



March 2, 2026

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

Re: K253593

Trade/Device Name: Clarius Ejection Fraction AI
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: January 30, 2026
Received: January 30, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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,

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

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and
Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K253593

Device Name

Clarius Ejection Fraction AI

Indications for Use (Describe)

Clarius Ejection Fraction AI is intended for semi-automatic non-invasive measurement of the left ventricular ejection fraction on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., phased array and curvilinear 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 Ejection Fraction AI is intended 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 Ejection Fraction 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: February 28, 2026

Predicate Device Information:

Device Trade Name:	Caption Interpretation Automated Ejection Fraction Software
510(k) Reference:	K210747
Manufacturer Name:	Caption Health, 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 device has not been subject to a design-related recall.

Device Description

Clarius Ejection Fraction 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 cardiac ultrasound applications, specifically intended for use by trained healthcare practitioners for semi-automatic real-time

measurement of the left ventricular (LV) ejection fraction (EF) on ultrasound image data acquired by the Clarius Ultrasound Scanner system (i.e., phased array and curvilinear 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., Cardiac Basic, Cardiac Advanced) from the Clarius App in which Clarius Ejection Fraction AI will engage when enabled by the user to place a segmentation mask or landmark markers on the ultrasound image to identify the left ventricle (LV) in both End Diastolic (ED) and End Systolic (ES) phases. Using the segmentation volume or landmark markers in both phases, Clarius Ejection Fraction AI will calculate the EF of the cardiac images obtained in Parasternal Long Axis (PLAX), Parasternal Short Axis (PSAX), and Apical (AP4, AP2) views.

Clarius Ejection Fraction AI operates by performing the following tasks:

- Automatic capture of the ED and ES frames used to create the EF measurement
- Automatic calculations and measurements for the left ventricular ejection fraction.

The user has the option to manually adjust the measurements made by Clarius Ejection Fraction AI by moving the caliper crosshairs. Clarius Ejection Fraction AI does not perform any functions that could not be accomplished manually by a trained and qualified user.

Clarius Ejection Fraction 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 Ejection Fraction AI is indicated for use only in adult patients.

Clarius Ejection Fraction 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 and K232704). Clarius Ejection Fraction AI is not a stand-alone software device.

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

Indications for Use for Clarius Ejection Fraction AI

Clarius Ejection Fraction AI is intended for semi-automatic non-invasive measurement of the left ventricular ejection fraction on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., phased array and curvilinear 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 Ejection Fraction 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 Ejection Fraction AI, to the predicate device, Caption Interpretation Automated Ejection Fraction Software. 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 for measurement of left ventricular ejection fraction, 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)
Device Trade Name	Clarius Ejection Fraction AI	Caption Interpretation Automated Ejection Fraction Software	
510(k) Holder/ Manufacturer	Clarius Mobile Health Corp.	Caption Health, Inc.	Not applicable
Submission Reference	Current Submission	K210747	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 utilizing an artificial intelligence/machine learning-based algorithm for semi-automated measurement of cardiac ultrasound images for determination of left ventricular ejection fraction.	Intended for use as an assistive tool utilizing an artificial intelligence/machine learning-based algorithm for semi-automated measurement of cardiac ultrasound images for determination of left ventricular ejection fraction.	Same as predicate device.
Indications for Use	Clarius Ejection Fraction AI is intended for semi-automatic non-invasive measurement of the left ventricular ejection fraction on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., phased array and curvilinear scanners). The user shall be a healthcare professional trained and qualified in ultrasound. The user retains the responsibility of confirming the validity of the	The Caption Interpretation Automated Ejection Fraction software is used to process previously acquired transthoracic cardiac ultrasound images, to store images, and to manipulate and make measurements on images using an ultrasound device, personal computer, or a compatible DICOM-compliant PACS system in order to provide automated estimation of left ventricular	Equivalent to the predicate device. Both the subject device and the predicate device are indicated for automated/semi-automated measurement of the left ventricular ejection fraction on ultrasound data acquired using ultrasound devices. Both devices are intended for use as assistive “tools” to aid the clinician in performing cardiac assessments. The minor differences in the indications for use between the subject device and the predicate

