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

Re: K232257

November 13, 2023

Trade/Device Name: Clarius Bladder AI
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: October 20, 2023
Received: October 23, 2023

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.

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).

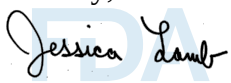
Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless 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.

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, Ph.D.
Assistant Director
Imaging Software Team
DHT 8B: Division of Radiological Imaging
Devices and Electronic Products
OHT 8: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232257

Device Name
Clarius Bladder AI

Indications for Use *(Describe)*
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 responsibility of ascertaining the measurements based on standard practices and clinical judgment. Clarius Bladder 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 Bladder 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: October 20, 2023

Predicate Device Information:

Device Trade Name:	Bladder AI (AIBV01)
510(k) Reference:	K230497
Manufacturer Name:	Exo Inc.
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 Information:

Device Trade Name:	LVivo Software Application (LVivo Bladder)
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

Device Description

Clarius Bladder AI is a radiological (ultrasound) image processing software application which implements artificial intelligence (AI), utilizing 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 bladder ultrasound imaging applications. Clarius Bladder AI is intended for use by trained healthcare practitioners for non-invasive measurements of bladder volume on ultrasound data acquired by the Clarius Ultrasound Scanner system (i.e., curvilinear and phased array scanners) using an artificial intelligence (AI) image segmentation algorithm.

During the ultrasound imaging procedure, the anatomical site (bladder) is selected through a preset software selection (i.e., bladder) within the Clarius App in which Clarius Bladder AI will engage to segment the bladder and place calipers for calculation of bladder volume.

Clarius Bladder AI operates by performing the following automations:

- Automatic detection and measurement of bladder depth
- Automatic detection and measurement of bladder width
- Automatic detection and measurement of bladder height
- Automatic detection of the corresponding image view (sagittal vs. transverse)

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

Clarius Bladder 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 Bladder AI is indicated for use in adult patients only.

Clarius Bladder AI is incorporated 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 Bladder AI is not a stand-alone software device.

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

Indications for Use for Clarius Bladder AI

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 responsibility of ascertaining the measurements based on standard practices and clinical judgment. Clarius Bladder AI is indicated for use in adult 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 Bladder AI, to the predicate device and reference device. A comparison of the subject device to the predicate device and reference 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 automated radiological image processing with segmentation and measurement of bladder volume, comparable to the legally marketed devices referenced herein.

clarius ultrasound anywhere

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 Bladder AI	**Bladder AI (AIBV01)**	**LVivo Software Application (LVivo Bladder)**	
510(k) Holder/ Manufacturer	Clarius Mobile Health Corp.	Exo Inc.	DiA Imaging Analysis Ltd	Not applicable
Submission Reference	Current Submission	K230497	K200232	Not applicable
Product Code(s)	QIH	QIH	QIH	Same as predicate device and reference device
Device Classification Name	Automated Radiological Image Processing Software	Automated Radiological Image Processing Software	Automated Radiological Image Processing Software	Same as predicate device and reference device
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050	Same as predicate device and reference 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 and reference device
Intended Use	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 ultrasound images using automatic image segmentation and measurement of anatomical structures utilizing artificial intelligence/machine learning algorithms.	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 and reference device
Indications for Use	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	Bladder AI uses machine-learning techniques to aid in the quantification of bladder volume from ultrasound images. The device is intended to be used on images of patients aged two years or older.	LVivo platform is intended for non-invasive processing of ultrasound images to detect, measure, and calculate relevant medical parameters of structures and function of patients with suspected disease.	The Clarius Bladder AI indications for use are very similar to the predicate device's indications for use as both devices are indicated for measurement of bladder volume from ultrasound image data.

