



Clarius Mobile Health Corp.  
Agatha Szeliga  
Director, Regulatory Affairs  
205-2980 Virtual Way  
VANCOUVER, BC V5M 4X3  
CANADA

May 8, 2025

Re: K250226  
Trade/Device Name: Clarius Median Nerve AI  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Medical Image Management And Processing System  
Regulatory Class: Class II  
Product Code: QIH  
Dated: April 4, 2025  
Received: April 7, 2025

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 (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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style. Behind the signature, there is a large, light blue watermark of the letters "FDA".

Jessica Lamb, Ph.D.  
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

510(k) Number (if known)

Device Name

Clarius Median Nerve AI

Indications for Use (Describe)

Clarius Median Nerve AI is intended for segmentation and semi-automatic non-invasive measurements of the median nerve cross-sectional area on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., linear array scanners). The user shall be a healthcare professional trained and qualified in ultrasound. The user retains the responsibility of confirming the validity of the measurements based on standard practices and clinical judgment. Clarius Median Nerve AI is indicated for use in adult patients only.

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

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 Median Nerve AI

**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.  
205-2980 Virtual Way  
Vancouver, BC V5M 4X3 Canada

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

**Date 510(k) Summary Prepared:** May 8, 2025

**Predicate Device Information:**

<b>Device Trade Name:</b>	Clarius AI
<b>510(k) Reference:</b>	K222406
<b>Manufacturer Name:</b>	Clarius Mobile Health Corp.
<b>Regulation Name:</b>	Medical Image Management and Processing System
<b>Device Classification Name:</b>	Automated Radiological Image Processing Software
<b>Primary Product Code:</b>	QIH
<b>Regulation Number:</b>	21 CFR § 892.2050
<b>Regulatory Class:</b>	Class II

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

**Device Description**

Clarius Median Nerve AI is a machine learning algorithm that is integrated into the Clarius App software as part of the complete Clarius Ultrasound Scanner system for use in musculoskeletal ultrasound applications, specifically intended for segmentation and measurement of the cross-sectional area of the median nerve. Clarius Median Nerve AI is intended for use by trained healthcare practitioners for

measurement of the cross-sectional area (CSA) of the median nerve on ultrasound data acquired by the Clarius Ultrasound Scanner system (i.e., linear array scanners) using a deep learning image segmentation algorithm.

During the ultrasound imaging procedure, the anatomical site is selected through a preset software selection (i.e., Hand/Wrist) from the Clarius App in which Clarius Median Nerve AI will segment the median nerve in transverse view (with a segmentation mask placed on the ultrasound image) and engage to automatically place calipers on the segmentation mask to measure the median nerve’s cross-sectional area.

Clarius Median Nerve AI operates by performing the following tasks:

- Automatic detection and measurement of the median nerve in transverse view

Clarius Median Nerve AI operates by identifying and segmenting the median nerve in the forearm and wrist and performs automatic measurements of the median nerve’s cross-sectional area. The user has the option to manually adjust the measurements made by Clarius Median Nerve AI by moving the caliper crosshairs. Clarius Median Nerve AI does not perform any functions that could not be accomplished manually by a trained and qualified user.

Clarius Median Nerve AI is an assistive tool 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 Median Nerve AI is indicated for use in adult patients only.

Clarius Median Nerve AI is integrated into the Clarius App software, which is compatible with iOS and Android operating systems two versions prior to the latest iOS or Android stable release build and is intended for use with the following Clarius Ultrasound Scanner system transducers (previously 510(k)-cleared in K213436). Clarius Median Nerve AI is not a stand-alone software device.

<b>Clarius Ultrasound Transducers</b>	L7 HD3; L15 HD3; L20 HD3
<b>Clarius App Software</b>	Clarius Ultrasound App (Clarius App) for iOS; Clarius Ultrasound App (Clarius App) for Android

**Indications for Use for Clarius Median Nerve AI**

Clarius Median Nerve AI is intended for segmentation and semi-automatic non-invasive measurements of the median nerve cross-sectional area on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., linear array scanners). The user shall be a healthcare professional trained and qualified in ultrasound. The user retains the responsibility of confirming the validity of the measurements based on standard practices and clinical judgment. Clarius Median Nerve AI is intended for use in adult patients only.

