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

June 14, 2024

Re: K233955
Trade/Device Name: Clarius OB AI
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, QIH
Dated: May 7, 2024
Received: May 7, 2024

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).

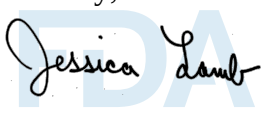
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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

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)*

K233955

Device Name

Clarius OB AI

Indications for Use *(Describe)*

Clarius OB AI is intended to assist in measurements of fetal biometric parameters (i.e., head circumference, abdominal circumference, femur length, bi-parietal diameter, crown rump length) on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., curvilinear scanner). 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 OB 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 OB AI

Device Classification Name: Ultrasonic Pulsed Doppler Imaging System; Automated Radiological Image Processing Software

Regulation Number, Name and Product Code:

Regulation Number	Regulation Name	Primary Product Code
21 CFR § 892.1550	Ultrasonic Pulsed Doppler Imaging System	IYN
Regulation Number	**Regulation Name**	**Secondary 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: June 13, 2024

Predicate Device Information:

Device Trade Name:	Sonio Detect
510(k) Reference:	K230365
Manufacturer Name:	Sonio
Regulation Name:	Ultrasonic Pulsed Doppler Imaging System
Device Classification Name:	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System Medical Image Management and Processing System
Product Code(s):	IYN; IYO; QIH
Regulation Number:	21 CFR § 892.1550; 21 CFR § 892.1560; 21 CFR § 892.2050
Regulatory Class:	Class II

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

Device Description

Clarius OB AI is a machine learning algorithm that is incorporated into the Clarius App software as part of the complete Clarius Ultrasound Scanner system for use in obstetric (OB) ultrasound imaging applications. Clarius OB AI is intended for use by trained healthcare practitioners for non-invasive measurements of fetal biometric parameters on ultrasound data acquired by the Clarius Ultrasound Scanner system (i.e., curvilinear scanner) using a deep learning image segmentation algorithm.

During the ultrasound imaging procedure, the anatomical site is selected through a preset software selection (i.e., OB, Early OB) within the Clarius App in which Clarius OB AI will engage to segment the fetal anatomy and place calipers for measurement of fetal biometric parameters.

Clarius OB AI operates by performing the following tasks:

- Automatic detection and measurement of head circumference (HC)
- Automatic detection and measurement of abdominal circumference (AC)
- Automatic detection and measurement of femur length (FL)
- Automatic detection and measurement of bi-parietal diameter (BPD)
- Automatic detection and measurement of crown rump length (CRL)

Clarius OB AI operates by performing automatic measurements of fetal biometric parameters. The user has the option to manually adjust the measurements made by Clarius OB AI by moving the caliper crosshairs. Clarius OB AI does not perform any functions that could not be accomplished manually by a trained and qualified user. Clarius OB AI is intended for use in B-Mode only.

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

Clarius OB 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 transducer (previously 510(k)-cleared in K213436). Clarius OB AI is not a stand-alone software device.

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

Indications for Use for Clarius OB AI

Clarius OB AI is intended to assist in measurements of fetal biometric parameters (i.e., head circumference, abdominal circumference, femur length, bi-parietal diameter, crown rump length) on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., curvilinear scanner). 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 OB AI is indicated 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 OB AI, to the predicate device. A comparison of the subject device to the predicate device shows that the subject device has the same intended use, similar indications for use, the same principle of operation, and is based on a similar AI/ML algorithm providing segmentation and measurement of fetal biometric parameters, comparable to the legally marketed device referenced herein.

