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

May 14, 2018

Re: K180799
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: May 8, 2018
Received: May 9, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*

K180799

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.

Indications for Use Tables

Clarius Ultrasound Scanner

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**	**PW Doppler**	**Combined (Specify)**	**Other***
Ophthalmic	Ophthalmic	P						
Fetal Imaging & Other	Fetal	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	
	Abdominal	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Intra-operative (Abdominal organs & vascular)	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Laparoscopic							
	Pediatric	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	P		P	P	N	B+CD; B+PD; B+PWD	Note 1
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	
	Trans-rectal	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	
	Trans-vaginal	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	
	Trans-urethral							
	Trans-esophageal (non-Cardiac)							
	Musculo-skeletal (Conventional)	P		P	P	N	B+CD; B+PD; B+PWD	Note 1
	Musculo-skeletal (Superficial)	P		P	P	N	B+CD; B+PDN	Note 1
	Intravascular							
	Other (Urology, Gynecology)	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	

SYSTEM: CLARIUS ULTRASOUND SCANNER

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

Cardiac	Cardiac Adult	P	P	P		N	B+M; B+CD; B+PWD	
	Cardiac Pediatric	P	P	P		N	B+M; B+CD; B+PWD	
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other							
Peripheral Vessel	Peripheral Vessel	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Other (Carotid)	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	Note 1
N = new indication; P = previously cleared by K172385 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**	**PW Doppler**	**Combined (Specify)**	**Other***
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	
	Abdominal	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	
	Intra-operative (Abdominal organs & vascular)	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	
	Laparoscopic							
	Pediatric	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	
	Small Organ (Thyroid, Prostate, Scrotum, Breast)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esophageal (non-Cardiac)							
	Musculo-skeletal (Conventional)	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology, Gynecology)	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	

DEVICE NAME: C3 CONVEX SCANNER

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

Cardiac	Cardiac Adult	P	P	P		N	B+M; B+CD; B+PWD	
	Cardiac Pediatric	P	P	P		N	B+M; B+CD; B+PWD	
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other							
Peripheral Vessel	Peripheral Vessel	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	
	Other (Carotid)							

N = new indication; P = previously cleared by K172385

Note 1: Needle Enhancement in B-Mode.

C7 Convex Scanner

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**	**PW Doppler**	**Combined (Specify)**	**Other***
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	
	Abdominal	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	
	Intra-operative (Abdominal organs & vascular)	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	
	Laparoscopic							
	Pediatric	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esophageal (non-Cardiac)							
	Musculo-skeletal (Conventional)	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology, Gynecology)	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	

DEVICE NAME: C7 CONVEX SCANNER

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

Cardiac	Cardiac Adult	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	
	Cardiac Pediatric	P	P	P		N	B+M; B+CD; B+PWD	
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other							
Peripheral Vessel	Peripheral Vessel	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	
	Other (Carotid)							

N = new indication; P = previously cleared by K172385

Note 1: Needle Enhancement in B-Mode.

L7 Linear Scanner

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**	**PW Doppler**	**Combined (Specify)**	**Other***
Ophthalmic	Ophthalmic	P						
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Intra-operative (Abdominal organs & vascular)	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Laparoscopic							
	Pediatric	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	P		P	P	N	B+CD; B+PD; B+PWD	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esophageal (non-Cardiac)							
	Musculo-skeletal (Conventional)	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Musculo-skeletal (Superficial)	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Intravascular							
	Other (Urology, Gynecology)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other							

DEVICE NAME: L7 LINEAR SCANNER

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

Peripheral Vessel	Peripheral Vessel	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Other (Carotid)	P	P	P	P	N	B+M; B+CD; B+PD; B+PWD	Note 1
N = new indication; P = previously cleared by K172385 Note 1: Needle Enhancement in B-Mode.								