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

The following table provides a comparison of the subject device, Clarius Median Nerve AI, to the predicate device, Clarius AI. The comparison of the subject device to the legally marketed device shows that the subject device has the same intended use, similar indications for use, the same principle of operation, and

is based on a similar AI/ML algorithm providing segmentation and measurement of musculoskeletal structures, comparable to the legally marketed device referenced herein.

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

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	RATIONALE (if subject device differs from predicate device)
<b>Device Trade Name</b>	<b>Clarius Median Nerve AI</b>	<b>Clarius AI</b>	
510(k) Holder/ Manufacturer	Clarius Mobile Health Corp.	Clarius Mobile Health Corp.	Same as predicate device.
Submission Reference	Current Submission	K222406	Not applicable
Primary Product Code	QIH	QIH	Same as predicate device.
Device Classification Name	Automated Radiological Image Processing Software	Automated Radiological Image Processing Software	Same as predicate device.
Regulation Name	Medical Image Management and Processing System	Medical Image Management and Processing System	Same as predicate device.
Regulation Number	21 CFR § 892.2050	21 CFR § 892.2050	Same as predicate device.
Intended Use	Intended for use as an assistive tool during the acquisition and interpretation of ultrasound images utilizing an artificial intelligence/machine-learning algorithm for segmentation and measurement of anatomical structures.	Non-invasive processing of ultrasound images using automatic image segmentation and measurement of anatomical structures utilizing artificial intelligence/ machine learning algorithms.	Same as predicate device.
Indications for Use	Clarius Median Nerve AI is intended for segmentation and semi-automatic non-invasive measurements of the median nerve cross-sectional area on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., linear array scanners). The user shall be a healthcare professional trained and qualified in ultrasound. The user retains the responsibility of confirming the validity of the measurements based on standard practices and clinical	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.	Both the predicate device and subject device are indicated for semi-automated measurements of anatomical (musculoskeletal) structures on ultrasound image data acquired by the Clarius Ultrasound Scanner using AI/ML-based technology. Both devices detect the anatomical structure, perform segmentation, and perform measurements of the structure. Both the predicate and subject devices are intended for use as an adjunctive ‘tool’ or aid by the user for the segmentation and anatomical measurements of

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	RATIONALE (if subject device differs from predicate device)
Device Trade Name	Clarius Median Nerve AI	Clarius AI	
	judgment. Clarius Median Nerve AI is indicated for use in adult patients only.		ultrasound images and are not intended to replace clinical decision-making. The minor differences in the indications for use do not impact the safety and effectiveness of the subject device relative to the predicate device.
Radiological application/ Supported modality	Ultrasound	Ultrasound	Same as predicate device.
Principle of Operation/ Technology	Ultrasound image processing software implementing artificial intelligence utilizing non-adaptive machine learning algorithms trained with clinical and/or artificial data intended for segmentation and measurements of ultrasound data.	Ultrasound image processing software implementing artificial intelligence utilizing non-adaptive machine learning algorithms trained with clinical and/or artificial data intended for segmentation and measurements of ultrasound data.	Same as predicate device.
Quantitative and/or Qualitative Analysis	Median nerve cross-sectional area measurement	Tendon thickness measurement	Equivalent to the predicate device. The subject device performs semi-automated measurements of the median nerve cross-sectional area, whereas the predicate device performs semi-automated measurements of tendon thickness.
Segmentation	Yes – Segmentation of anatomical structures (median nerve)	Yes – Segmentation of anatomical structures (tendons)	Equivalent to the predicate device. The only difference is the anatomical structure (median nerve vs. tendons).
Measurement	Yes – Measurement of anatomical structures (median nerve cross-sectional area)	Yes – Measurement of anatomical structures (tendon thickness of	Equivalent to the predicate device. The only difference is the