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

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	RATIONALE (if subject device differs from predicate device)
	Clarius OB AI	**Sonio Detect**	
510(k) Holder/ Manufacturer	Clarius Mobile Health Corp.	Sonio	Not applicable
Submission Reference	Current Submission	K230365	Not applicable
Product Code(s)	IYN; QIH	IYN; IYO; QIH	The "IYN" primary product code is the same as the predicate device and the "QIH" secondary product code is the same as the predicate device.
Device Classification Name	Ultrasonic Pulsed Doppler Imaging System; Medical Image Management and Processing System	Ultrasonic Pulsed Doppler Imaging System; Ultrasonic Pulsed Echo Imaging System; Medical Image Management and Processing System	The "Ultrasonic Pulsed Doppler Imaging System" and the "Medical Image Management and Processing System" device classification names are the same as the predicate device.
Regulation Number	21 CFR § 892.1550; 21 CFR § 892.2050	21 CFR § 892.1550; 21 CFR § 892.1560; 21 CFR § 892.2050	The "21 CFR § 892.1550" regulation number and the "21 CFR § 892.2050" regulation number are the same as the predicate device.
Intended Use	Intended for use as an assistive tool/aid during the acquisition and interpretation of fetal ultrasound images through non-invasive processing of ultrasound images utilizing an artificial intelligence/machine-learning algorithm.	Intended for use as an assistive tool/aid during the acquisition and interpretation of fetal ultrasound images through non-invasive processing of ultrasound images utilizing an artificial intelligence/machine-learning algorithm.	Same as predicate device.
Indications for Use	Clarius OB AI is intended to assist in measurements of fetal biometric parameters (i.e., head circumference, abdominal circumference, femur	Sonio Detect is intended to analyze fetal ultrasound images and clips using machine learning techniques to automatically detect views, detect	Both the predicate and subject device are indicated for analysis of fetal ultrasound images

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	RATIONALE (if subject device differs from predicate device)
	Clarius OB AI	Sonio Detect	
	length, bi-parietal diameter, crown rump length) on ultrasound data acquired by the Clarius Ultrasound Scanner (i.e., curvilinear scanner). 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 OB AI is indicated for use in adult patients only.	anatomical structures within the views and verify quality criteria of the views. The device is intended for use as a concurrent reading aid during the acquisition and interpretation of fetal ultrasound images.	using AI/ML techniques. Both devices detect various fetal anatomies; the predicate device provides qualitative information to the user, whereas the subject device provides semi-automated quantitative information regarding fetal biometrics. Both the predicate and subject devices are intended for use as an adjunctive 'tool' or aid by the user for the interpretation of fetal ultrasound images and are not intended to replace clinical decision making. The differences in the indications for use do not impact the safety and effectiveness of the subject device relative to the predicate device.
Radiological application/ Supported modality	Ultrasound	Ultrasound	Same as predicate device.
Clinical application(s)	Obstetrics/Fetal	Obstetrics/Fetal	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	Ultrasound image processing software application implementing artificial intelligence utilizing non-adaptive machine learning algorithms trained with clinical and/or artificial data intended for	Same as predicate device.

Criteria	SUBJECT DEVICE	PREDICATE DEVICE	RATIONALE (if subject device differs from predicate device)
	Clarius OB AI	Sonio Detect	
	non-invasive analysis (i.e., quantitative and/or qualitative) of ultrasound data.	non-invasive analysis (i.e., quantitative and/or qualitative) of ultrasound data.	
Quantitative and/or Qualitative Analysis	Fetal biometry/measurement of fetal biometric parameters (i.e., HC, AC, BPD, CRL, FL)	Detection, verification, and qualitative analysis of fetal anatomical structures	The subject device performs semi-automated measurements of fetal biometrics, whereas the predicate device detects, verifies, and performs qualitative analysis of fetal anatomies.
Algorithm Methodology	Artificial Intelligence (AI)	Artificial Intelligence (AI)	Same as predicate device.
Automation (Yes or No)	Yes	Yes	Same as predicate device.
Environment of Use	Healthcare setting (e.g., hospital, clinic)	Healthcare setting (e.g., hospital, clinic)	Same as predicate device.
Intended Users	Licensed healthcare professionals	Licensed healthcare professionals	Same as predicate device.
Platform	Embedded in the Clarius ultrasound app	Cloud-based and stand-alone software	The subject device is embedded in the ultrasound app, which is part of the ultrasound system, whereas, the predicate device is cloud-based, stand-alone software.

