Largely Similar
Intended Patient Population	Not subject to restrictions other than above the age of 22.	Not subject to restrictions other than above the age of 18, not pregnant, without postoperative complication, tumors, infections, complex hardware	Largely Similar
Supported Body Part	Thorax and Thoracic Spine	Lumbar Spine	· Similar to Predicate Device and Reference Device 2 · Different from Reference Device 1
Segmentation	Yes, Segmentation and Quantitative Analysis	Yes, Segmentation and Quantitative Analysis	Same
Measurement	Yes, Quantitative comparison of structure with normative data or user set thresholds	Yes, Quantitative comparison of structure with normative data.	Same.
Reporting	Yes, Exploration of results with the findings for further reporting.	Yes, Exploration of results with the findings for further reporting.	Same. Reports radiologists of physicians evaluate, authorized and modify reports
SaMD	Yes	Yes	Same
Algorithm	3D Image to Image Network	Mask Region-based Convolutional Neural Network	Similar
Supported Modality	CT	MR	Same as Predicate device, similar to reference devices.

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 MSKai 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 performance testing demonstrated that MSKai complies with the following voluntary FDA recognized Consensus Standards listed in the table below.

Recognition #	Standard
13-79	IEC 62304:2006/AMD 1:2015 Medical device software — Software life cycle processes — Amendment 1
5-125	ISO 14971:2019 Medical devices — Application of risk management to medical devices
5-129	IEC 62366-1:2015+AMD1:2020 Medical devices — Part 1: Application of usability engineering to medical devices
5-117	ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
12-300	NEMA PS 3.1 - 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set

7.5 Non Clinical Tests

MSKai 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 MSKai software from a clinical perspective, a clinical data based standalone software performance assessment study was conducted in the U.S. Three blind independent data sets were used to train, test and measure within the model. Each data set was independent with no overlap of images across datasets.

- Ground Truth dataset: 255 patient images
- Pass/Fail Criteria dataset: 575 patient images
- Testing dataset: 238 patient images

The standalone software performance assessment study of MSKai included 238 MR image studies for 238 patients of different ages and racial groups, collected from five sites across the U.S (Table 7). The standalone software performance assessment study compared the MSKai software outputs without any editing by a radiologist to the ground truth defined by 3 neurosurgeons, 1 interventional radiologist, and 1 PhD in Biomechanics on segmentations and measurements. Measurement analysis was performed by 4 separate and independent experts (2 neurosurgeons, 2 radiologist) Additionally, a confusion matrix analysis was conducted for pass/fail analysis of anatomical segmentation. Inter-rater reliabilities were conducted in the experts who performed the training/testing measurements.

Table 7
Participant Demographics

	Number of Subjects	Percent Total
Total Number of Subjects	238	100.0%
Gender-Male	125	52.5%
Gender-Female	113	47.5%
Age-18 through 21	51	21.4%
Age-22 through 50	132	55.4%
Age-51 and above	55	23.2%
Racial-Caucasian	146	61.3%
Racial-Black/African American	55	23.1%
Racial-Hispanic	28	11.7%
Racial-American Indian	3	1.2%
Racial-Other	6	2.5%

Imaging Systems

The 238 MR studies were acquired on MRI imaging systems made by three (3) manufacturers.

Table 8
Image Systems

Manufacturer	Number of MRI Exams Collected	Percent total
GE (1.5 & 3.0T)	116	48.7%
Philips (1.5 & 3.0T)	80	33.6%
Siemens (1.5 & 3.0T)	42	17.6%
Total	238	100.0%

Ground Truth

To support model accuracy, error analysis is performed before and after applying data augmentation and pre-trained weights. Ground truth data, curated by five experts in a two-phase process, underpins model training. In order to have a blind tested model a dataset 255 images were utilized in the ground truth development with a second independent dataset of 238 patients being utilized for testing being measured by an independent group of 4 experts. A third dataset represented a pass/fail analysis for anatomy segmentation identification. This comprehensive approach supports MSKai's aim of accurate, reliable spine image analysis in a clinical setting.

