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

November 30, 2016

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

Re: K163138
Trade/Device Name: Clarius Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: November 7, 2016
Received: November 8, 2016

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 yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163138

Device Name
Clarius Ultrasound System

Indications for Use *(Describe)*
The Clarius Ultrasound System is a software-based ultrasound imaging system and accessories intended for use in Point-of-Care Imaging of Medical Conditions on the general public.

Point-of-Care clinical applications include:

· Emergency triage exam to look at trauma conditions

· Procedure guidance to guide needles into the body; and

· Other targeted diagnostic and measurement applications: fetal, fetal echo, abdominal, small organ, musculo-skeletal (conventional), musculo-skeletal (superficial), urology, gynecology, cardiac adult, cardiac pediatric, peripheral vessel, pediatric, carotid

· The Clarius Ultrasound System is intended for use in environments where healthcare is provided by trained medical professionals. The device is not intended for use in emergency medical service, ambulance, or aircraft.

Users will be trained medical professionals (e.g., doctors, nurses, technicians).

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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"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."

DIAGNOSTIC ULTRASOUND INDICATION FOR USE FORM

510(k) Number: NA
Device Name: Clarius Ultrasound System
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	PWD	CWD	Color Doppler	Combined (specify)	Other*
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N						
	Abdominal	N						
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N						
	Small organ (thyroid, scrotum, prostate, breast)	N						
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N						
	Musculo-skeletal (Superficial)	N						
	Intravascular							
	Other (Urology, Gynecology)	N						
Cardiac	Cardiac Adult	N						
	Cardiac Pediatric	N						
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Fetal Echo)	N						
Peripheral	Peripheral Vessel	N						
Vessel	Other (Carotid)	N						

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

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging.

Additional Comments: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for nerve block procedures.

DIAGNOSTIC ULTRASOUND INDICATION FOR USE FORM

510(k) Number: NA
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	PWD	CWD	Color Doppler	Combined (specify)	Other*
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N						
	Abdominal	N						
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N						
	Small organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N						
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology, Gynecology)	N						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Fetal Echo)	N						
Peripheral	Peripheral Vessel	N						
Vessel	Other (Carotid)							

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

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging.

Additional Comments: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for nerve block procedures.

DIAGNOSTIC ULTRASOUND INDICATION FOR USE FORM

510(k) Number: NA
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	PWD	CWD	Color Doppler	Combined (specify)	Other*
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N						
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N						
	Small organ (thyroid, scrotum, prostate, breast)	N						
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N						
	Musculo-skeletal (Superficial)	N						
	Intravascular							
	Other (Urology, Gynecology)							
Cardiac	Cardiac Adult	N						
	Cardiac Pediatric	N						
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Fetal Echo)							
Peripheral	Peripheral Vessel	N						
Vessel	Other (Carotid)	N						

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

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging.

Additional Comments: Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for nerve block procedures.

Summary

1. Submitter's name, address, telephone number; Contact person

Submitter: Abhijit Ahir, Director of QA/RA
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Contact Person: Emergo Global Representative, LLC
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Austin, TX 78701 USA
Tel: (+1) 512-327-9997

Date Prepared: November 28, 2016

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 System

Common Name: Diagnostic Ultrasound System and Accessories

Classification: Class II

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
SONON Ultrasound Imaging System (Model: SONON 300C)	K151339
Philips Lumify Diagnostic Ultrasound System	K152899
FUJIFILM SonoSite Edge II Ultrasound System.	K153626

1. 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.

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 includes:

Product/Package Components:

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

2. Transducers/Scanners:
   - Clarius Scanner C3 (C3 Convex Transducer); OR
   - Clarius Scanner L7 (L7 Linear Transducer)

