Clarius Mobile Health Corp.
Agatha Szeliga
Director, Regulatory Affairs
130-2985 Virtual Way
Vancouver, British Columbia V5M 4X7
Canada

January 23, 2023

Re: K222406
Trade/Device Name: Clarius AI
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: December 16, 2022
Received: December 21, 2022

Dear Agatha Szeliga:

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 and Part 809); 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

Indications for Use

510(k) Number *(if known)*
K222406

Device Name
Clarius AI

Indications for Use *(Describe)*

Clarius AI is intended to semi-automatically place calipers for non-invasive measurements of musculoskeletal structures (e.g., Achilles' tendon, plantar fascia, patellar tendon) on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., L7 and L15). The user shall be a healthcare professional trained and qualified in MSK (musculoskeletal) ultrasound. The user shall retain the ultimate responsibility of ascertaining the measurements based on standard practices and clinical judgment.

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.

510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR § 807.92.

Subject Device Trade Name: Clarius AI

Subject Device Model: MSK

Device Classification Name: Automated Radiological Image Processing Software

Regulation Number, Name and Product Code:

Regulation Number	Regulation Name	Product Code
21 CFR § 892.2050	Medical Image Management and Processing System	QIH

FDA 510(k) Review Panel: Radiology

Classification: Class II

Manufacturer: Clarius Mobile Health Corp.
          130-2985 Virtual Way
          Vancouver, BC V5M 4X7 Canada

Contact Name: Agatha Szeliga
          Director, Regulatory Affairs
          agatha.szeliga@clarius.com

Date 510(k) Summary Prepared: December 15, 2022

Predicate Device Information:

Device Trade Name:	LVivo Software Application
510(k) Reference:	K200232
Manufacturer Name:	DiA Imaging Analysis Ltd
Regulation Name:	Medical Image Management and Processing System
Device Classification Name:	Automated Radiological Image Processing Software
Product Code(s):	QIH
Regulation Number:	21 CFR § 892.2050
Regulatory Class:	Class II

Note: The predicate device has not been subject to a design-related recall.

Reference Device #1 Information:

Device Trade Name:	CoLumbo
510(k) Reference:	K220497
Manufacturer Name:	Smart Soft Healthcare AD
Regulation Name:	Medical Image Management and Processing System
Device Classification Name:	Automated Radiological Image Processing Software
Product Code(s):	QIH
Regulation Number:	21 CFR § 892.2050
Regulatory Class:	Class II

Reference Device #2 Information:

Device Trade Name:	AI-Rad Companion (Musculoskeletal)
510(k) Reference:	K193267
Manufacturer Name:	Siemens Medical Solutions USA, Inc.
Regulation Name:	Computed tomography x-ray system
Device Classification Name:	Computed tomography x-ray system
Product Code(s):	JAK
Regulation Number:	21 CFR § 892.1750
Regulatory Class:	Class II

Device Description

Clarius AI is a radiological (ultrasound) image processing software application which implements artificial intelligence (AI), including non-adaptive machine learning algorithms, and is incorporated into the Clarius App software for use as part of the complete Clarius Ultrasound Scanner system product offering in musculoskeletal (MSK) ultrasound imaging applications. Clarius AI (MSK model) is intended for use by trained healthcare practitioners for non-invasive measurements of ultrasound data from musculoskeletal (MSK) ultrasound imaging acquired by the Clarius Ultrasound Scanner system using an artificial intelligence (AI) image segmentation algorithm. Clarius AI (MSK model) is intended to semi-automatically place adjustable calipers and provide supplementary information to the user regarding tendon thickness measurements (i.e., foot/plantar fascia, ankle/Achilles' tendon, knee/patellar tendon). Clarius AI is intended to inform clinical management and is not intended to replace clinical decision-making. The clinician retains the ultimate responsibility of ascertaining the measurements based on standard practices and clinical judgment. Clarius AI is indicated for use in adult patients only.

During the ultrasound imaging procedure, the anatomical site is selected through a preset software selection (e.g., foot, ankle, knee), in which the Clarius AI will engage to segment the correlating tendon. Clarius AI analyzes ultrasound images in real-time and outputs probabilities for each pixel within the image for determination of the particular tendon thickness.