Non-Clinical Performance Testing Summary

Clarius OB 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 OB 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 OB AI have 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 *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions* (issued September 27, 2023).

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 OB AI was tested and 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. 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 Testing Summary

Following completion of the Clarius OB 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 OB AI was evaluated through a retrospective analysis of anonymized ultrasound images from 25 clinical sites in the United States, Canada, Philippines, Australia, Kenya, Belgium, and Malaysia, representing different ethnic groups and ages. The age of the subjects in the study ranged from 15 - 45 years. The verification data was entirely independent from the training, validation (tuning), and test datasets.

The Clarius OB 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 OB AI auto-measurements are non-inferior to manual measurements performed by qualified experts with relevant (i.e., OB/fetal) ultrasound experience.

Summary of the Verification Study

Ultrasound images were randomly obtained from an anonymized multi-center database of images from the United States, Philippines, Australia, Kenya, Belgium, Malaysia, and Canada, representing various ethnicities and ages. The age of the subjects in the study ranged from 15 - 45 years. Institutions included in the Clarius OB AI model training and tuning dataset were excluded from this study. Images of the fetal head, abdomen, and femur were collected in cases where the gestational age was greater than 13 weeks and images of the entire fetus were collected in cases where the gestational age was less than 13 weeks. The total sample size included in the study was 347 subjects.

The primary objective of the retrospective verification study was to verify that Clarius OB AI fetal biometric measurements (i.e., CRL, BPD, HC, AC, and FL) are non-inferior to manual measurements performed by expert clinicians. The secondary objective of the study was to verify a high correlation between fetal gestational age calculated using manual expert measurements and Clarius OB AI biometric measurements. To calculate the gestational age from fetal biometric measurements Hadlock equations were used. Each reviewer also outlined the boundaries (segmentation) of the fetus, fetal head, and femur as applicable. Each image had fetal biometric measurements performed by 3 reviewers (clinical truthers). Each reviewer was blinded to the Clarius OB AI output and the other reviewers' annotations as well. All obstetric exams of the fetus/fetal anatomy were captured using a Clarius C3 (curvilinear) ultrasound scanner.

An assessment of the magnitude of the difference between Clarius OB AI and human experts' fetal biometric measurements was performed to ascertain whether Clarius OB AI measurement is non-inferior to those of human experts/ qualified ultrasound users. Clarius OB AI was found to be non-inferior to human experts with statistically significant p-values (<2.2 e-16) for the various fetal biometric measurements. The fetal gestational age in the study ranged from around 58 days to 271 days.

Strong agreement was shown between the Clarius OB AI measurements and the mean of the expert clinicians' measurements for all fetal biometrics (HC, BPD, FL, AC, and CRL). The Clarius OB 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 OB AI output and the mean reviewer measurement. ICC across all fetal biometrics between Clarius OB AI and the reviewers was calculated to be 0.99 (95% CI 0.994—0.997). To assess the segmentation performance of Clarius OB AI, the average dice and Jaccard scores between the Clarius OB AI model vs. each reviewer and between each reviewer pair were also calculated. The range of the average Jaccard scores (for all anatomical structures) between Clarius OB AI and the reviewers was 0.73 (95% CI 0.72--0.74) to 0.94 (95% CI 0.93--0.94), and the range of the average dice scores (for all anatomical structures) between Clarius OB AI and the reviewers was 0.84 (95% CI 0.83--0.87) to 0.97 (95% CI 0.96--0.97).