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE	RATIONALE (if subject device differs from predicate device)
	Clarius Bladder AI	Bladder AI (AIBV01)	LVivo Software Application (LVivo Bladder)	
	shall be a healthcare professional trained and qualified in ultrasound. The user shall retain the ultimate responsibility of ascertaining the measurements based on standard practices and clinical judgment.			
Radiological application/ Supported modality	Ultrasound	Ultrasound	Ultrasound	Same as predicate device and reference device
Compatible Scanner Frequency	C3: 2 to 6 MHz PA: 1 to 5 MHz	1.3 to 9 MHz	Not available	The subject device's compatible scanner frequency falls within the range of the predicate device's compatible scanner frequency
Principle of Operation/ Technology	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.	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.	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.	Same as predicate device and reference device

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE	RATIONALE (if subject device differs from predicate device)
	Clarius Bladder AI	Bladder AI (AIBV01)	LVivo Software Application (LVivo Bladder)	
Segmentation	Yes – Segmentation of anatomical structures (bladder)	Yes – Segmentation of anatomical structures (bladder)	Yes – Segmentation of anatomical structures (bladder)	Same as predicate device and reference device
Measurement	Yes – Measurement of anatomical structures (bladder)	Yes – Measurement of anatomical structures (bladder)	Yes – Measurement of anatomical structures (bladder)	Same as predicate device and reference device
Frame	Transverse and Sagittal	Transverse and Sagittal	Transverse and Sagittal	Same as predicate device and reference device
Quantitative Analysis	Distance, Bladder Volume	Distance, Bladder Volume	Distance, Bladder Volume	Same as predicate device and reference device
AI/ML Algorithm	Image segmentation for border detection, and bladder view classification using a Deep Neural Network.	Image segmentation for border detection.	Image segmentation for border detection using machine learning and active contour.	Similar to predicate device and reference device
Automation (Yes or No)	Yes	Yes	Yes	Same as predicate device and reference device
Display Calipers	Yes	Yes	Yes	Same as predicate device and reference device
Manual adjustment/ Manual editing by user capability (Yes or No)	Yes	Yes	Yes	Same as predicate device and reference device
Operating System	iOS and Android	Web browser (Google Chrome)	Web browser (Google Chrome) and Android	Similar to predicate device
Anatomical Site	Bladder	Bladder	Bladder	Same as predicate device and reference 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 and reference device
Intended Users	Licensed healthcare professionals	Licensed healthcare professionals	Licensed healthcare professionals	Same as predicate device and reference device

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE	RATIONALE (if subject device differs from predicate device)
	Clarius Bladder AI	Bladder AI (AIBV01)	LVivo Software Application (LVivo Bladder)	
Patient Population	Adults	Adults and pediatrics (2 years and older)	Adults	Similar to the predicate device and same as the reference device.

clarius ultrasound anywhere

Non-Clinical Performance Testing Summary

Clarius Bladder 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 Bladder 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 Bladder AI has been evaluated through verification and validation testing in accordance with applicable specifications 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 *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices* (issued October 2, 2014).

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 Bladder AI was tested and found to be safe and effective for the intended users, intended use, intended patient population, 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

Following completion of the Clarius Bladder AI model training and tuning, which was conducted to create a documented baseline of the AI model, verification testing and clinical validation were performed.

The clinical performance of Clarius Bladder AI was evaluated through a retrospective analysis of anonymized ultrasound images and also through a prospective study. The verification data was entirely independent from the training, validation (tuning), and test datasets.

The Clarius Bladder AI deep neural network (DNN) model was trained using three data sets: training, validation (tuning), and testing. The validation (tuning) data was 10% of the training data, while the test data was independent and labelled by experts. The DNN parameters and weights were updated based on the validation (tuning) data at each epoch. The model's generalizability was evaluated on the test data. The test data was exclusive and independent to ensure robust results.

