October 5, 2023

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

Re: K232704
Trade/Device Name: Clarius Ultrasound Scanner
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: September 1, 2023
Received: September 5, 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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K232704

Device Name
Clarius Ultrasound Scanner

Indications for Use *(Describe)*

The Clarius Ultrasound Scanner is a software-based ultrasound imaging system and accessories, intended for diagnostic imaging. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: ophthalmic, fetal, abdominal, intra-operative (non-neurological), pediatric, small organ, cephalic (adult), trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), urology, gynecology, cardiac (adult, pediatric), peripheral vessel, carotid, and procedural guidance of needles into the body.

The system is a transportable ultrasound system intended for use in environments where healthcare is provided by trained healthcare professionals.

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.

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510(k) Summary K232704

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 Ultrasound Scanner

Subject Device Model Number: PAL HD3

Common Name: Diagnostic Ultrasound System and Accessories

Regulation Number, Name and Product Codes:

Regulation Number	Regulation Name	Product Code
21 CFR § 892.1550	Ultrasonic Pulsed Doppler Imaging System	IYN
21 CFR § 892.1560	Ultrasound Pulsed Echo Imaging System	IYO
21 CFR § 892.1570	Diagnostic Ultrasonic Transducer	ITX

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 2, 2023

Predicate Device Information:

Device Trade Name:	Clarius Ultrasound Scanner
510(k) Reference:	K213436
Submitter Name:	Clarius Mobile Health Corp.
Regulation Name:	Ultrasonic Pulsed Doppler Imaging System
Classification Product Code(s):	IYN
Subsequent Product Codes	IYO, ITX
Regulation Number:	21 CFR § 892.1550; 21 CFR § 892.1560; 21 CFR § 892.1570
Classification:	Class II

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

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Device Description

The Clarius Ultrasound Scanner is a portable, general-purpose, software-controlled, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data through an off-the-shelf (OTS) iOS or Android device. The Clarius Ultrasound Scanner comprises a series of wireless transducers employing Bluetooth and Wi-Fi-based technology to communicate with traditional tablet/smartphone devices via direct Wi-Fi. This allows the user to export ultrasound images and display them across a range of portable personal devices.

The Clarius Ultrasound Scanner system is a transportable ultrasound system intended for use in environments where healthcare is provided by trained healthcare professionals, including the emergency medical services (EMS) environment. The Clarius Ultrasound Scanner is intended for use by qualified healthcare practitioners (e.g., doctors, nurses, sonographers) who are trained in the use of ultrasound imaging technology.

The Clarius Scanner PAL HD3 ("PAL HD3") (subject device of this 510(k) premarket notification) is a multipurpose dual-array transducer that incorporates high-frequency linear array (equivalent to the L15 HD3 transducer cleared under K213436)) and low-frequency phased array (equivalent to the PA HD3 transducer cleared under K213436) ultrasound functionalities where the two separate transducer ceramics are arranged side-by-side within the same transducer model (PAL HD3). The Clarius Scanner PAL HD3 is a new Clarius HD3 transducer variant introduced into the HD3 product line of the Clarius Ultrasound Scanner device family and represents a design modification to the existing PA HD3 transducer of the Clarius Ultrasound Scanner system, which was most recently 510(k)-cleared under K213436.

The Clarius Scanner PAL HD3 has two separate transducer ceramics positioned side-by-side which consist of the linear array and the phased array. The Clarius Scanner PAL HD3 offers a wide frequency range of 1 – 15 MHz within a single transducer. The body and electronics of the PAL HD3 scanner are identical to the currently released HD3 scanner models (the PA HD3 and the L15 HD3) of the Clarius Ultrasound Scanner device family (cleared under K213436); the main difference is in the scanner head. The Clarius Scanner PAL HD3 will allow clinicians to switch between the phased array and the linear array without having to use two separate scanners during exams and procedures.

The Clarius Ultrasound Scanner, subject of this 510(k) premarket notification, comprises the following:

Transducer/ Scanner	PAL HD3
Software	Clarius Ultrasound App (Clarius App) for iOS; Clarius Ultrasound App (Clarius App) for Android
Accessories	Clarius Charger HD3 Clarius Power Fan HD3

Indications for Use for the Clarius Ultrasound Scanner

The Clarius Ultrasound Scanner is a software-based ultrasound imaging system and accessories, intended for diagnostic imaging. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: ophthalmic, fetal, abdominal, intra-operative (non-neurological), pediatric, small organ, cephalic (adult), trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial),

urology, gynecology, cardiac (adult, pediatric), peripheral vessel, carotid, and procedural guidance of needles into the body.

