DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 14, 2017

Clarius Mobile Health Corp.
% Mr. Mark Job
Official Correspondent
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO MN 55313

Re: K172385
Trade/Device Name: Clarius Ultrasound Scanner
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: August 4, 2017
Received: August 8, 2017

Dear Mr. Job:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172385

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 in B-mode, M-mode, Color Doppler, Power Doppler, and Combined (B+M; B+Color Doppler; and B+Power Doppler). 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), musculo-skeletal (conventional, superficial), urology, gynecology, cardiac (adult, pediatric), fetal echo, 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.

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SYSTEM: CLARIUS ULTRASOUND SCANNER

INTENDED USE: DIAGNOSTIC ULTRASOUND IMAGING OR FLUID FLOW ANALYSIS OF THE HUMAN BODY AS FOLLOWS:

Clinical Application		Mode of Operation					
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	Color Doppler	Power Doppler	Combined (Specify)	Other*
Ophthalmic	Ophthalmic	N					
Fetal Imaging & Other	Fetal	P	N	N	N	B+M; B+CD; B+PD	
	Abdominal	P	N	N	N	B+M; B+CD; B+PD	Note 1
	Intra-operative (Abdominal organs & vascular)	N	N	N	N	B+M; B+CD; B+PD	Note 1
	Laparoscopic						
	Pediatric	P	N	N	N	B+M; B+CD; B+PD	Note 1
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	P		N	N	B+CD; B+PD	Note 1
	Neonatal Cephalic						
	Adult Cephalic	N	N	N	N	B+M; B+CD; B+PD	
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esophageal (non-Cardiac)						
	Musculo-skeletal (Conventional)	P		N	N	B+CD; B+PD	Note 1
	Musculo-skeletal (Superficial)	P		N	N	B+CD; B+PD	Note 1
	Intravascular						
	Other (Urology, Gynecology)	P	N	N	N	B+M; B+CD; B+PD	
Cardiac	Cardiac Adult	N	N	N		B+M; B+CD	
	Cardiac Pediatric	N	N	N		B+M; B+CD	
	Intravascular (Cardiac)						
	Trans-esophageal (Cardiac)						
	Intra-cardiac						
	Other (Fetal Echo)	P	N	N	N	B+M; B+CD; B+PD	
Peripheral Vessel	Peripheral Vessel	P	N	N	N	B+M; B+CD; B+PD	Note 1
	Other (Carotid)	P	N	N	N	B+M; B+CD; B+PD	Note 1

SYSTEM: CLARIUS ULTRASOUND SCANNER

INTENDED USE: DIAGNOSTIC ULTRASOUND IMAGING OR FLUID FLOW ANALYSIS OF THE HUMAN BODY AS FOLLOWS:

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Needle Enhancement in B-Mode.

DEVICE NAME: C3 CONVEX SCANNER

INTENDED USE: DIAGNOSTIC ULTRASOUND IMAGING OR FLUID FLOW ANALYSIS OF THE HUMAN BODY AS FOLLOWS:

Clinical Application		Mode of Operation					
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	Color Doppler	Power Doppler	Combined (Specify)	Other*
Ophthalmic	Ophthalmic						
Fetal Imaging & Other	Fetal	P	N	N	N	B+M; B+CD; B+PD	
	Abdominal	P	N	N	N	B+M; B+CD; B+PD	
	Intra-operative (Abdominal organs & vascular)	N	N	N	N	B+M; B+CD; B+PD	
	Laparoscopic						
	Pediatric	P	N	N	N	B+M; B+CD; B+PD	
	Small Organ (Thyroid, Prostate, Scrotum, Breast)						
	Neonatal Cephalic						
	Adult Cephalic	N	N	N	N	B+M; B+CD; B+PD	
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esophageal (non-Cardiac)						
	Musculo-skeletal (Conventional)	P	N	N	N	B+M; B+CD; B+PD	
	Musculo-skeletal (Superficial)						
	Intravascular						
	Other (Urology, Gynecology)	P	N	N	N	B+M; B+CD; B+PD	
Cardiac	Cardiac Adult	N	N	N		B+M; B+CD	
	Cardiac Pediatric	N	N	N		B+M; B+CD	
	Intravascular (Cardiac)						
	Trans-esophageal (Cardiac)						
	Intra-cardiac						
	Other (Fetal Echo)	P	N	N	N	B+M; B+CD; B+PD	
Peripheral Vessel	Peripheral Vessel	P	N	N	N	B+M; B+CD; B+PD	
	Other (Carotid)						