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	RATIONALE (if subject device differs from predicate device)
Device Trade Name	Clarius Ejection Fraction AI	Caption Interpretation Automated Ejection Fraction Software	
	measurements based on standard practices and clinical judgment. Clarius Ejection Fraction AI is intended for use in adult patients only.	ejection fraction. This measurement can be used to assist the clinician in a cardiac evaluation. The Caption Interpretation Automated Ejection Fraction Software is indicated for use in adult patients.	device 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 measurements of cardiac ultrasound data.	Ultrasound image processing software implementing artificial intelligence utilizing non-adaptive machine learning algorithms trained with clinical and/or artificial data intended for measurements of cardiac ultrasound data.	Same as predicate device.
Quantitative and/or Qualitative Analysis	LV EF measurement	LV EF measurement	Same as predicate device.
Segmentation	Yes – Segmentation of anatomical structures (cardiac anatomy/ heart)	Yes – Segmentation of anatomical structures (cardiac anatomy/ heart)	Same as predicate device.
Measurement	Yes – Measurement of LV ejection fraction	Yes – Measurement of LV ejection fraction	Same as predicate device.
Algorithm Methodology	Artificial Intelligence (AI)/Machine Learning (ML)	Artificial Intelligence (AI)/Machine Learning (ML)	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.

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	RATIONALE (if subject device differs from predicate device)
Device Trade Name	Clarius Ejection Fraction AI	Caption Interpretation Automated Ejection Fraction Software	
Environment of Use	Professional healthcare setting (e.g., hospital, clinic)	Professional healthcare setting (e.g., hospital, clinic)	Same as predicate device.
Anatomical Site	Heart	Heart	Same as predicate device.
Intended Users	Licensed healthcare professionals	Licensed healthcare professionals	Same as predicate device.
Patient Population	Adults	Adults	Same as reference device.

Non-Clinical Performance Testing Summary

Clarius Ejection Fraction 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 Ejection Fraction 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
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 Ejection Fraction 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 Ejection Fraction AI:

- Risk Analysis
- Design Reviews
- Integration Testing
- System Testing
- Performance Testing
- Usability Engineering
- Software Verification & Validation

- Cybersecurity Analysis

Clarius Ejection Fraction 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 Ejection Fraction AI model algorithmic 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 Ejection Fraction 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 Ejection Fraction 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 cardiac anatomy, segmenting the left ventricle, and performing measurements. 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 Ejection Fraction 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 Ejection Fraction AI was entirely independent from the training, tuning (validation) and internal testing datasets used in the development of the AI model.

The Clarius Ejection Fraction 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.

Summary of the Clinical Verification Study

Ultrasound images were randomly obtained from an anonymized multi-center database of images from the United States, Canada, Germany, Turkey, United Kingdom, Philippines, Australia, Italy, Sweden,

Mexico, Belgium, Singapore, El Salvador, Lithuania, Norway, Venezuela, Malaysia, Switzerland, South Africa, Indonesia, Greece, Nigeria, New Zealand, Austria, Morocco, Iraq, South Korea, Jamaica, Israel, Taiwan, The Netherlands, Dominican Republic, Uganda, Ireland, Bahrain, and Vatican, 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 Ejection Fraction AI model development (i.e., training, tuning, and internal testing datasets) were excluded from this study. Images of the cardiac anatomy were collected and the total sample size included in the study was 279 exams, with the majority representing patients from the United States. The geographic distribution of data collected is shown in Table 1:

Table 1: Geographic Data	
Location	Number of Images
United States	72
Canada	44
Germany	22
Unknown	21
Turkey	18
United Kingdom	10
Philippines	9
Australia	8
Italy	7
Sweden	7
Mexico	6
Belgium	5
Singapore	5
El Salvador	4
Lithuania	4
Norway	3
Venezuela	3
Malaysia	2
Switzerland	2
South Africa	2
Indonesia	2
Greece	2
Nigeria	2
New Zealand	2
Austria	2
Morocco	2
Iraq	2
South Korea	1

Jamaica	1
Israel	1
Taiwan	1
The Netherlands	2
Dominican Republic	1
Uganda	1
Ireland	1
Bahrain	1
Vatican	1
Total	279

The primary objective of the retrospective verification study was to determine whether Clarius Ejection Fraction AI measurements are non-inferior to those obtained manually by human experts/qualified ultrasound users by determining if the magnitude of the mean absolute difference between Clarius Ejection Fraction AI and mean reviewer measurements is greater than the magnitude of the mean absolute difference among reviewers themselves. The significance level was set to 0.025, and the equivalence margin was set at 10% (0.10). The secondary objective was to determine the correlation between Clarius Ejection Fraction AI predictions and those of human experts among the different Clarius scanner models (i.e., C3 HD3, PA HD3).