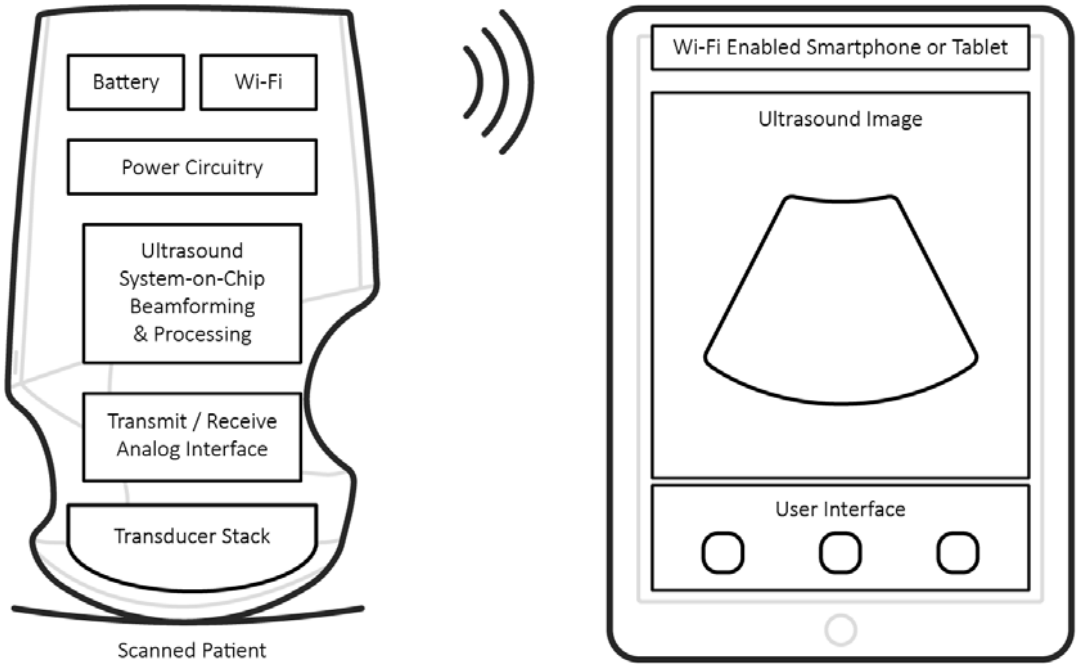
3. Accessories:
   a. Clarius-Built:

- Battery Pack (Li-ion)
- Battery Charger

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.

Aquasonic 100 Ultrasound Transmission Gel (Off-the-shelf ultrasound gel from Parker Laboratories Inc., USA; Approved in the US.



Ultrasound Probe *User Interface / Display*

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 not intended for use in Emergency Medical Service, ambulance, or aircraft environments.

2. Indication for Use

The Clarius Ultrasound System is a software-based ultrasound imaging system and accessories intended for use in Point-of-Care Imaging of Medical Conditions on the general public.

Point-of-Care clinical applications include:

- Emergency triage exam to look at trauma conditions
- Procedure guidance to guide needles into the body; and
- Other targeted diagnostic and measurement applications: fetal, fetal echo, abdominal, small organ, musculo-skeletal (conventional), musculo-skeletal (superficial), urology, gynecology, cardiac adult, cardiac pediatric, peripheral vessel, pediatric, carotid
- The Clarius Ultrasound System is intended for use in environments where healthcare is provided by trained medical professionals. The device is not intended for use in emergency medical service, ambulance, or aircraft.

Users will be trained medical professionals (e.g., doctors, nurses, technicians).

2.1 Contraindications

Do not use the Clarius Ultrasound System 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).
- Ophthalmic use or any use causing the acoustic beam to pass through the eye.
- Intra-operative use (e.g., defined as introducing a scanner into a surgical incision or burr hole).
- Endocavitary use (i.e., defined as introducing a scanner within a (body) cavity or organ. E.g. an atrium, esophagus, rectum, or vagina).
- Imaging an open wound.
- During transportation of a patient to a professional healthcare facility, or between professional healthcare facilities.
- At the scene of an emergency outside of a professional healthcare facility.

In terms of equivalent devices, we will refer to FDA's standard terminology for comparable devices: "predicate devices". The predicate devices selected to demonstrate equivalence are;

1. Device Name — FDA 510(k) Number
   SONON Ultrasound Imaging System. (Model 300C) — (K151339)

2. Device Name — FDA 510(k) Number
   Lumify Diagnostic Ultrasound System. — (K152899)

3. Device Name — FDA 510(k) Number
   FUJIFILM SonoSite Edge II Ultrasound System. — (K153626)

3. Determination of Substantial Equivalence

They Clarius Ultrasound system is a Track 3 system that employs the same fundamental scientific technology as that cleared with K151339, K152899 and K153626. All indications for use introduced by Clarius are indications used by one of the predicate devices. The K152899) and (K153626) do not connect with the display wirelessly. The Clarius ultrasound system is equivalent to the K151339in this respect.

Non-Clinical Performance Data

Non-clinical performance tests relied on this premarket notification submission for a determination of substantial equivalence include rests which show compliance to the following standards:

Reference No.	Year	Title
IEC 60601-1	2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. (Edition 3.1)

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. (4th Edition)
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)
ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

4. Quality Assurance measures

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

5. Conclusion

The Clarius Ultrasound System is essentially the same as it's predicate devices.
These are prescription devices. This statement appears in the labeling.
Sterilization is not applicable.

This is a Class II Device.