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Needle Enhancement in B-Mode.

DEVICE NAME: C7 CONVEX SCANNER

INTENDED USE: DIAGNOSTIC ULTRASOUND IMAGING OR FLUID FLOW ANALYSIS OF THE HUMAN BODY AS FOLLOWS:

Clinical Application		Mode of Operation					
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	Color Doppler	Power Doppler	Combined (Specify)	Other*
Ophthalmic	Ophthalmic						
Fetal Imaging & Other	Fetal	N	N	N	N	B+M; B+CD; B+PD	
	Abdominal	N	N	N	N	B+M; B+CD; B+PD	
	Intra-operative (Abdominal organs & vascular)	N	N	N	N	B+M; B+CD; B+PD	
	Laparoscopic						
	Pediatric	N	N	N	N	B+M; B+CD; B+PD	
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	N	N	N	N	B+M; B+CD; B+PD	
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esophageal (non-Cardiac)						
	Musculo-skeletal (Conventional)	N	N	N	N	B+M; B+CD; B+PD	
	Musculo-skeletal (Superficial)						
	Intravascular						
	Other (Urology, Gynecology)	N	N	N	N	B+M; B+CD; B+PD	
Cardiac	Cardiac Adult	N	N	N	N	B+M; B+CD; B+PD	
	Cardiac Pediatric	N	N	N		B+M; B+CD	
	Intravascular (Cardiac)						
	Trans-esophageal (Cardiac)						
	Intra-cardiac						
	Other (Fetal Echo)	N	N	N	N	B+M; B+CD; B+PD	
Peripheral Vessel	Peripheral Vessel	N	N	N	N	B+M; B+CD; B+PD	
	Other (Carotid)						

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Needle Enhancement in B-Mode.

DEVICE NAME: L7 LINEAR SCANNER

INTENDED USE: DIAGNOSTIC ULTRASOUND IMAGING OR FLUID FLOW ANALYSIS OF THE HUMAN BODY AS FOLLOWS:

Clinical Application		Mode of Operation					
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	Color Doppler	Power Doppler	Combined (Specify)	Other*
Ophthalmic	Ophthalmic	N					
Fetal Imaging & Other	Fetal						
	Abdominal	P	N	N	N	B+M; B+CD; B+PD	Note 1
	Intra-operative (Abdominal organs & vascular)	N	N	N	N	B+M; B+CD; B+PD	Note 1
	Laparoscopic						
	Pediatric	P	N	N	N	B+M; B+CD; B+PD	Note 1
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	P		N	N	B+CD; B+PD	Note 1
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esophageal (non-Cardiac)						
	Musculo-skeletal (Conventional)	P	N	N	N	B+M; B+CD; B+PD	Note 1
	Musculo-skeletal (Superficial)	P	N	N	N	B+M; B+CD; B+PD	Note 1
	Intravascular						
	Other (Urology, Gynecology)						
Cardiac	Cardiac Adult						
	Cardiac Pediatric						
	Intravascular (Cardiac)						
	Trans-esophageal (Cardiac)						
	Intra-cardiac						
	Other (Fetal Echo)						
Peripheral Vessel	Peripheral Vessel	P	N	N	N	B+M; B+CD; B+PD	Note 1
	Other (Carotid)	P	N	N	N	B+M; B+CD; B+PD	Note 1

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Needle Enhancement in B-Mode.