The combination of all the pixels meeting a programmed threshold will render an overlay being displayed on top of the ultrasound image with a pre-programmed transparency so that the ultrasound greyscale is still visible. Once the user has obtained the best view, imaging can be manually paused, in which the Clarius AI will further analyze the tendon segmentation to determine the greatest thickness, in number of

pixels, and subsequently place two measurement calipers that correspond to the top and bottom of the tendon at its thickest region, outputting a value in millimeters. The user can then manually alter the measurement calipers to make any necessary adjustments if desired. Clarius AI does not perform any functions that could not be accomplished manually by a trained and qualified user.

Clarius AI (MSK model) is incorporated into the Clarius App software and is intended for use with the following Clarius Ultrasound Scanner system transducers (previously 510(k)-cleared in K180799, K192107, and K213436):

Clarius Ultrasound Transducers	L7 and L15
Clarius App Software	Clarius Ultrasound App (Clarius App) for iOS; Clarius Ultrasound App (Clarius App) for Android

Indications for Use for Clarius AI (MSK)

Clarius AI is intended to semi-automatically place calipers for non-invasive measurements of musculoskeletal structures (e.g., Achilles' tendon, plantar fascia, patellar tendon) on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., L7 and L15). The user shall be a healthcare professional trained and qualified in MSK (musculoskeletal) ultrasound. The user shall retain the ultimate responsibility of ascertaining the measurements based on standard practices and clinical judgment.

Comparison of the Subject Device and Legally Marketed Devices for Demonstration of Substantial Equivalence

The following table provides a comparison of the subject device, Clarius AI, to the predicate device and reference devices. A comparison of the subject device to the predicate and reference devices shows that the subject device has similar indications for use, is based on a similar AI algorithm, and provides automated radiological image processing with segmentation and measurement of anatomical structures, comparable to the legally marketed devices referenced herein.

Table 1 - Comparison of the Subject Device to the Legally Marketed Devices

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE #1	REFERENCE DEVICE #2	RATIONALE (if subject device differs from predicate device)
	Clarius AI	**LVivo Software Application**	**CoLumbo**	**AI-Rad Companion (Musculoskeletal)**	
510(k) Holder/ Manufacturer	Clarius Mobile Health Corp.	DiA Imaging Analysis Ltd	Smart Soft Healthcare AD	Siemens Medical Solutions USA, Inc.	Not applicable
Submission Reference	Current Submission	K200232	K220497	K193267	Not applicable
Product Code(s)	QIH	QIH	QIH	JAK	Same as predicate device and reference device #1
Device Classification Name	Automated Radiological Image Processing Software	Automated Radiological Image Processing Software	Automated Radiological Image Processing Software	Computed tomography x-ray system	Same as predicate device and reference device #1
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.1750	Same as predicate device and reference device #1
Regulation Name	Medical Image Management and Processing System	Medical Image Management and Processing System	Medical Image Management and Processing System	Computed tomography x-ray system	Same as predicate device and reference device #1
Intended Use	Non-invasive processing of ultrasound images using automatic image segmentation and measurement of anatomical structures utilizing artificial intelligence algorithms.	Non-invasive processing of ultrasound images using automatic image segmentation and measurement of anatomical structures utilizing artificial intelligence algorithms.	Non-invasive processing of MR images using automatic image segmentation and measurement of anatomical structures utilizing artificial intelligence algorithms.	Non-invasive processing of CT images using automatic image segmentation and measurement of anatomical structures utilizing artificial intelligence algorithms.	Same as predicate device and similar to reference devices
Indications for Use	Clarius AI is intended for use by trained healthcare professionals to semi-automatically place	LVivo platform is intended for non-invasive processing of ultrasound images to detect, measure, and	CoLumbo is an image post-processing and measurement software tool that provides quantitative	AI-Rad Companion (Musculoskeletal) is an image processing software that provides quantitative and	Clarius AI indications for use are similar to the predicate device's indications for use as both devices are