DEVICE NAME: EC7 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**	**PW Doppler**	**Combined (Specify)**	**Other***
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	
	Abdominal	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	
	Intra-operative (Abdominal organs & vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	
	Trans-vaginal	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	
	Trans-urethral							
	Trans-esophageal (non-Cardiac)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology, Gynecology)	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	

DEVICE NAME: EC7 SCANNER

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

Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other							
Peripheral Vessel	Peripheral Vessel							
	Other (Carotid)							
N = new indication; P = previously cleared by K172385 Note 1: Needle Enhancement in B-Mode.								

510(k) Summary

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

Submitter: Brendan Seward
QA/RA Manager
Clarius Mobile Health Corp.
350 – 3605 Gilmore Way, Burnaby, B.C., Canada, V5G 4X5
Email: brendan.seward@clarius.me
Tel: (+1) 778-800-9975
Fax: N/A

Date Prepared: February 20, 2018

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:

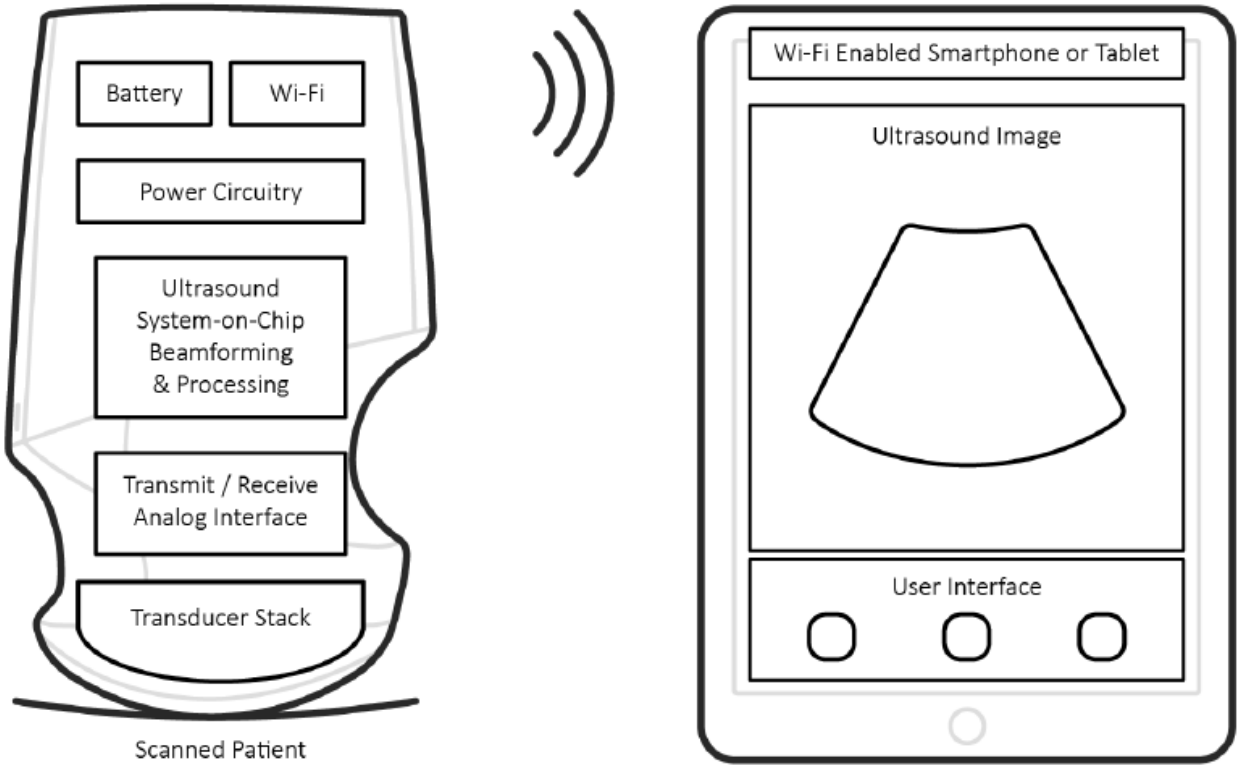
21 CFR Section	Classification Name	Product Code
892.1550	Ultrasonic Pulsed Doppler Imaging System	90 IYN
892.1560	Ultrasonic Pulsed Echo Imaging System	90 IYO
892.1570	Diagnostic Ultrasound Transducer	90 ITX

3. Substantially Equivalent Devices:

Device Name	510(k) Number
Clarius Ultrasound Scanner	K172385
ACUSON S3000, S2000, S1000 Diagnostic Ultrasound Systems	K172162

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 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.