Acceptance Criteria and Study Results

Primary Endpoints: - For 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. Table 10.

Secondary Endpoints: - For segmentations of 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. Table 9a.

Table 9a
Mean Dice Coefficient Results

Anatomy Segmentation	View	Mean Dice Coefficient (MDC)	95% Confidence Interval (CI)	MDC_{Limit}
Vertebral Body (L1)	Sagittal	0.968	0.92-0.98	0.8
Vertebral Body (L2)	Sagittal	0.977	0.93-0.98	0.8
Vertebral Body (L3)	Sagittal	0.981	0.94-0.99	0.8
Vertebral Body (L4)	Sagittal	0.963	0.92-0.98	0.8
Vertebral Body (L5)	Sagittal	0.985	0.91-0.98	0.8
Vertebral Body (S1)	Sagittal	0.945	0.93-0.99	0.8
L5/S1 Disc	Sagittal	0.993	0.91-0.99	0.8
L4/L5 Disc	Sagittal	0.991	0.93-0.99	0.8
L3/L4 Disc	Sagittal	0.992	0.93-0.99	0.8
L2/L3 Disc	Sagittal	0.989	0.91-0.99	0.8
L1/L2 Disc	Sagittal	0.986	0.94-0.99	0.8
Cord Canal	Sagittal	0.983	0.93-0.99	0.8
Axial Disc	Axial	0.984	0.89-0.97	0.8
Vertebral Body	Axial	0.991	0.93-0.99	0.8
Dural Sac	Axial	0.978	0.90-0.98	0.8
Nerve Root	Axial	0.952	0.90-0.95	0.8
Posterior Arch	Axial	0.911	0.90-0.96	0.8

Table 10
Maximum Mean Absolute Error Results

Structural Measurements	View	Mean Absolute Error (MAE)	95% Confidence interval	MAE_{Limit}
Protruding Disc Material (L5/S1)	Sagittal	1.19mm	1.11 - 1.68mm	2mm
Protruding Disc Material (L4/L5)	Sagittal	1.22mm	1.12 - 1.71mm	2mm
Protruding Disc Material (L3/L4)	Sagittal	1.23mm	1.14 - 1.65mm	2mm
Protruding Disc Material (L2/L3)	Sagittal	1.19mm	1.07 - 1.61mm	2mm
Protruding Disc Material (L1/L2)	Sagittal	1.21mm	1.11 - 1.63mm	2mm
Intervertebral Angle (L5/S1)	Sagittal	2.6°	1.58 - 2.45°	6°
Intervertebral Angle (L4/L5)	Sagittal	2.7°	1.61 - 2.59°	6°
Intervertebral Angle (L3/L4)	Sagittal	2.7°	1.57 - 2.54°	6°
Intervertebral Angle (L2/L3)	Sagittal	2.9°	1.64 - 2.62°	6°
Intervertebral Angle (L1/L2)	Sagittal	2.4°	1.66 - 2.48°	6°
Vertebral Body Height (Anterior) (L1)	Sagittal	0.66mm	0.62 - 0.91mm	2mm
Vertebral Body Height (Anterior) (L2)	Sagittal	0.68mm	0.61 - 0.88mm	2mm
Vertebral Body Height (Anterior) (L3)	Sagittal	0.69mm	0.61 - 0.93mm	2mm
Vertebral Body Height (Anterior) (L4)	Sagittal	0.64mm	0.58 - 0.91mm	2mm

