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

April 16, 2025

Re: K243853
Trade/Device Name: Clarius Prostate AI
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: March 16, 2025
Received: March 17, 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) 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243853

Device Name

Clarius Prostate AI

Indications for Use *(Describe)*

Clarius Prostate AI is intended for semi-automatic measurements of prostate volume on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., curvilinear and endo-cavitary 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 Prostate AI is intended for use in adult male 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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clarius ultrasound anywhere

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 Prostate 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: April 11, 2025

Predicate Device Information:

Device Trade Name:	Clarius Bladder AI
510(k) Reference:	K232257
Manufacturer Name:	Clarius Mobile Health Corp.
Regulation Name:	Medical Image Management and Processing System
Device Classification Name:	Automated Radiological Image Processing Software
Primary Product Code:	QIH
Regulation Number:	21 CFR § 892.2050
Regulatory Class:	Class II

Reference Device Information:

Device Trade Name:	AI-Rad Companion Prostate MR
510(k) Reference:	K193283
Manufacturer Name:	Siemens Medical Solutions USA Inc.
Regulation Name:	Medical Image Management and Processing System

Device Classification Name:	Automated Radiological Image Processing Software
Primary Product Code:	QIH
Regulation Number:	21 CFR § 892.2050;
Regulatory Class:	Class II

Note: The predicate and reference devices have not been subject to a design-related recall.

Device Description

Clarius Prostate AI is a machine learning algorithm that is integrated into the Clarius App software as part of the comprehensive Clarius Ultrasound Scanner system for use in prostate ultrasound imaging applications. Clarius Prostate AI is intended for use by trained healthcare practitioners for measurement of prostate volume on ultrasound data acquired by the Clarius Ultrasound Scanner system (i.e., curvilinear and endo-cavitary 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., Prostate) from the Clarius App in which Clarius Prostate AI will engage to segment the prostate gland and place calipers for measurement of prostate volume.

Clarius Prostate AI operates by performing the following tasks:

- Automatic detection and measurement of prostate length
- Automatic detection and measurement of prostate width
- Automatic detection and measurement of prostate height
- Automatic detection of the corresponding image view

Clarius Prostate AI operates by performing automatic measurements of prostate height, width, and length, and calculates prostate volume. The user has the option to manually adjust the measurements made by Clarius Prostate AI by moving the caliper crosshairs. Clarius Prostate AI does not perform any functions that could not be accomplished manually by a trained and qualified user. Clarius Prostate AI is intended for use in B-Mode only.

Clarius Prostate 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 Prostate AI is indicated for use in adult male patients only.

Clarius Prostate 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 Prostate AI is not a stand-alone software device.

Clarius Ultrasound Transducers	C3 HD3; EC7 HD3
Clarius App Software	Clarius Ultrasound App (Clarius App) for iOS; Clarius Ultrasound App (Clarius App) for Android

Indications for Use for Clarius Prostate AI

Clarius Prostate AI is intended for semi-automatic measurements of prostate volume on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., curvilinear and endo-cavitary 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 Prostate AI is intended for use in adult male patients only.