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	RATIONALE (if subject device differs from predicate device)
Device Trade Name	Clarius Median Nerve AI	Clarius AI	
		the Achilles' tendon, plantar fascia, patellar tendon)	anatomical structure (median nerve vs. tendons).
Algorithm Methodology	Artificial Intelligence (AI)/Machine Learning (ML)  Image segmentation for border detection, and median nerve view classification using a Deep Neural Network.	Artificial Intelligence (AI)/Machine Learning (ML)  Image segmentation for border detection, and tendon view classification using a Deep Neural Network.	Same as predicate device.
Automation (Yes or No)	Yes	Yes	Same as predicate device.
Manual adjustment/Manual editing capability (Yes or No)	Yes	Yes	Same as predicate device.
Environment of Use	Healthcare setting (e.g., hospital, clinic)	Healthcare setting (e.g., hospital, clinic)	Same as predicate device.
Anatomical Site	Wrist, forearm	Foot, ankle, knee	The difference in anatomical site does not impact the safety and effectiveness of the subject device relative to the predicate device.
Intended Users	Licensed healthcare professionals	Licensed healthcare professionals	Same as predicate device.
Patient Population	Adults	Adults	Same as reference device.
Operating System Compatibility	iOS and Android	iOS and Android	Same as predicate device.
Platform	Embedded in the Clarius ultrasound app for use with the Clarius Ultrasound Scanner system	Embedded in the Clarius ultrasound app for use with the Clarius Ultrasound Scanner system	Same as predicate device.

**Non-Clinical Performance Testing Summary**

Clarius Median Nerve AI 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 Median Nerve AI 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
5-125	ISO 14971:2019 Medical devices — Application of risk management to medical devices
12-349	NEMA PS 3.1 - 3.20 (2022d) Digital Imaging and Communications in Medicine (DICOM) Set
5-129	IEC 62366-1:2015 + A1:2020 Medical devices — Part 1: Application of usability engineering to medical devices
5-134	ISO 15223-1:2021 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied

Safety and performance of Clarius Median Nerve AI have been evaluated through verification and validation testing in accordance with applicable specifications, acceptance criteria, and performance standards. The traceability analysis provides traceability between the requirement specifications, design specifications, risks, and verification testing of the subject device. All requirements and risk controls have been successfully verified and traced. A comprehensive risk analysis was performed for the subject device and appropriate risk controls have been implemented to mitigate hazards.

Software verification and validation activities were conducted in accordance with *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 relevant 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 Device Software Functions* (issued June 14, 2023), and *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions* (issued September 27, 2023).

Cybersecurity and vulnerability analyses were conducted, and it has been determined that 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.

The following processes were followed and applied during the design and development of Clarius Median Nerve AI:

- Risk Analysis
- Design Reviews
- Integration Testing
- System Testing
- Performance Testing
- Usability Engineering

- Software Verification & Validation
- Cybersecurity Analysis

Clarius Median Nerve AI was tested and was found to be safe and effective for the intended use, intended users, intended patient population, and use environments, as demonstrated through verification and validation testing evaluating its clinical usage and performance. Validation testing was performed to ensure that the final product meets 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 Evaluation Summary**

Following the completion of Clarius Median Nerve AI model development (i.e., training, tuning (validation), and internal testing), which was intended to create a documented baseline of the AI model, clinical verification testing and clinical design validation were performed to evaluate its clinical performance. Data used for model development was collected from the Clarius Cloud and/or partner clinics and was partitioned by unique anonymous patient identifiers to ensure there was no data overlap between the training, internal testing, and clinical verification datasets.

As part of the truthing process, Clarius only included data from the institutions/clinical sites that were not represented in the data used for algorithmic development of the Clarius Median Nerve AI model (i.e., training, tuning, and internal testing data) to prevent data leakage. The exclusion criteria used were that images of inadequate quality were not added to the sample size (non-diagnostic images with artifacts obstructing specific anatomy) and images with incomplete anatomy and views. In measurement comparisons, Clarius excluded the subjects where the Median Nerve AI model failed to generate a measurement since there was no value to compare. To aggregate measurements from different truthers, the mean of the three values was taken and was treated as one reviewer mean. No clinical information was provided to the clinicians regarding patients utilized in the clinical truthing process. The clinicians only had access to the ultrasound image for identifying the anatomy, segmenting the median nerve, and performing measurements by placing the calipers. The lighting and monitor size/resolution were operator-dependent using their clinical judgement. The truthing process was not based on any follow-up medical examination.