Each reviewer was blinded to the Clarius Ejection Fraction AI output and the other reviewers' annotations. All ultrasound exams were captured using Clarius' 510(k)-cleared curvilinear and phased array ultrasound scanners.

An assessment of the magnitude of the difference between Clarius Ejection Fraction AI and human experts' ejection fraction measurement data was performed to ascertain whether Clarius Ejection Fraction AI measurement is non-inferior to those of human experts/ qualified ultrasound users.

The mean absolute difference between reviewer pairs was calculated and compared to the mean absolute difference between the Clarius Ejection Fraction AI measurement and mean reviewer measurement using a one-sided t-test and an equivalence/error margin of 10%. The automatic LV EF measurement was found to be non-inferior to that of experienced ultrasound users as shown by statistically significant p-values of 5.57e-21 (97.5%CI: -inf, -3.00), 1.57e-36 (97.5%CI: -inf, -2.1) and 1.12e-18 (97.5%CI: -inf, -2.38) for the Apical, PSAX and PLAX views respectively.

The automatic EF measurement was found to be non-inferior with statistically significant p-values for the various views/measurement methods. The non-inferiority performance testing summary is shown in Table 2:

Table 2: Non-Inferiority (T-Test) Result Summary for Clinical Performance of Clarius Ejection Fraction AI					
EF measurement method	Scanning view	p-value	t-value	Equivalence Margin	Mean Difference
Simpsons single plane	Apical	5.57e-21 (97.5%CI: -inf, -3.00)	-11	10	-6.27

Fractional Area Change	PSAX	1.57e-36 (97.5%CI: - inf, - 2.18)	-18	10	-3.87
Teicholz method	PLAX	1.12e-18 (97.5%CI: - inf, -2.38)	-10	10	-5.92

The Intraclass Correlation Coefficient (ICC) was calculated to show reliability among reviewers and Clarius EF AI for the various views/measurement methods, as shown in Table 3 below:

Table 3: ICC values of Reviewers and Clarius Ejection Fraction AI		
Comparison Pair	ICC	95% CI
Reviewer1 vs. Reviewer2	0.67	[0.59 0.74]
Reviewer1 vs. Reviewer3	0.64	[0.53 0.71]
Reviewer2 vs. Reviewer3	0.54	[0.41 0.64]
AI_EF vs. Mean_Reviewers	0.78	[0.71 0.83]

The results of the clinical verification study (retrospective analysis) evaluating the performance of Clarius Ejection Fraction AI have demonstrated that Clarius Ejection Fraction AI's performance is non-inferior to that of experienced ultrasound reviewers/clinicians for measurement of the left ventricular ejection fraction, thus meeting the primary objective of the study. Furthermore, the study validated that there is moderate to good correlation between human experts and Clarius EF AI across different Clarius scanners (C3 HD3 and PA HD3).

Therefore, the clinical performance of Clarius Ejection Fraction AI has been adequately verified for automated left ventricular ejection fraction 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 Ejection Fraction 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 left ventricular ejection fraction. 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 Ejection Fraction AI using Clarius' curvilinear and phased array ultrasound scanners (i.e., C3 HD3, PA HD3), image the cardiac anatomy to identify the left ventricle, perform live segmentation with the segmentation mask or landmark markers, perform automated measurements of the ejection fraction of the cardiac images obtained in PLAX, PSAX, and/or Apical (AP2 and/or AP4) chamber views, visualize the ES and ED frames that the AI uses in calculating the EF, manually adjust the measurements, change the segmentation mask opacity, and display and save the LV EF measurement with each exam.

Therefore, based on the results of the clinical validation study it has been determined that Clarius Ejection Fraction AI performs as intended and meets user needs for use in semi-automated left ventricular ejection fraction measurements in cardiac ultrasound applications.