The results of the retrospective analysis have demonstrated that Clarius OB AI measurement output adequately aligns with expert clinicians' manual measurement, confirming that Clarius OB AI measurements of fetal biometric parameters are non-inferior to those of human clinical experts. Therefore, the performance of Clarius OB AI has been verified for fetal biometric measurements for use in obstetric/fetal 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 OB 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 fetal biometric 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 Clarius OB AI using Clarius' C3 scanner and choose the appropriate preset (i.e., OB, Early OB), obtain images of the fetal anatomy of interest (i.e., fetal head, femur, abdomen, or fetus), perform live segmentation, perform automatic measurements of fetal biometric parameters (AC, FL, HC, BPD, CRL), manually adjust the measurements, change the segmentation mask opacity, and save the fetal biometric measurements with each exam.

Therefore, based on the results of the clinical validation study it has been determined that Clarius OB AI performs as intended and meets user needs for use in semi-automated measurements of fetal biometric parameters in obstetric/fetal ultrasound applications for calculation of fetal gestational age.

Predetermined Change Control Plan (PCCP)

Clarius OB AI uses a machine learning (ML) algorithm for measurement of fetal biometric parameters (i.e., head circumference, abdominal circumference, femur length, bi-parietal diameter, crown rump length) on ultrasound image data acquired by the Clarius Ultrasound Scanner.

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

Summary of changes to Clarius OB AI per the PCCP:

Modification	Rationale	Testing Methods	Impact Assessment
Modification of model architecture	Improvement and optimization of Clarius OB AI's performance	Re-training of the OB AI model with new data to optimize its performance followed by internal testing and a comparison of the original OB AI model to the modified OB AI model (using performance metrics) and clinical performance testing (verification and validation).	Improved performance metrics of modified OB AI model with increased accuracy and more robust gestational age estimates displayed to users. Benefit-Risk Analysis: Benefits: Improved performance; generalization for diverse cases. 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 training methods and parameters	Improvement and optimization of Clarius OB AI's performance	Internal testing and a comparison of the original OB AI model to the modified OB AI model (using	Improved performance metrics of modified OB AI model.

Modification	Rationale	Testing Methods	Impact Assessment
		performance metrics) and clinical performance testing (verification and validation).	Benefit-Risk Analysis: Benefits: Improved performance; generalization for diverse cases. 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 post-processing algorithms	Improvement and optimization of Clarius OB AI's performance and robustness	Internal testing and a comparison of the original OB AI model to the modified OB AI model (using performance metrics) and clinical performance testing (verification and validation).	Improved performance metrics of modified OB AI model. Benefit-Risk Analysis: Benefits: Improved performance; generalization for diverse cases. Risks: Overfitting; unintended bias. Risk Mitigation: Proper regularization techniques and cross-validation and dropout will be employed to mitigate overfitting.

Modification	Rationale	Testing Methods	Impact Assessment
			Internal testing and verification will be conducted to mitigate unintended biases.
Modification of data input sources	To enable use of Clarius OB AI on newer models of the 510(k)-cleared Clarius Ultrasound Scanner system	Re-training of the OB AI model to expand its use with new data sources (i.e., new 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 new 510(k)-cleared Clarius scanners, the updated OB AI model will be better equipped to handle different 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. <u>Risk Mitigation:</u> Internal testing and verification datasets within the intended patient population will ensure that data skewing and concept drift are mitigated.

<u>Conclusion & Summary of Substantial Equivalence</u>

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 OB 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 non-invasive analysis of ultrasound data, utilizing similar machine-learning based algorithms for use in obstetric/fetal ultrasound imaging applications for assessment of fetal anatomy and biometrics.

Performance testing of Clarius OB AI, including the results from verification and validation studies, has demonstrated that Clarius OB AI measurement output adequately aligns with expert clinicians' manual measurements, and thereby performs as intended for use in semi-automated fetal biometric measurements for calculation of fetal gestational age, meeting user needs.

Any 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 OB AI is as safe and effective as the predicate device, Sonio Detect (K230365), and therefore substantially equivalent.