DEVICE NAME: C3 CONVEX SCANNER WITH C3-L CLIP-ON

INTENDED USE: DIAGNOSTIC ULTRASOUND IMAGING OR FLUID FLOW ANALYSIS OF THE HUMAN BODY AS FOLLOWS:

Clinical Application		Mode of Operation					
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	Color Doppler	Power Doppler	Combined (Specify)	Other*
Ophthalmic	Ophthalmic						
Fetal Imaging & Other	Fetal						
	Abdominal						
	Intra-operative (Abdominal organs & vascular)						
	Laparoscopic						
	Pediatric						
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	N					
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esophageal (non-Cardiac)						
	Musculo-skeletal (Conventional)	N					
	Musculo-skeletal (Superficial)	N					
	Intravascular						
	Other (Urology, Gynecology)						
Cardiac	Cardiac Adult						
	Cardiac Pediatric						
	Intravascular (Cardiac)						
	Trans-esophageal (Cardiac)						
	Intra-cardiac						
	Other (Fetal Echo)						
Peripheral Vessel	Peripheral Vessel	N					
	Other (Carotid)	N					

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: Needle Enhancement in B-Mode.

510(k) Summary

1. Submitter's name, address, telephone number, and contact person:

Submitter: Abhijit Ahir
Director of QA/RA
Clarius Mobile Health Corp.
#350 – 3605 Gilmore Way Burnaby, B.C. V5G 4X5 Canada Email: abhijit.ahir@clarius.me Tel: (+1) 778-800-9975
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Contact Person: Emergo Global Representative, LLC
816 Congress Avenue, Suite 1400
Austin, TX 78701 USA Tel: (+1) 512-327-9997

Date Prepared: September 5, 2017

2. Name of the device, including the trade or proprietary name, if applicable, the common or usual name, and the classification, if known:

Device Name: Clarius Ultrasound Scanner

Common Name: Diagnostic Ultrasound System and Accessories

Classification: Class II

Classification Names:

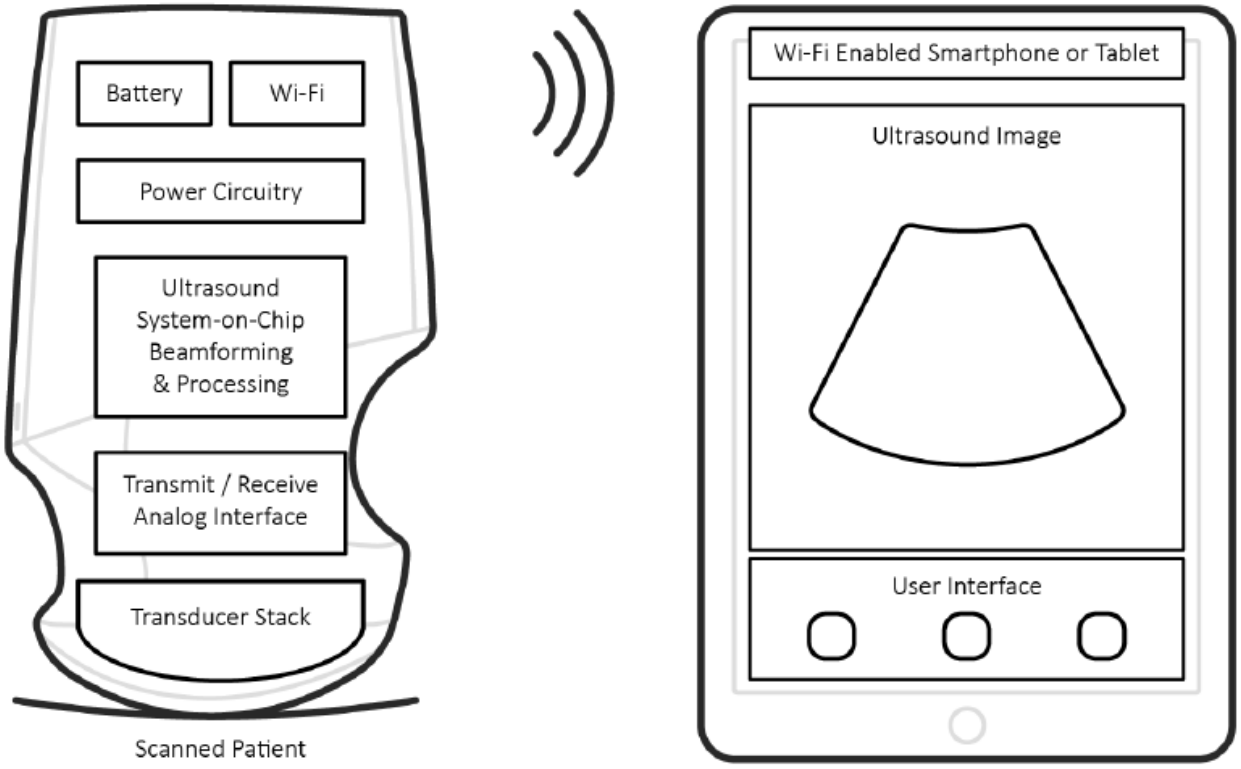
21 CFR Section	Classification Name	Product Code
892.1550	Ultrasonic Pulsed Doppler Imaging System	90 IYN
892.1560	Ultrasonic Pulsed Echo Imaging System	90 IYO
892.1570	Diagnostic Ultrasound Transducer	90 ITX