The clinical performance of Clarius Median Nerve AI was evaluated through a retrospective analysis of anonymized ultrasound images obtained from multiple clinical sites predominantly from the United States, representing different ethnic groups, genders, and ages. The clinical verification data to evaluate the clinical performance of Clarius Median Nerve AI was entirely independent from the training, tuning (validation) and internal testing datasets used in the development of the AI model.

The Clarius Median Nerve AI Deep Neural Network (DNN) model was developed and trained using three data sets: training, tuning, and internal testing. The DNN parameters and weights were updated on the training data and evaluated on the validation (tuning) data at each epoch. Once the AI model was fully trained, its generalizability was tested by evaluating it on the internal testing dataset (internal testing prior to clinical (external) verification). The internal test data was fully independent of the training/tuning dataset and was labelled by experts. Then, following internal testing, a single model was selected, and a completely separate test dataset was used for performance testing of the AI model (clinical verification). This verification dataset was independent of the training/tuning, and internal testing datasets, in order to ensure robust results.

The objective of clinical performance testing was to verify that Clarius Median Nerve AI auto-measurements are non-inferior to manual measurements performed by qualified experts with relevant (i.e., musculoskeletal) ultrasound experience.

Summary of the Clinical Verification Study

Ultrasound images were randomly obtained from an anonymized multi-center database of images from the United States, Canada, Brazil, United Kingdom, Australia, Belgium, Germany, South Africa, Dominican Republic, Poland, The Netherlands, and Philippines, representing various ethnicities, genders, and ages of the subjects. The verification study was conducted using de-identified ultrasound data previously collected and stored on a cloud platform. No clinical or sociodemographic information—such as age, gender, or clinical diagnosis—was available or accessible at any point during the study. This data was fully anonymized prior to Clarius’ access and use, in accordance with applicable privacy laws and ethical guidelines. Institutions included in the Clarius Median Nerve AI model development (i.e., training, tuning, and internal testing datasets) were excluded from this study. Images of the median nerve were collected and the total sample size included in the study was 182 images collected from 126 subjects, with the majority representing patients from the United States. The images collected were cross sectional (transverse view) images on the median nerve at the level of the forearm and wrist. Some subjects had images collected at both levels (forearm and wrist), which accounts for the 182 images collected from 126 subjects. The geographic distribution of data collected is shown in Table 1:

<b>Table 1: Geographic Data</b>	
<b>Location</b>	<b>Number of Images</b>
United States	130
Brazil	13
Canada	10
Australia	9
Belgium	4
unknown	4
Germany	3
United Kingdom	3
South Africa	2
Dominican Republic	1
Philippines	1
Poland	1
The Netherlands	1
<b>Total</b>	<b>182</b>

The primary objective of the retrospective verification study was to determine whether Clarius Median Nerve AI measurements are non-inferior to those obtained manually by human experts/qualified ultrasound users (if the magnitude of the difference (the absolute difference/error) between Clarius Median Nerve AI and mean reviewer (human expert) measurements is greater than the magnitude of the mean difference (mean absolute difference/error) between the reviewers themselves). The secondary objective was to determine the correlation between Clarius Median Nerve AI segmentation and those of human experts, whether it can accurately identify the median nerve in transverse view at the level of the wrist or mid forearm.

Each reviewer was blinded to the Clarius Median Nerve AI output and the other reviewers' annotations as well. All ultrasound exams were captured using Clarius' 510(k)-cleared linear-array ultrasound scanners.

An assessment of the magnitude of the difference between Clarius Median Nerve AI and human experts' median nerve cross-sectional area (CSA) measurements was performed to ascertain whether Clarius Median Nerve AI measurement is non-inferior to those of human experts/ qualified ultrasound users.

The absolute difference between reviewer pairs was calculated and compared to the absolute difference between the Clarius Median Nerve AI measurement and mean reviewer measurement using a one-sided t-test and an equivalence/error margin of 3 mm<sup>2</sup>. The automatic median nerve CSA measurement was found to be non-inferior (p value of 6.497e-47 (97.5% CI: -inf, 0.3285)). The mean difference between the differences among human experts and Clarius Median Nerve AI was -0.065 mm<sup>2</sup>. The Intraclass Correlation Coefficient (ICC) of the Clarius Median Nerve AI versus the Mean of Reviewers cross sectional area is 0.81 (95% CI: 0.74, 0.87).