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 Prostate AI, to the predicate device and reference device. The comparison of the subject device to the legally marketed devices 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 prostate volume, 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	RATIONALE (if subject device differs from predicate device)
	Clarius Prostate AI	**Clarius Bladder AI**	**AI-Rad Companion Prostate MR**	
510(k) Holder/ Manufacturer	Clarius Mobile Health Corp.	Clarius Mobile Health Corp.	Siemens Medical Solutions USA Inc.	Not applicable
Submission Reference	Current Submission	K232257	K193283	Not applicable
Primary Product Code	QIH	QIH	QIH	Same as predicate device.
Device Classification Name	Automated Radiological Image Processing Software	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	Medical Image Management and Processing System	Same as predicate device.
Regulation Number	21 CFR § 892.2050	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.	Non-invasive processing of MR images using automatic image segmentation and measurement of anatomical structures utilizing artificial intelligence algorithms.	Same as predicate device.
Indications for Use	Clarius Prostate AI is intended for semi-automatic measurements of prostate volume on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., curvilinear and endo-cavitary scanners). The user shall be a healthcare professional trained and qualified in ultrasound. The user retains the responsibility of	Clarius Bladder AI is intended for semi-automatic non-invasive measurements of bladder volume on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., curvilinear and phased array scanners). The user shall be a healthcare professional trained and qualified in ultrasound. The user shall retain the ultimate	AI-Rad Companion Prostate MR is a post-processing image analysis software that assists clinicians in viewing, manipulating, analyzing and evaluating MR prostate images for biopsy support. AI-Rad Companion Prostate MR provides the following functionalities:	Both the predicate and subject device are indicated for semi-automated measurements of ultrasound image data using AI/ML-based technology. Both devices detect the anatomical structure, perform segmentation, perform measurements of the structure, and perform measurement of the

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE	RATIONALE (if subject device differs from predicate device)
	Clarius Prostate AI	Clarius Bladder AI	AI-Rad Companion Prostate MR	
	confirming the validity of the measurements based on standard practices and clinical judgment. Clarius Prostate AI is intended for use in adult male patients only.	responsibility of ascertaining the measurements based on standard practices and clinical judgment.	• Automatic segmentation and quantitative analysis of the prostate gland • Manual annotation of relevant findings • Presentation and export of results for further processing and reporting	structure's volume. Both the predicate and subject devices are intended for use as an adjunctive 'tool' or aid by the user for the interpretation of 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	Magnetic Resonance (MR)	Same as predicate device.
Principle of Operation/ Technology	Ultrasound image processing software application 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 application 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 (MR) image processing software implementing artificial intelligence including non-adaptive machine learning algorithms trained with clinical and/or artificial data intended for automated segmentation of the prostate gland with the possibility of manual adjustment and annotation.	Same as predicate device.
Quantitative and/or Qualitative Analysis	Distance; Prostate Volume	Distance; Bladder Volume	Distance; Prostate Volume	Equivalent to the predicate device. The subject device performs semi-automated measurements of the prostate gland and prostate

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE	RATIONALE (if subject device differs from predicate device)
	Clarius Prostate AI	Clarius Bladder AI	AI-Rad Companion Prostate MR	
				volume, whereas the predicate device performs semi-automated measurements of the bladder and bladder volume.
Segmentation	Yes – Segmentation of anatomical structures (prostate)	Yes – Segmentation of anatomical structures (bladder)	Yes – Segmentation of anatomical structures (prostate)	Equivalent to the predicate device. The only difference is the anatomical structure (prostate gland vs. bladder).
Measurement	Yes – Measurement of anatomical structures (prostate)	Yes – Measurement of anatomical structures (bladder)	Yes – Measurement of anatomical structures (prostate)	Equivalent to the predicate device. The only difference is the anatomical structure (prostate gland vs. bladder).
Algorithm Methodology	Artificial Intelligence (AI)/Machine Learning (ML) Image segmentation for border detection, and prostate view classification using a Deep Neural Network.	Artificial Intelligence (AI)/Machine Learning (ML) Image segmentation for border detection, and bladder view classification using a Deep Neural Network.	Artificial Intelligence (AI)/Machine Learning (ML) Image segmentation of the prostate gland with the possibility of manual adjustment and annotation.	Same as predicate device.
Automation (Yes or No)	Yes	Yes	Yes	Same as predicate device.
Manual adjustment/Manual editing capability (Yes or No)	Yes	Yes	Yes	Same as predicate device.
Environment of Use	Healthcare setting (e.g., hospital, clinic)	Healthcare setting (e.g., hospital, clinic)	Healthcare setting (e.g., hospital, clinic)	Same as predicate device.
Anatomical Site	Prostate gland	Bladder	Prostate gland	Equivalent to predicate device; same as reference device.
Intended Users	Licensed healthcare professionals	Licensed healthcare professionals	Licensed healthcare professionals	Same as predicate device.