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE #1	REFERENCE DEVICE #2	RATIONALE (if subject device differs from predicate device)
	Clarius AI	LVivo Software Application	CoLumbo	AI-Rad Companion (Musculoskeletal)	
	calipers for non-invasive anatomical measurements on ultrasound data acquired by the Clarius Ultrasound Scanner.	calculate relevant medical parameters of structures and function of patients with suspected disease.	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 out-of-range measurements: -Feature segmentation; -Feature measurement; Threshold based labeling of out of range measurement; and -Export of measurement results to a written report for user's review, revise and approval. CoLumbo does not produce or recommend any type of medical diagnosis or treatment. Instead, it simply helps users to	qualitative analysis from previously acquired Computed Tomography DICOM images to support radiologists and physicians from emergency medicine, specialty care, urgent care, and general practice in the evaluation and assessment of musculoskeletal disease. It provides the following functionality: -Segmentation of vertebras -Labelling of vertebras -Measurements of heights in each vertebra and indication if they are critically different -Measurement of mean Hounsfield value in volume of interest within vertebra. Only DICOM images of adult patients are considered to be valid input.	indicated for non-invasive processing of ultrasound data/ images for measurements of anatomical structures.

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE #1	REFERENCE DEVICE #2	RATIONALE (if subject device differs from predicate device)
	Clarius AI	LVivo Software Application	CoLumbo	AI-Rad Companion (Musculoskeletal)	
			more easily identify and classify features in lumbar MR images and compile a report. The user is responsible for confirming/ modifying settings, reviewing and verifying the software-generated measurements, inspecting out-of-range measurements, and approving draft report content using their medical judgment and discretion. The device is intended to be used only by hospitals and other medical institutions. Only DICOM images of MRI acquired from lumbar spine exams of patients aged 18 and above are considered to be valid input. CoLumbo does not support DICOM images of patients that are pregnant, undergo MRI scan with contrast media, or have post-		

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE #1	REFERENCE DEVICE #2	RATIONALE (if subject device differs from predicate device)
	Clarius AI	LVivo Software Application	CoLumbo	AI-Rad Companion (Musculoskeletal)	
			operational complications, scoliosis, tumors, infections, fractures.		
Radiological application/ Supported modality	Ultrasound	Ultrasound	MR	CT	Same as predicate device
Principle of Operation/ Technology	Ultrasound image processing software implementing artificial intelligence including non-adaptive machine learning algorithms trained with clinical and/or artificial data intended for non-invasive segmentation and measurements of ultrasound data.	Ultrasound image processing software implementing artificial intelligence including non-adaptive machine learning algorithms trained with clinical and/or artificial data intended for non-invasive segmentation and measurements of ultrasound data.	Radiological image processing software implementing artificial intelligence including non-adaptive machine learning algorithms trained with clinical and/or artificial data intended for non-invasive segmentation and measurements of MR data	Radiological image processing software implementing artificial intelligence including non-adaptive machine learning algorithms trained with clinical and/or artificial data intended for non-invasive segmentation and measurements of CT data	Same as predicate device
Segmentation	Yes – Segmentation of anatomical structures (tendons)	Yes – Segmentation of anatomical structures (LV, RV, bladder)	Yes – Segmentation of anatomical structures (spinal vertebrae)	Yes – Segmentation of anatomical structures (spinal vertebrae)	Similar to predicate device and reference devices
Measurement	Yes – Measurement of anatomical structures (tendons)	Yes – Measurement of anatomical structures (LV, RV, bladder)	Yes – Measurement of anatomical structures (spinal vertebrae)	Yes – Measurement of anatomical structures (spinal vertebrae)	Similar to predicate device and reference devices
AI Algorithm	Image segmentation, anatomical identification, and measurement utilizing the machine learning-based algorithm Exception U-Net	Image segmentation for border detection. Algorithm combines image processing and Deep Learning Neural Network for analysis.	Deep Convolutional Image-to-Image Neural Network	3D Deep Image-to-Image Network	Similar to predicate device and reference devices