The non-inferiority performance testing summary is shown in Table 2:

<b>Table 2: Non-Inferiority Test Result Summary for Clinical Performance of Clarius Median Nerve AI</b>			
	<b>p-value</b>	<b>Equivalence Margin</b>	<b>Mean Difference</b>
<b>Clarius Median Nerve AI vs Human Experts</b>	6.497e-47 (97.5% CI: -inf, 0.3285)	3 mm <sup>2</sup>	-0.065 mm <sup>2</sup>

The Jaccard scores were calculated between the segmentation mask provided by Clarius Median Nerve AI and a trace from the expert reviewers, as well as the reviewers against each other. Table 3 presents the results:

<b>Table 3: Jaccard Scores of Segmentation masks</b>	
<b>Comparison</b>	<b>Jaccard Score</b>
Reviewer 1 vs Clarius Median Nerve AI	0.62 [95%CI: 0.62, 0.68]
Reviewer 2 vs Clarius Median Nerve AI	0.71 [95%CI: 0.69, 0.74]
Reviewer 3 vs Clarius Median Nerve AI	0.68 [95%CI: 0.65, 0.71]
Reviewer 1 vs Reviewer 2	0.76 [95%CI: 0.74, 0.78]
Reviewer 1 vs Reviewer 3	0.72 [95%CI: 0.70, 0.75]
Reviewer 2 vs Reviewer 3	0.77 [95%CI: 0.75, 0.79]

Bland-Altman plots indicated strong agreement between Clarius Median Nerve AI and human expert measurements. The ICC scores for different probe models (i.e., L7 HD3, L15 HD3, L20 HD3) demonstrated reliability.

The results of the clinical verification study (retrospective analysis) evaluating the performance of Clarius Median Nerve AI have demonstrated that Clarius Median Nerve AI's performance is non-inferior to that of experienced ultrasound reviewers/clinicians for measurement of the cross-sectional area of the median nerve, thus meeting the primary objective of the study. Furthermore, the study validated Clarius Median Nerve AI's accuracy in identifying median nerve views.

Therefore, the clinical performance of Clarius Median Nerve AI has been adequately verified for median nerve cross-sectional area measurements and has been determined to be as reliable and accurate as compared to human clinical experts.

Summary of the Clinical Validation Study

A clinical validation study was conducted to evaluate the design and clinical usage of Clarius Median Nerve AI, as it is integrated into the Clarius App software, to determine if it performs as intended in a representative user environment, meets the product requirements, is clinically usable, and meets users’ needs for use in semi-automated measurements of the median nerve cross-sectional area. Testing was performed using production equivalent units in a simulated use environment.

The results of the clinical validation study showed consistent results among all users, meeting the pre-defined acceptance criteria. The users were able to activate Clarius Median Nerve AI using Clarius’ linear-array ultrasound scanners (L7 HD3, L15 HD3, L20 HD3), image the median nerve, perform live segmentation, perform automated measurements of the median nerve, manually adjust the measurements, change the segmentation mask opacity, calculate and display the median nerve cross-sectional area, and save the measurement with each exam.

Therefore, based on the results of the clinical validation study it has been determined that Clarius Median Nerve AI performs as intended and meets user needs for use in semi-automated median nerve measurements in musculoskeletal ultrasound applications.

**Predetermined Change Control Plan (PCCP)**

Clarius Median Nerve AI uses a machine learning (ML) algorithm for measurement of the median nerve cross-sectional area on ultrasound image data acquired by the Clarius Ultrasound Scanner.

Modifications to Clarius Median Nerve AI will be made in accordance with its Predetermined Change Control Plan (PCCP). The PCCP provides a description of the device’s planned modifications, a modification protocol to test, verify, validate, and implement the modifications in a manner that ensures the continued safety and effectiveness of the device, mitigating risks associated with changes to the Median Nerve AI model to not adversely impact the device’s performance, safety, or effectiveness associated with its indications for use, and an impact assessment of the planned modifications.

The modifications outlined in the PCCP are summarized in the table below. In accordance with the PCCP, the modified Clarius Median Nerve AI algorithm will be adequately trained, tuned, tested, and locked before release of the modified Median Nerve AI model. Implemented modifications to the Clarius Median Nerve AI algorithm will be communicated to users via the Clarius App software update notification and through updated labelling.