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE	RATIONALE (if subject device differs from predicate device)
	Clarius Prostate AI	Clarius Bladder AI	AI-Rad Companion Prostate MR	
Patient Population	Adult males	Adults	Adult males	Equivalent to predicate device; same as reference device.
Operating System Compatibility	iOS and Android	iOS and Android	Cloud-only solution	Same as predicate device.
Platform	Embedded in the Clarius ultrasound app	Embedded in the Clarius ultrasound app	Cloud-based and stand-alone software	The subject device and predicate device are embedded in the ultrasound app, which is part of the ultrasound system, whereas, the reference device is cloud-based, stand-alone software.

Non-Clinical Performance Testing Summary

Clarius Prostate 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 Prostate 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 Prostate 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 Prostate AI:

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

- Software Verification & Validation
- Cybersecurity Analysis

Clarius Prostate 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 completion of the Clarius Prostate AI model training, tuning (validation), and internal testing, which were conducted to create a documented baseline of the AI model, verification testing and clinical validation were performed to evaluate its clinical performance.

The clinical performance of Clarius Prostate AI was evaluated through a retrospective analysis of anonymized ultrasound images obtained from multiple clinical sites in the United States, Canada, Peru, United Kingdom, Germany, Argentina, Jamaica, Barbados, Greece, Bulgaria, and Italy, representing different ethnic groups and ages. The patient data was predominantly from US-based institutions. The clinical verification data to evaluate the clinical performance of Clarius Prostate AI was entirely independent from the training, tuning (validation) and internal testing datasets.

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

The objective of clinical performance testing was to verify that Clarius Prostate AI auto-measurements are non-inferior to manual measurements performed by qualified experts with relevant (i.e., Prostate) 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, Peru, United Kingdom, Germany, Argentina, Jamaica, Barbados, Greece, Bulgaria, and Italy, representing various ethnicities and ages of male subjects. Institutions included in the Clarius Prostate AI model training, tuning, and internal testing datasets were excluded from this study. Images of the prostate gland were collected and the total sample size included in the study was 139 subjects, with the majority representing patients from the United States.

The primary objective of the retrospective verification study was to determine whether Clarius Prostate AI prostate volume measurements are non-inferior to those obtained manually by human experts/qualified ultrasound users (if the magnitude of the difference (the absolute percent error) between Clarius Prostate AI and mean reviewer (human expert) measurements is greater than the magnitude of the mean difference (mean absolute percent error) between the reviewers themselves). The secondary objective was to determine the correlation between Clarius Prostate AI segmentation and those of human experts, whether it can accurately identify transverse and sagittal prostate views.

Each reviewer was blinded to the Clarius Prostate AI output and the other reviewers' annotations as well. All prostate exams were captured using Clarius' curvilinear and endo-cavitary ultrasound scanners.

An assessment of the magnitude of the difference between Clarius Prostate AI and human experts' prostate measurements was performed to ascertain whether Clarius Prostate AI measurement is non-inferior to those of human experts/ qualified ultrasound users.

The absolute percent (%) difference between reviewer pairs was calculated and compared to the absolute percent (%) difference between the Clarius Prostate AI measurement and mean reviewer measurement using a one-sided t-test and an equivalence margin of 22%. The automated prostate volume measurement was found to be non-inferior to human experts with statistically significant results (p-value of 1.146e-5). The mean difference between percent differences of the expert mean, and the Clarius Prostate AI mean was 0.1192 (95% CI 0.0738, 0.1646).

Bland-Altman plots indicated strong agreement between Clarius Prostate AI and expert measurements, with the model showing high accuracy in view prediction (95%). The ICC scores for different probe models (i.e., C3 HD3, EC7 HD3) were 0.87 for endo-cavitary probes and 0.67 for curvilinear probes, highlighting expected variations in performance.