Vertebral Body Height (Anterior) (L5)	Sagittal	0.67mm	0.61 - 0.91mm	2mm
Vertebral Body Height (Midline) (L1)	Sagittal	0.94mm	0.62 - 0.87mm	2mm
Vertebral Body Height (Midline) (L2)	Sagittal	0.93mm	0.54 - 1.03mm	2mm
Vertebral Body Height (Midline) (L3)	Sagittal	0.96mm	0.61 - 0.1.01mm	2mm
Vertebral Body Height (Midline) (L4)	Sagittal	0.97mm	0.57 - 1.13mm	2mm
Vertebral Body Height (Midline) (L5)	Sagittal	0.94mm	0.57 - 0.99mm	2mm
Vertebral Body Height (Posterior) (L1)	Sagittal	0.92mm	0.67 - 0.99mm	2mm
Vertebral Body Height (Posterior) (L2)	Sagittal	0.93mm	0.61 - 1.01mm	2mm
Vertebral Body Height (Posterior) (L3)	Sagittal	0.91mm	0.68 - 0.99mm	2mm
Vertebral Body Height (Posterior) (L4)	Sagittal	0.92mm	0.71 - 1.06mm	2mm
Vertebral Body Height (Posterior) (L5)	Sagittal	0.93mm	0.68 - 1.09mm	2mm
Disc Height (Anterior) (L5/S1)	Sagittal	0.91mm	0.67 - 0.99mm	2mm
Disc Height (Anterior) (L4/L5)	Sagittal	0.90mm	0.57 - 1.06mm	2mm
Disc Height (Anterior) (L3/L4)	Sagittal	0.87mm	0.62 - 1.03mm	2mm

Disc Height (Anterior) (L2/L3)	Sagittal	0.89mm	0.78 - 1.06mm	2mm
Disc Height (Anterior) (L1/L2)	Sagittal	0.93mm	0.71 - 1.23mm	2mm
Disc Height (Midline) (L5/S1)	Sagittal	0.93mm	0.73 - 1.12mm	2mm
Disc Height (Midline) (L4/L5)	Sagittal	0.90mm	0.68 - 1.01mm	2mm
Disc Height (Midline) (L3/L4)	Sagittal	0.89mm	0.71 - 1.13mm	2mm
Disc Height (Midline) (L2/L3)	Sagittal	0.91mm	0.64 - 1.03mm	2mm
Disc Height (Midline) (L1/L2)	Sagittal	0.92mm	0.69 - 1.11mm	2mm
Disc Height (Posterior) (L5/S1)	Sagittal	0.87mm	0.58 - 1.03mm	2mm
Disc Height (Posterior) (L4/L5)	Sagittal	0.93mm	0.67 - 0.99mm	2mm
Disc Height (Posterior) (L3/L4)	Sagittal	0.87mm	0.66 - 1.07mm	2mm
Disc Height (Posterior) (L2/L3)	Sagittal	0.93mm	0.72 - 1.21mm	2mm
Disc Height (Posterior) (L1/L2)	Sagittal	0.89mm	0.58 - 0.91mm	2mm
Anterio-Lithesis (L5/S1)	Sagittal	1.04mm	0.81 - 1.43mm	2mm
Anterio-Lithesis (L4/L5)	Sagittal	1.02mm	0.77 - 1.52mm	2mm
Anterio-Lithesis (L3/L4)	Sagittal	1.05mm	0.88 - 1.61mm	2mm
Anterio-Lithesis (L2/L3)	Sagittal	1.07mm	0.84 - 1.43mm	2mm
Anterio-Lithesis (L1/L2)	Sagittal	1.02mm	0.79 - 1.33mm	2mm
Retro-Lithesis (L5/S1)	Sagittal	1.07mm	0.82 - 1.51mm	2mm

Retro-Lithesis (L4/L5)	Sagittal	1.049mm	0.78 - 1.42mm	2mm
Retro-Lithesis (L3/L4)	Sagittal	1.01mm	0.81 - 1.29mm	2mm
Retro-Lithesis (L2/L3)	Sagittal	1.05mm	0.77 - 1.34mm	2mm
Retro-Lithesis (L1/L2)	Sagittal	1.08mm	0.83 - 1.27mm	2mm
Lordotic Angle	Sagittal	2.99°	2.01 - 3.62°	6°
Protruding Disc Material	Axial	0.97 mm	0.72 - 1.42mm	2mm
Dural Sac Diameter	Axial	1.3 mm	0.87 - 1.39mm	2mm

The MSKai 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.

Training, Testing and Validation Data Independence:

The MSKai 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.

8.0 Conclusions

The MSKai 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.

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

Therefore, the MSKai software demonstrates substantial equivalence to the predicate.