Summary of planned modifications to Clarius Median Nerve AI per the PCCP:

Modification	Rationale	Testing Methods	Impact Assessment
Modification of training hyperparameters (initial learning rate, width multiplier, dropout rate)	Improvement and optimization of Clarius Median Nerve AI’s performance	Re-training of the Median Nerve AI model with modified hyperparameters to optimize its performance	Improved performance metrics of modified Median Nerve AI model with

Modification	Rationale	Testing Methods	Impact Assessment
		<p>followed by internal testing and a comparison of the original Median Nerve AI model to the modified Median Nerve AI model (using performance metrics) followed with clinical performance testing (verification and validation).</p>	<p>increased accuracy and more robust measurements displayed to users.</p> <p><u>Benefit-Risk Analysis:</u> Benefits: Improved performance; generalization. Risks: Overfitting; unintended bias.</p> <p><u>Risk Mitigation:</u> Proper regularization techniques and cross-validation and dropout will be employed to mitigate overfitting. Internal testing and verification will be conducted to mitigate unintended biases.</p>
<p>Modification of post-processing algorithms (adjustments to measurement validity thresholds)</p>	<p>Improvement and optimization of Clarius Median Nerve AI's performance and robustness</p>	<p>Internal testing and a comparison of the original Median Nerve AI model to the modified Median Nerve AI model (using performance metrics) and clinical performance testing (verification and validation).</p>	<p>Improved performance metrics of modified Median Nerve AI model.</p> <p><u>Benefit-Risk Analysis:</u> Benefits: Improved performance; generalization. Risks: Overfitting; unintended bias.</p> <p><u>Risk Mitigation:</u> Proper regularization techniques and cross-validation and</p>

Modification	Rationale	Testing Methods	Impact Assessment
			<p>dropout will be employed to mitigate overfitting. Internal testing and verification will be conducted to mitigate unintended biases.</p>
<p>Modification of data input sources (Clarius probes)</p>	<p>To add data from current Clarius scanners and future 510(k) cleared scanners to the Clarius Median Nerve AI model so the model can be deployed on more scanners.</p>	<p>Re-training of the Median Nerve AI model to expand its use with additional data input sources (i.e., 510(k)-cleared models of the Clarius Ultrasound Scanner), internal testing, and clinical performance testing (verification and validation) to assesses its performance with the new data input sources.</p>	<p>By accommodating a wider array of image geometries and characteristics with the use of new 510(k)-cleared Clarius ultrasound scanners, the updated Median Nerve AI model will be better equipped to handle different transducer models of the Clarius Ultrasound Scanner used in varying clinical scenarios.</p> <p><u>Benefit-Risk Analysis:</u>            Benefits: Enhanced compatibility;            Flexibility for diverse clinical settings.            Risks: Data skewing and concept drift.</p> <p><u>Risk Mitigation:</u>            Internal testing and verification datasets within the intended patient population will ensure that data skewing and concept drift are mitigated.</p>

### **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/machine learning algorithms, technological characteristics, principle of operation, intended use, intended patient population, and environment of use, Clarius Median Nerve AI has been determined to be substantially equivalent in terms of safety and effectiveness to the legally marketed predicate device, Clarius AI.

The subject device and the predicate device employ radiological (ultrasound) image processing software applications which implement artificial intelligence/machine learning algorithms trained with clinical and/or artificial data intended for analysis of ultrasound data acquired by the Clarius Ultrasound Scanner, utilizing very similar machine-learning algorithms for detection, segmentation, and measurement of musculoskeletal structures.

Performance testing of Clarius Median Nerve AI, including the results from clinical verification and validation studies, has demonstrated that Clarius Median Nerve AI measurement output adequately aligns with expert clinicians' manual measurements, and thereby performs as intended for use in semi-automated median nerve measurements.

Any differences in the indications for use or technological characteristics between the subject device and the legally marketed predicate device do not raise any issues related to safety or effectiveness. Therefore, Clarius Median Nerve AI is as safe and effective as the predicate device, Clarius AI (K222406), and therefore substantially equivalent.