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE #1	REFERENCE DEVICE #2	RATIONALE (if subject device differs from predicate device)
	Clarius AI	LVivo Software Application	CoLumbo	AI-Rad Companion (Musculoskeletal)	
Automation (Yes or No)	Yes	Yes	Yes	Yes	Same as predicate device and reference devices
Display Calipers	Yes	Yes	Yes	Yes	Same as predicate device and reference devices
Manual adjustment/ Manual editing by user capability (Yes or No)	Yes	Yes	Yes	Yes	Same as predicate device and reference devices
Anatomical Site	Foot, Ankle, Knee	Bladder, Heart	Lumbar Spine	Thoracic Spine	Although the anatomical sites/ structures for use of the predicate device (bladder, heart) are different from the subject device (foot, ankle, knee), the predicate device and subject device share a very similar intended use in terms of identifying/ viewing, measuring/ quantifying and reporting results acquired by ultrasound devices for non-invasive measurements of anatomical structures utilizing artificial

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE #1	REFERENCE DEVICE #2	RATIONALE (if subject device differs from predicate device)
	Clarius AI	**LVivo Software Application**	**CoLumbo**	**AI-Rad Companion (Musculoskeletal)**	
					intelligence algorithms.
Environment of Use	Healthcare setting (e.g., hospital, clinic)	Healthcare setting (e.g., hospital, clinic)	Healthcare setting (e.g., hospital, clinic)	Healthcare setting (e.g., hospital, clinic)	Same as predicate device and reference devices
Intended Users	Licensed healthcare professionals	Licensed healthcare professionals	Licensed healthcare professionals	Licensed healthcare professionals	Same as predicate device and reference devices
Patient Population	Adults	Adults	Adults	Adults	Same as predicate device and reference devices

Non-Clinical Performance Testing Summary

Clarius AI (MSK) was designed and developed by Clarius Mobile Health Corp. in accordance with the applicable requirements, design controls, and standards to establish safety and effectiveness of the device.

Non-clinical performance testing has demonstrated that Clarius AI (MSK) complies with the following FDA-recognized consensus standards:

Standard Recognition Number	Title of Standard
13-79	IEC 62304:2006 + A1:2015 - Medical device software — Software life cycle processes
5-40	ISO 14971:2019 Medical devices — Application of risk management to medical devices
12-300	NEMA PS 3.1 - 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set
5-114	IEC 62366-1:2015 + A1:2020 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

Safety and performance of Clarius AI (MSK) has been evaluated through verification and validation testing in accordance with software specifications and applicable performance standards. The traceability analysis provides traceability between requirements, design specifications, risks, and verification testing of the subject device. All software requirements and risk analysis have been successfully verified and traced. Software verification and validation activities were conducted per *IEC 62304:2006 + AMD1:2015 – Medical device software – Software lifecycle processes* and *ISO 14971:2019 Medical devices – Application of risk management to medical devices*, and in accordance with FDA guidance documents, *General Principles of Software Validation, Final Guidance for Industry and FDA Staff* (issued January 11, 2002), *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (issued May 11, 2005)*,* and *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices* (issued October 2, 2014).

Applicable software documentation for a Moderate Level of Concern software, per FDA *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (May 11, 2005) has been provided.

A comprehensive risk analysis was performed for the subject device and appropriate risk controls have been implemented to mitigate hazards.

Clarius 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.

Clarius AI (MSK) was tested and found to be safe and effective for the intended users, uses, and use environments, as demonstrated through verification and validation testing. Validation testing was performed to ensure that the final product is capable of meeting the requirements for the specified clinical application and performs as intended to meet users' needs, while demonstrating substantial equivalence to the predicate device.

Clinical Performance Testing Summary

Clarius performed AI model training to create a documented baseline of the AI model. Training consisted of a basic hyperparameter exploration over a static dataset optimizing towards a static validation set sampled from the training data. U-net with MobileNetV2 backbone was used as the model architecture for Clarius AI.