3. Substantially Equivalent Devices:

Device Name	510(k) Number
FUJIFILM SonoSite Edge Ultrasound System	K133454
Clarius Ultrasound System	K163138

Device Description

The Clarius Ultrasound System is a portable, general-purpose, software-controlled, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data through a commercial off the-shelf (COTS) iOS or Android device. The Clarius Ultrasound System 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.



Ultrasound Probe *User Interface / Display*

Piezoelectric material in the systems 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. This image is sent wirelessly to an external (COTS) iOS or Android viewing device on which the image can be displayed. The transducer houses a battery and power generator, multichannel beam former, pre-scan converter, and Wi-Fi components. The battery is removable and comes with a separate charger. Communication between the transducer and the compatible viewing device will be via Wi-Fi Direct® (Ad-Hoc mode with security) for easy pairing.

The Clarius Ultrasound System product/package components include:

1. Software:
   - The Ultrasound App (Clarius App) for iOS; OR
   - The Ultrasound App (Clarius App) for Android.

2. Transducers/Scanners:
   - Clarius C3 Scanner (C3 Convex Transducer);
   - Clarius C3 Scanner (C3 Convex Transducer) with Clarius C3-L Clip-on;
   - Clarius C7 Scanner (C7 Convex Transducer); OR
   - Clarius L7 Scanner (L7 Linear Transducer).

3. Accessories:
    a. Clarius-Built:
        - Battery Pack (Li-ion); and
        - Battery Charger.
    b. OEM/Off-The-Shelf Product(s):
        - Medical Power Supply (Off-the-shelf power adaptor from SL Power Electronics, USA; Model Number ME20A1203B02; Approved in the US); and
        - Aquasonic 100 Ultrasound Transmission Gel (Off-the-shelf ultrasound gel from Parker Laboratories Inc., USA; Approved in the US).

The concept of the Clarius Ultrasound System transducers and software is primarily to provide an easy to use, high-performance, low-cost, ultrasound platform for teaching and clinical applications. The Clarius Ultrasound System is intended for use in professional healthcare facilities where healthcare is provided by trained medical professionals. The device is also intended for use in Emergency Medical Service, ambulance, or rotary aircraft environments.

Changes Implemented

The Clarius Ultrasound System obtained market clearance on November 30, 2016, under 510(k) submission number K163138. Two devices were listed on the previous submission – the Clarius C3 Scanner (C3 Convex Transducer) and the Clarius L7 Scanner (L7 Linear Transducer) – which were approved for B-mode only.