The system is a transportable ultrasound system intended for use in environments where healthcare is provided by trained healthcare professionals.

Comparison of the Subject Device and Predicate Device for Demonstration of Substantial Equivalence

Criteria	SUBJECT DEVICE	PREDICATE DEVICE
	Clarius Ultrasound Scanner	Clarius Ultrasound Scanner
510(k) Holder/ Manufacturer	Clarius Mobile Health Corp.	Clarius Mobile Health Corp.
Submission Reference	Current Submission	K213436
510(k) Track	Track 3	Track 3
Product Codes	IYN[1], IYO[2], ITX[3]	IYN[1], IYO[2], ITX[3]
Regulation Number	21 CFR 892.1550[1] 21 CFR 892.1560[2] 21 CFR 892.1570[3]	21 CFR 892.1550[1] 21 CFR 892.1560[2] 21 CFR 892.1570[3]
Regulation Name	Ultrasonic Pulsed Doppler Imaging System[1]; Ultrasonic Pulsed Echo Imaging System[2]; Diagnostic Ultrasonic Transducer[3]	Ultrasonic Pulsed Doppler Imaging System[1]; Ultrasonic Pulsed Echo Imaging System[2]; Diagnostic Ultrasonic Transducer[3]
Transducer Model(s)	PAL HD3	PA HD3, L15 HD3
Transducer Types	Phased Array and Linear Array (the phased array and linear array are arranged side-by-side within the same transducer model)	Phased Array, Linear Array (the phased array and linear array are represented in two separate transducer models)
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic ultrasound imaging or fluid flow analysis of the human body
Indications for Use and Clinical Usage	The Clarius Ultrasound Scanner is a software-based ultrasound imaging system and accessories, intended for diagnostic imaging. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: ophthalmic, fetal, abdominal, intra-operative (non-neurological), pediatric, small organ, cephalic (adult), trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), urology, gynecology, cardiac (adult, pediatric), peripheral vessel, carotid, and procedural guidance of needles into the body. The system is a transportable ultrasound system intended for use in environments where healthcare is provided by trained healthcare professionals.	The Clarius Ultrasound Scanner is a software-based ultrasound imaging system and accessories, intended for diagnostic imaging. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: ophthalmic, fetal, abdominal, intra-operative (non-neurological), pediatric, small organ, cephalic (adult), trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), urology, gynecology, cardiac (adult, pediatric), peripheral vessel, carotid, and procedural guidance of needles into the body. The system is a transportable ultrasound system intended for use in environments where healthcare is provided by trained healthcare professionals.

Criteria	SUBJECT DEVICE	PREDICATE DEVICE
	Clarius Ultrasound Scanner	**Clarius Ultrasound Scanner**
	Phased Array (PAL HD3): • Fetal • Abdominal • Intraoperative • Pediatric • Cardiac (adult, pediatric) Linear Array (PAL HD3): • Ophthalmic • Abdominal • Intraoperative • Pediatric • Small Organ (thyroid, prostate, scrotum, breast) • Musculoskeletal (conventional, superficial) • Peripheral vessel • Carotid • Needle enhance in B-Mode	Phased Array (PA HD3): • Fetal • Abdominal • Intraoperative (abdominal organs and vascular) • Pediatric • Cephalic (adult) • Cardiac (adult, pediatric) Linear Array (L15 HD3): • Ophthalmic • Abdominal • Intraoperative (abdominal organs and vascular) • Pediatric • Small Organ (thyroid, prostate, scrotum, breast) • Musculoskeletal (conventional, superficial) • Peripheral vessel • Carotid • Needle enhance in B-Mode
Principle of Operation	Piezoelectric material in the system's transducer transmits high frequency, non-ionizing sound waves to the designated region of the body and converts the subsequent echoes detected to electronic signals in order to construct an image of the internal structures of an anatomical field. The image is sent wirelessly from the transducer to an external iOS or Android viewing device on which the image can be displayed.	Piezoelectric material in the system's transducer transmits high frequency, non-ionizing sound waves to the designated region of the body and converts the subsequent echoes detected to electronic signals in order to construct an image of the internal structures of an anatomical field. The image is sent wirelessly from the transducer to an external iOS or Android viewing device on which the image can be displayed.
Power Source	Internal integrated built-in (non-removable) lithium-ion battery	Internal integrated built-in (non-removable) lithium-ion battery
Display	iOS or Android mobile device	iOS or Android mobile device
Wireless Capability	Communicates wirelessly via Wi-Fi and Bluetooth	Communicates wirelessly via Wi-Fi and Bluetooth
Portability	Portable ultrasound system	Portable ultrasound system
System Components	Transducer/scanner Software (Clarius App) Accessories (Charger and Power Fan)	Transducers/scanners Software (Clarius App) Accessories (Charger and Power Fan)
Frequency	1-5 MHz (Phased Array) and 5-15 MHz (Linear Array)	1-5 MHz (Phased Array-PA HD3) and 5-15 MHz (Linear Array-L15 HD3)
Modes of Operation	B-mode M-mode Color Doppler Power Doppler	B-mode M-mode Color Doppler Power Doppler