The results of the clinical verification study (retrospective analysis) evaluating the performance of Clarius Prostate AI have demonstrated that Clarius Prostate AI's performance is non-inferior to that of experienced ultrasound reviewers/clinicians for measurement of prostate volume, thus meeting the primary objective of the study. Furthermore, the study validated Clarius Prostate AI's high accuracy in predicting prostate views and provided insight into probe performance differences, thus meeting the secondary objective of the study.

Therefore, the clinical performance of Clarius Prostate AI has been adequately verified for prostate volume 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 Prostate 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 prostate volume measurements. 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 Prostate AI using the C3 HD3 and EC7 HD3 Clarius ultrasound scanners, image the prostate gland, perform live segmentation, perform automated measurements of the prostate, manually adjust the measurements, change the segmentation mask opacity, calculate and display the prostate volume, and save the measurement with each exam.

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

Predetermined Change Control Plan (PCCP)

Clarius Prostate AI uses a machine learning (ML) algorithm for measurement of prostate volume on ultrasound image data acquired by the Clarius Ultrasound Scanner.

Modifications to Clarius Prostate 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 Prostate 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 Prostate AI algorithm will be adequately trained, tuned, tested, and locked before release of the modified Prostate AI model. Implemented modifications to the Clarius Prostate AI algorithm will be communicated to users via the Clarius App software update notification and through updated labelling.

Summary of planned modifications to Clarius Prostate AI per the PCCP:

Modification	Rationale	Testing Methods	Impact Assessment
Modification of data input sources (Clarius probes)	To add data from current Clarius scanners and future 510(K) cleared scanners to the Clarius Prostate AI model so the model can be deployed on more scanners.	Re-training of the Prostate AI model to expand its use with additional data 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.	By accommodating a wider array of image geometries and characteristics with the use of additional 510(k)-cleared Clarius scanners, the updated Prostate AI model will be better equipped to handle different transducer models of the Clarius Ultrasound Scanner used in varying clinical scenarios. Benefit-Risk Analysis: Benefits: Enhanced compatibility; Flexibility for diverse clinical settings. Risks: Data skewing and concept drift. Risk Mitigation: Internal testing and verification datasets

Modification	Rationale	Testing Methods	Impact Assessment
			within the intended patient population will ensure that data skewing and concept drift are mitigated.
Modification to the filter counts	Improvement and optimization of Clarius Prostate AI's performance	Re-training of the Prostate AI model to optimize its performance followed by internal testing and a comparison of the original Prostate AI model to the modified Prostate AI model (using performance metrics) followed with clinical performance testing (verification and validation).	Improved performance metrics of modified Prostate AI model with increased accuracy and more robust prostate volume measurements displayed to users. Benefit-Risk Analysis: Benefits: Improved performance; generalization. Risks: Overfitting; unintended bias. Risk Mitigation: 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.
Modification of model parameter (initial learning rate)	Improvement and optimization of Clarius Prostate AI's performance	Re-training of the Prostate AI model to optimize its performance followed by internal testing and a comparison of the original Prostate AI model to the modified	Improved performance metrics of modified Prostate AI model. Benefit-Risk Analysis:

Modification	Rationale	Testing Methods	Impact Assessment
		Prostate AI model (using performance metrics) and clinical performance testing (verification and validation).	Benefits: Improved performance; generalization. Risks: Overfitting; unintended bias. Risk Mitigation: 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.

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, and environment of use, Clarius Prostate AI has been determined to be substantially equivalent in terms of safety and effectiveness to the legally marketed predicate device.

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 the same machine-learning algorithms for use in ultrasound imaging applications for assessment of anatomical structures and volume measurement of such structures.

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

Any minor differences in the indications for use or technological characteristics between the subject device and the legally marketed device do not raise any issues related to safety or effectiveness. Therefore, Clarius Prostate AI is as safe and effective as the predicate device, Clarius Bladder AI (K232257), and therefore substantially equivalent.