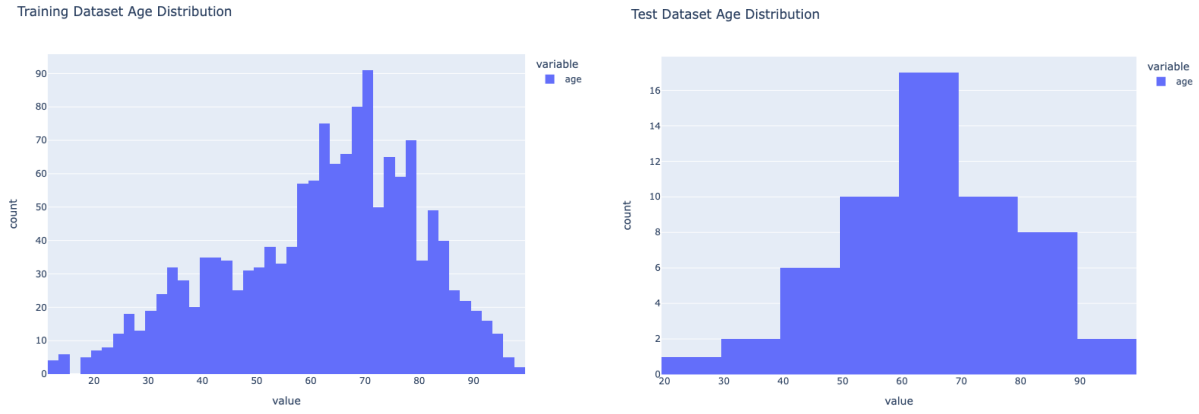
The objective of clinical performance testing (verification) was to verify that Clarius Bladder AI auto-measurements are non-inferior to manual measurements performed by qualified experts with relevant (i.e., bladder) ultrasound experience.

Demographic Distribution of the Datasets

Gender distribution of the subjects included in the training and test datasets are shown below.

Subject Gender	Training Dataset Number of Subjects	Test Dataset Number of Subjects
Female	353	12
Male	999	43

Age distribution of the subjects included in the training and test datasets are shown below.



Summary of the Retrospective Verification Study

Ultrasound images were randomly obtained from an anonymized multi-center database of images from predominantly the United States. Institutions included in the Bladder AI model training and tuning dataset were excluded from this study. For each subject, images of the bladder in sagittal and transverse views were included. The total sample size included in the study was 66 subjects; of the subjects, 10 were

female, 38 were male, and the gender of the remaining was unknown. The age of the subjects ranged from 31 – 92 years. The ethnicities of the subjects were unknown.

The purpose of the retrospective study was to verify that the Clarius Bladder AI is non-inferior to manual measurement by the expert clinician. Each exam had bladder volume measurements performed by 3 reviewers (clinical truthers). Each reviewer was blinded to the Clarius Bladder AI output and the other reviewers' annotations as well. The ground truth used as the reference data for bladder volume was obtained as the mean bladder volume measurement among three clinical experts.

Each reviewer measured the bladder volume manually using 2 views (sagittal and transverse). The length, width and height of the bladder were measured, and the volume was calculated. Clarius Bladder AI was then used to measure the same images. All exams of the bladder were captured using a Clarius C3, C7 (curvilinear) or PA (phased array) ultrasound scanner.

An assessment of the magnitude of the difference between Clarius Bladder AI and human experts' bladder volume measurements was performed to ascertain whether Bladder 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 Bladder AI measurement and mean reviewer measurement using a one-sided t-test and an equivalence margin of 25% (i.e., the mean difference between differences should be no greater than 25% of the measured bladder volume). The automatic bladder volume measurement was found to be non-inferior (p value of 1.87e-22). The mean difference between percent differences of the clinical expert mean, and Bladder AI mean was 0.0548 (95% CI 0.010, 0.099).

Strong agreement was shown between the Clarius Bladder AI measurements and the mean of the expert clinicians' measurements. The Clarius Bladder AI model also showed strong agreements with individual expert measurements. The intraclass correlation coefficients (ICC) for inter-rater reliability were calculated between reviewer pairs and between the Clarius Bladder AI output and the mean reviewer measurement. The average dice scores and Jaccard index between the Clarius Bladder AI model vs. each reviewer and between each reviewer pair were also calculated.

The difference between auto-measurements and mean manual measurements was found to be no greater than the mean difference between manual reviewer measurements within the clinically significant margin and with a statistical significance level of 0.05.