Criteria	SUBJECT DEVICE	PREDICATE DEVICE
	Clarius Ultrasound Scanner	**Clarius Ultrasound Scanner**
	Pulse-Wave Doppler (PWD) Combined (B+M; B+CD; B+PD; B+PWD)	Pulse-Wave Doppler (PWD) Combined (B+M; B+CD; B+PD; B+PWD)
Safety Standards	The Clarius Ultrasound Scanner complies with the following safety standards: 60601-1 60601-1-2 60601-1-6 60601-1-12 60601-2-37	The Clarius Ultrasound Scanner complies with the following safety standards: 60601-1 60601-1-2 60601-1-6 60601-1-12 60601-2-37
Intended Users	Licensed healthcare professionals (e.g., doctors, nurses, sonographers) trained in ultrasound use.	Licensed healthcare professionals (e.g., doctors, nurses, sonographers) trained in ultrasound use.
Environment of Use	Hospital, clinic, ambulatory setting	Hospital, clinic, ambulatory setting

Non-Clinical Performance Testing of the Clarius Ultrasound Scanner

The PAL HD3 scanner of the Clarius Ultrasound Scanner device family was designed and developed by Clarius Mobile Health Corp. in accordance with the applicable requirements and standards to establish performance and safety of the device. The device's safety and performance were verified by tests conducted by Clarius and accredited third-party laboratories. Validation testing was performed to ensure that the final product is capable of meeting the requirements for the specified clinical applications and performs as intended to meet users' needs, while demonstrating substantial equivalence to the predicate device.

Non-clinical performance testing of the PAL HD3 subject device, which is part of the Clarius Ultrasound Scanner device family, demonstrates compliance to the following standards:

Standard Designation No. and Date	Title of Standard
IEC 62304:2006 + A1:2015	Medical device software - Software life cycle processes
ISO 14971:2019	Medical Devices - Application of risk management to medical devices
IEC 60601-1:2005 + A1: 2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Capability – Requirements and tests
IEC 60601-1-6:2010 + A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-37:2015	Medical Electrical Equipment - Part 2-37: Particular Requirements For the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-1-12:2014	Medical Electrical Equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

IEC 62133:2012	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
AIUM/NEMA UD 2-2004 (R2009)	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3
IEC 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices
AIUM/NEMA UD 3-2004	NEMA Standards Publication UD 3-2004 (R2009) Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
IEC 60529:2013	Degrees of protection provided by enclosures (IP Code)
IEC 61157:2013	IEC 61157: Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment

Summary of Clinical Testing of the Clarius Ultrasound Scanner

The Clarius Ultrasound Scanner (PAL HD3 transducer model) did not require clinical studies to support the determination of substantial equivalence.

Conclusion & Summary of Substantial Equivalence

Based on the information presented in this Special 510(k) premarket notification, and based on the fundamental scientific technology, technological characteristics, principle of operation, intended use, environment of use, and indications for use, the modified Clarius Ultrasound Scanner has been determined to be substantially equivalent in terms of safety and effectiveness to the predicate device, the Clarius Ultrasound Scanner (510(k)-cleared in K213436).

The differences in design between the subject device (PAL HD3 scanner of the Clarius Ultrasound Scanner device family) and the predicate device (PA HD3 and L15 HD3 scanners of the Clarius Ultrasound Scanner device family 510(k)-cleared in K213436) do not raise any issues related to safety or effectiveness.