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 into electronic signals in order to construct an image of the internal structures of an anatomical field. This image is sent wirelessly to an external 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 is performed via Wi-Fi Direct® (Ad-Hoc mode with security) for easy pairing.

The Clarius Ultrasound System product/package components include:

1. Software:
   - The Clarius Ultrasound App (Clarius App) for iOS; OR
   - The Clarius Ultrasound App (Clarius App) for Android.
2. Transducers/Scanners:
   - Clarius Scanner C3 (C3 Convex Transducer);
   - Clarius Scanner EC7 (EC7 Convex Endocavitary Transducer);
   - Clarius Scanner C7 (C7 Convex Transducer); OR
   - Clarius Scanner L7 (L7 Linear Transducer).

3. Accessories:
    a. Clarius-Built:
        - Battery Pack (Li-ion);
        - Battery Charger;
        - Clarius Dock (Optional; charging station); and
        - Clarius Fan (Optional).
    b. OEM/Off-the-Shelf Product(s):
        - Medical Power Supply (Off-the-shelf power adaptor from SL Power Electronics; Model Number ME20A1203B02; approved in the US); and
        - Medical Power Supply (Optional for use with Clarius Dock; off-the-shelf power adaptor from MEAN WELL Enterprises Co., Ltd.; Model Number GSM160B12-R7B; approved in the US).

The concept of the Clarius Ultrasound System transducers and software is to provide an easy to use, high-performance, low-cost, ultrasound platform for teaching and clinical applications. The Clarius Ultrasound Scanner 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 present submission is an expansion based upon a previous clearance – K172385. The subject changes of this new submission are the added mode of operation of Power Doppler and the addition of a new transducer model, Clarius Scanner EC7, which functions as an endocavitary scanner. This new scanner adds trans-rectal and trans-vaginal to the indications for use of the system. Appropriate changes have been made to mitigate risks and ensure effectiveness of these new features.

Intended Use

Diagnostic ultrasound imaging and fluid flow analysis.

Indications for Use

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.

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 Scanner	**FDA 510(k) Number** (K172385)
2.	**Device Name** ACUSON S3000, S2000, S1000 Diagnostic Ultrasound Systems	**FDA 510(k) Number** K172162

Determination of Substantial Equivalence

The Clarius Ultrasound system is a Track 3 system that employs the same fundamental scientific technology as that cleared with K172385 and K172162. 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 (K172385)	ACCUSON S3000, S2000, S1000 Ultrasound Systems (K172162)
Portability	Portable ultrasound system	Portable ultrasound system	Mobile 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 – Intracavity	– Convex Array – Linear Array – Phased Array	– Convex Array – Linear Array – Phased Array – Intracavity Array – 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 for Use	– Ophthalmic – Fetal – Abdominal – Intraoperative (Ab/Vasc) – – Pediatric – Small organ – – Adult cephalic – Trans-rectal – Trans-vaginal – Musculo-skel. (Conv.) – Musculo-skel. (Superfic.) – Urology – Gynecology – Cardiac adult – Cardiac pediatric – – – Peripheral vessel – Carotid – Needle guidance	– 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 – 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 – PWD – CWD – – Combined (B+M; B+CD; B+PD; B+PWD)	– B-mode – M-mode – Color Doppler – – Power Doppler – – CWD – – Combined (B+M, B+CD, B+PD)	– B-Mode – M-Mode – Color Doppler – Color M Doppler – Power Doppler – PWD – CWD – Harmonic Imaging – Combined (B+M, B+PWD, B+CD, B+PD, 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
AAMI ANSI ES60601-1	2012	AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, Mod). (General II (ES/EMC))
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 10993-11	2017	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
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 to the predicate devices indicated.

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.