This submission includes the addition of M-mode, color doppler, power doppler, and combined modes (i.e., B+M; B+CD; B+PD) for these two devices. A new device has been added – the Clarius C7 Scanner (C7 Convex Transducer). This device will also operate using B-mode, M-mode, color doppler, power doppler, and combined modes. All three devices include the addition of intraoperative (abdominal organs & vascular) as a clinical application.

The Clarius C3 Scanner includes the addition of Cardiac Adult and Cardiac Pediatric in B-mode, M-mode, Color Doppler, and combined modes (i.e., B+M and B+CD). The Clarius L7 Scanner includes ophthalmic as an additional application available in B-mode only.

Clarius is also introducing a new accessory for the C3 Scanner; a linear adapter, which will be referred to as the Clarius C3-L Clip-on. This optional accessory provides enhanced versatility of the Clarius C3 Scanner to allow the device to be used a linear transducer.

All devices are compliant with IEC 60601-1-12 Edition 1.0 2014-06 (Recognition Number 19-15). This collateral standard defines the requirements for medical electrical equipment and systems intended for use in the emergency medical services environment. As such, the disclaimer that these devices cannot be used in emergency medical environments is no longer applicable. All devices are also IP67 rated, certifying that the device can be immersed in water of a depth of up to 1 meter for 30 minutes and is dust tight.

Intended Use

The Clarius Ultrasound Scanner is a software-based ultrasound imaging system and accessories, intended for diagnostic imaging in B-mode, M-mode, Color Doppler, Power Doppler, and Combined (B+M; B+Color Doppler; and B+Power Doppler). 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), musculo-skeletal (conventional, superficial),

urology, gynecology, cardiac (adult, pediatric), fetal echo, 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.

Contraindications

Do not use the Clarius Ultrasound Scanner in the following situations. Doing so may produce images with inaccurate results:

- Patients who have had surgery, which may have changed the composition of the examining tissue (for example, a mastectomy), as this could skew or alter the measured density.
- Patients whose bodies contain foreign artifacts (for example, implants), in the examining tissue.
- Endocavitary use; (i.e., defined as introducing a scanner within a (body) cavity or organ. E.g. an atrium, esophagus, rectum or vagina).

For Use in Surgical Environments

Before use of the Clarius Scanner for intra-operative procedures, follow instructions for high-level disinfection, then cover the Clarius Scanner with a sheath:

- Use only CIVCO REF 610-1212.
- Download the usage instructions from http://civco.com/mmi/ultrasound/covers/generalpurpose/Latex-Free-Wireless-Ultrasound-Probe-Covers-610-1212.htm and read all the information before use.

When finished, immediately clean the scanner, followed by another high-level disinfection.

If the sheath breaks during the intra-operative procedure, dispose the sheath and follow the same cleaning and high-level disinfecting process as above, then cover the Clarius Ultrasound Scanner with a new sheath before continuing to use it.

Predicate Devices

Equivalent devices are referred to as predicate devices in alignment with the FDA's standard terminology for comparable devices. The predicate devices selected to demonstrate equivalence are:

1.	**Device Name** Clarius Ultrasound System	**FDA 510(k) Number** (K163138)
2.	**Device Name** SonoSite Edge Ultrasound System	**FDA 510(k) Number** (K133454)

Determination of Substantial Equivalence

The Clarius Ultrasound system is a Track 3 system that employs the same fundamental scientific technology as that cleared with K133454 and K163138. All indications for use introduced by the Clarius Ultrasound Scanner are similar to at least one of the predicate devices. A comparison table is provided below:

Criteria for Comparison	Clarius Ultrasound Scanner	Clarius Ultrasound System (K163138)	FUJIFILM SonoSite Edge Ultrasound System (K133454)
Portability	Portable ultrasound system	Portable ultrasound system	Portable ultrasound system
Power Source	Removable battery (Li-ion)	Removable battery (Li-ion)	Battery or AC power
Display	iOS or Android mobile device	iOS or Android mobile device	Inbuilt digital display
Wireless Capability	Communicates wirelessly via Wi-Fi and Bluetooth	Communicates wirelessly via Wi-Fi and Bluetooth	Communicates via cable
510(k) Track	Track 3	Track 3	Track 3
Transducer Types	– Convex Array – Linear Array – Phased Array	– Convex Array – Linear Array	– Convex Array – Linear Array – Phased Array – Intracavity – Trans-esophageal
Intended Use	Diagnostic ultrasound imaging and fluid flow analysis	Diagnostic ultrasound imaging and fluid flow analysis	Diagnostic ultrasound imaging and fluid flow analysis
Indications of Use	– Ophthalmic – Fetal – Abdominal – Intraoperative (Ab/Vasc) – – Pediatric – Small organ – – Adult Cephalic – – – Musculo-skel. (Conv.) – Musculo-skel. (Superfic.) – Urology – Gynecology – Cardiac Adult – Cardiac Pediatric – – Fetal Echo – Peripheral vessel – Carotid – Needle guidance	– – Fetal – Abdominal – – – Pediatric – Small organ – – – – – Musculo-skel. (Conv.) – Musculo-skel. (Superfic.) – Urology – Gynecology – Cardiac Adult – Cardiac Pediatric – – Fetal Echo – Peripheral vessel – Carotid – Needle guidance	– Ophthalmic – Fetal – Abdominal – Intraoperative (Ab/Vasc) – Intraoperative (Neuro) – Pediatric – Small organ – Neonatal cephalic – Adult Cephalic – Trans-Rectal – Trans-Vaginal – Musculo-skel. (Conv.) – Musculo-skel. (Superfic.) – – Gynecology – Cardiac Adult – Cardiac Pediatric – Trans-esophageal (Card.) – – Peripheral vessel – – Needle guidance
Modes of Operation	– B-mode – M-mode – Color Doppler – – Power Doppler – – – – Combined (B+M, B+CD, B+PD)	– B-Mode – – – – – – – –	– B-Mode – M-Mode – Color Doppler – Color M Doppler – Power Doppler – PWD – CWD – Harmonic Imaging – Combined (B+M, B+PWD, B+CD, B+Power, B+CWD)

Equivalency Conclusion

The subject device does not introduce any new technology or indications for use; therefore, the system is substantially equivalent to the predicate devices.

Nonclinical Performance Data

Nonclinical performance tests show compliance to the following standards:

Reference No.	Year	Title
AAMI/ANSI ES60601-1	2012	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2	2007 & 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Capability – Requirements and tests. (4th Edition)
IEC 60601-1-6	2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
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 used in the emergency medical services environment
IEC 60601-2-37	2004	Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment. (3rd and 4th Edition)
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 [Including: Corrigendum 1 (2013)]
IEC 62366	2014	Consolidated Version Medical Devices - Application of Usability Engineering to Medical Devices
ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5	2014	Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
ISO 10993-10	2014	Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization
ISO-10993-12	2014	Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials
ISO 62304	2006	Medical Device Software - Software Life Cycle Processes
ISO 15223-1	2012	Medical Devices - Symbols to be Used with Medical Devices Labels, Labeling, and Information to be Supplied - Part 1: General Requirements
ISO 14971	2007	Medical Devices - Applications of Risk Management to Medical Devices
NEMA UD 2	2009	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment - Revision 3

Clinical Testing

The Clarius Ultrasound Scanner did not require clinical testing to establish substantial equivalence.

Quality Assurance Measures

Quality assurance measures applied to the system design and development include, but were not limited to: risk analysis, verification and validation, product specifications, and design reviews.

Conclusion

This device is a modification of an existing licensed device using technologies that exist on the market today. The development and testing conducted on the device ascertain that it is safe for use by physicians. The Clarius Ultrasound Scanner does not introduce indications for use, technological features, or system characteristics that are not seen in its predicate devices; therefore, the device is substantially equivalent in safety and effectiveness to these predicate devices.