The results of the retrospective analysis have demonstrated that Clarius Bladder AI measurement output adequately aligns with expert clinicians' manual measurement, confirming that Clarius Bladder AI measurements are non-inferior to those of human clinical experts. Therefore, the performance of Clarius Bladder AI has been verified for bladder volume measurement for use in bladder ultrasound applications and has been determined as reliable and accurate compared to clinical experts.

<u>Summary of the Prospective Verification Study</u>

The prospective study was performed at a healthcare institution in the United States. Only adult subjects were included in the study. For each subject, images of the bladder in sagittal and transverse views were obtained. The total sample size included in the study was 58 subjects of White, Black, Asian, and Hispanic

ethnicities; of the subjects, 40 were female and 18 were male. The age of the subjects ranged from 21 - 61 years.

The purpose of the prospective study was to verify that the Clarius Bladder AI is non-inferior to manual measurement by the expert clinician. Each exam had bladder volume measurements performed by 3 reviewers (clinical truthers). The length, width and height of the bladder were measured, and the volume was calculated. The reviewers were qualified experts with clinical experience in bladder ultrasound. Clarius Bladder AI was then used to measure the same images. All exams of the bladder were captured using a Clarius C3 (curvilinear) or a PA (phased array) ultrasound scanner. The subjects' demographic information was also collected (age, gender, height and weight). The ground truth used as the reference data for bladder volume was obtained as the mean bladder volume measurement among three clinical experts. An assessment of the magnitude of the difference between Clarius Bladder AI and human experts' bladder volume measurements was performed to ascertain whether Bladder 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 Bladder AI measurement and mean reviewer measurement using a one-sided t-test and an equivalence margin of 25% (i.e., the mean difference between differences should be no greater than 25% of the measured bladder volume). The automatic bladder volume measurement was found to be non-inferior (p value of 1.36e-14). The mean difference between percent differences of the clinical expert mean, and Bladder AI mean was -0.0228 (95% CI –0.074, 0.028).

Strong agreement was shown between the Clarius Bladder AI measurements and the mean of the expert clinicians' measurements. The Clarius Bladder AI model also showed strong agreements with individual expert measurements. The intraclass correlation coefficients (ICC) for inter-rater reliability were calculated between reviewer pairs and between the Clarius Bladder AI output and the mean reviewer measurement. The average dice scores and Jaccard index between the Clarius Bladder AI model vs. each reviewer and between each reviewer pair were also calculated.

The difference between auto-measurements and mean manual measurements was found to be no greater than the mean difference between manual reviewer measurements within the clinically significant margin and with a statistical significance level of 0.05.

The results of the prospective study have demonstrated that Clarius Bladder AI measurement output adequately aligns with expert clinicians' manual measurement, confirming that Clarius Bladder AI measurements are non-inferior to those of human clinical experts. The algorithm's performance was shown to be consistent among the various patient demographics including age, gender, and BMI.
Therefore, the performance of Clarius Bladder AI has been verified for bladder volume measurement for use in bladder ultrasound applications and has been determined as reliable and accurate compared to clinical experts.

Summary of the Clinical Validation Study

A clinical validation study was conducted to evaluate the design and clinical utility of Clarius Bladder AI, as incorporated into the Clarius App software, to determine if the device performs as intended in a representative user environment, meets the product requirements, is clinically usable, and meets users' needs for use in semi-automated bladder volume measurements.

The results of the validation study showed consistent results among all users, meeting the pre-defined acceptance criteria. The users were able to activate Bladder AI using both scanners (C3 and PA), image the bladder, perform live segmentation using Clarius Bladder AI, perform automatic measurements of bladder height, width, and length, measure bladder volume, manually adjust the measurements, change the segmentation mask opacity, and save the bladder measurement with each exam.

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

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, environment of use, and indications for use, Clarius Bladder 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 are both radiological (ultrasound) image processing software applications which implement artificial intelligence/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.

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

Any minor differences in the indications for use between the subject device and the predicate device do not raise any issues related to safety or effectiveness. Therefore, Clarius Bladder AI is as safe and effective as the predicate device, Bladder AI (AIBV01) (K230497), and therefore substantially equivalent.