Three datasets of ultrasound images of Achilles' Tendons, Plantar Fascia and Patellar Tendons, were used in the study. All the images had segmentation ground truth. The images in the dataset were classified into tendon and background. Images were captured in-house from volunteer subjects and by clinical partners in outpatient clinics mainly located in the USA. The data was anonymized and queried from Clarius Cloud storage. Ultrasound recordings were acquired with the subjects in various positions depending on preference. Tendons were imaged in longitudinal views. The plantar fascia was imaged in dorsiflexion, plantar flexion, and neutral positions. The Achilles' tendon was imaged with the ankle at 90 degrees. The knee was imaged in 30 degrees flexion. Images with and without the structures of interest were collected to create a dataset that was large and heterogeneous. Images were acquired in different depths to mitigate different use cases for users. The data were acquired using two Clarius ultrasound linear probes with a frequency of 5 - 15 MHz and 4 - 13 MHz. A total of 20,287 images were acquired. For the training phase, the tendon regions in the images were annotated by a clinical scientist as the ground truth.

A total of 73 subjects were used to evaluate the performance of the AI model in the validation phase. Each subject had multiple studies of the above-mentioned tendons, resulting in a total of 2,503 ultrasound images/frames. The reported average Dice score was 96% and the mean IoU was 94% for tendon segmentation.

Verification testing was performed to verify if Clarius AI auto-measurements are non-inferior to manual measurements performed by licensed clinicians with relevant (i.e., musculoskeletal) ultrasound experience. Verification testing of Clarius AI was performed through a retrospective analysis of anonymized ultrasound images. The objective was to determine whether the Clarius AI (MSK model) software measurement output adequately aligned with expert clinicians' manual caliper placement. The features tested during the verification study were tendon thickness measurement and segmentation mask. The difference between auto-measurements and mean manual measurements was found to be no greater than the mean difference between manual measurements within the clinically significant margin and with a statistical significance level of 0.05.

Measurement Accuracy:

The absolute percent (%) difference between reviewer pairs was calculated and compared to the absolute percent (%) difference between the automatic thickness measurement and mean reviewer measurement using a one-sided t-test and an equivalence margin of 20%. The automatic thickness measurement was found to be non-inferior (p value of 9.0×10^{-7}). The mean difference between differences was 0.03% (95% CI (-0.05)-(-0.01)).

A difference of >20% constitutes a clinically significant difference for all structures, which corresponds to the following differences based on normal thickness measurements: 0.6 mm for plantar fascia; 1 mm for patellar tendon; 1.2 mm for Achilles' tendon.

Verification testing of Clarius AI was successfully completed with the results demonstrating that Clarius AI (MSK model) software measurement output adequately aligned with expert clinicians' manual caliper placement. As such, Clarius AI has been verified for tendon thickness measurement and segmentation mask for use in musculoskeletal ultrasound applications.

A design validation study was performed to validate the essential functionality of Clarius AI as incorporated into the Clarius App software for the specified application and intended use in automatic segmentation highlight, semi-automatic caliper placement with manual caliper adjustment, and persistent storage, to determine if Clarius AI is clinically usable and meets user needs in musculoskeletal ultrasound applications. The results of the validation study demonstrated that Clarius AI performs as intended and meets user needs in musculoskeletal ultrasound applications for use in automatic segmentation highlight, semi-automatic caliper placement with manual caliper adjustment, and persistent storage.

Conclusion & Summary of Substantial Equivalence

Based on the information presented in this Traditional 510(k) premarket notification and based on the fundamental scientific technology utilizing artificial intelligence algorithms, technological characteristics, principle of operation, intended use, environment of use, and indications for use, Clarius AI has been determined to be substantially equivalent in terms of safety and effectiveness to the legally marketed predicate/reference devices.

Performance testing of Clarius AI, including results from verification and validation studies, has demonstrated that Clarius AI software measurement output adequately aligns with expert clinicians' manual measurements, and thereby performs as intended for automatic segmentation with semi-automatic caliper placement with manual caliper adjustment in musculoskeletal ultrasound applications, meeting user needs.

The subject device and the predicate device are both radiological (ultrasound) image processing software applications which implement artificial intelligence (AI) including non-adaptive machine learning algorithms trained with clinical and/or artificial data intended for non-invasive measurements of ultrasound data, utilizing similar machine-learning based algorithms to detect, measure, and calculate relevant medical parameters of structures with manual adjustment capability by the user.

Any minor differences in the indications for use/anatomical structures between the subject device and the legally marketed devices do not raise any issues related to safety or effectiveness, thereby demonstrating that Clarius AI is as safe and effective as the legally marketed devices, and therefore substantially equivalent.