Predetermined Change Control Plan (PCCP)

Clarius Ejection Fraction AI uses a machine learning (ML) algorithm for automated measurement of the left ventricular ejection fraction on ultrasound image data acquired by the Clarius Ultrasound Scanner.

Modifications to Clarius Ejection Fraction 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, while mitigating any risks associated with changes to the Ejection Fraction 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 Ejection Fraction AI model will be adequately trained, tuned, tested, and validated before release of the modified Ejection Fraction AI model. Implemented modifications to the Clarius Ejection Fraction AI algorithm will be communicated to users via the Clarius App software update notification and through updated labelling.

Summary of planned modifications to Clarius Ejection Fraction AI per the PCCP:

Modification	Rationale	Testing Methods	Impact Assessment
Modification of data input sources (Clarius ultrasound scanners)	To add data from current Clarius scanners and future 510(k) cleared Clarius scanners to the Clarius Ejection Fraction AI model so the model can be deployed on more scanners.	Internal testing, clinical design validation and usability validation to assess the model's performance and ensure it performs as intended to meet users' needs.	By accommodating a wider array of image geometries and characteristics with the use of new 510(k)-cleared Clarius ultrasound scanners, the updated Ejection Fraction AI model will be better equipped to handle different transducer models of the Clarius Ultrasound Scanner used in varying clinical scenarios. <u>Benefit-Risk Analysis:</u> Benefits: Enhanced compatibility; Flexibility for diverse clinical settings. Risks: Data skewing and concept drift.

Modification	Rationale	Testing Methods	Impact Assessment
			<u>Risk Mitigation:</u> Internal testing to ensure that data skewing and concept drift are mitigated.
Modification of training hyperparameters (initial learning rate, width multiplier, dropout rate)	Improvement and optimization of Clarius Ejection Fraction AI's performance	Re-training of the Ejection Fraction AI model with modified hyperparameters to optimize its performance followed by internal testing and a comparison of the original Ejection Fraction AI model to the modified Ejection Fraction AI model (using performance metrics) followed with clinical performance testing (verification and validation).	Improved performance metrics of modified Ejection Fraction AI model with increased accuracy and more robust measurements displayed to users. <u>Benefit-Risk Analysis:</u> Benefits: Improved performance; generalization. Risks: Overfitting; unintended bias. <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.
Modification of post-processing steps	Improvement and optimization of Clarius Ejection Fraction AI's performance and robustness	Internal testing and a comparison of the original Ejection Fraction AI model to the modified Ejection Fraction AI model (using performance metrics) and clinical performance	Improved performance metrics of modified Ejection Fraction AI model. <u>Benefit-Risk Analysis:</u>

Modification	Rationale	Testing Methods	Impact Assessment
		testing (verification and validation).	Benefits: Improved performance; generalization. Risks: Overfitting; unintended bias. <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.
Modification of masked autoencoder architecture and training	Optimization of model robustness, accuracy, and generalizability across diverse patient populations and scanning conditions	Internal testing and a comparison of the original Ejection Fraction AI model to the modified Ejection Fraction AI model (using performance metrics) and clinical performance testing (verification and validation).	Improved performance metrics of modified Ejection Fraction AI model with increased accuracy, improved generalizability, and more robust measurements displayed to users. <u>Benefit-Risk Analysis:</u> Benefits: Improved performance; generalization. Risks: Overfitting; unintended bias. <u>Risk Mitigation:</u> Proper regularization techniques and cross-validation and dropout will be

Modification	Rationale	Testing Methods	Impact Assessment
			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, intended patient population, and environment of use, Clarius Ejection Fraction AI has been determined to be substantially equivalent in terms of safety and effectiveness to the legally marketed predicate device, Caption Interpretation Automated Ejection Fraction Software (K210747).

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, utilizing very similar machine-learning algorithms for detection, segmentation, and measurement of left ventricular ejection fraction.

Performance testing of Clarius Ejection Fraction AI, including the results from clinical verification and validation studies, has demonstrated that Clarius Ejection Fraction AI automated measurement adequately aligns with expert clinicians' manual measurements, and thereby performs as intended for use in semi-automated cardiac ultrasound measurements of the left ventricular ejection fraction.

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 Ejection Fraction AI is as safe and effective as the predicate device, Caption Interpretation Automated Ejection Fraction Software (K210747), and therefore substantially equivalent.