Clarius Mobile Health Corp.
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite #510k
SAINT PAUL MN 55114

August 29, 2019

Re: K192107
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: August 2, 2019
Received: August 5, 2019

Dear Prithul Bom:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192107

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.

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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	P	B+M; B+CD; B+PD; B+PWD	Note 1
	Abdominal	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	Note 1
	Intra-operative (Abdominal organs & vascular)	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	Note 1
	Laparoscopic							
	Pediatric	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	Note 1
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	Note 1
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	Note 1
	Trans-rectal	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	
	Trans-vaginal	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	
	Trans-urethral							
	Trans-esophageal (non-Cardiac)							
	Musculo-skeletal (Conventional)	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	Note 1
	Musculo-skeletal (Superficial)	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	Note 1
	Intravascular							
	Other (Urology, Gynecology)	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	
Cardiac	Cardiac Adult	P	P	P	N	P	B+M; B+CD; B+PD; B+PWD	Note 1
	Cardiac Pediatric	P	P	P	N	P	B+M; B+CD; B+PD; B+PWD	Note 1
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral Vessel	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	Note 1
	Other (Carotid)	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	Note 1
N = new indication; P = previously cleared by K180799 Note 1: Needle Enhancement in B-Mode.								

Clarius Scanner C3 HD

DEVICE NAME: CLARIUS SCANNER C3 HD

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)	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	
	Laparoscopic							
	Pediatric	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	
	Small Organ (Thyroid, Prostate, Scrotum, Breast)							
	Neonatal Cephalic							
	Adult Cephalic	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esophageal (non-Cardiac)							
	Musculo-skeletal (Conventional)	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology, Gynecology)	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	
Cardiac	Cardiac Adult	N	N	N		N	B+M; B+CD; B+PWD	
	Cardiac Pediatric	N	N	N		N	B+M; B+CD; B+PWD	
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral Vessel	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	
	Other (Carotid)							

N = new indication; P = previously cleared by K180799

Note 1: Needle Enhancement in B-Mode.

Clarius Scanner C7 HD

DEVICE NAME: CLARIUS SCANNER C7 HD

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)	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	
	Laparoscopic							
	Pediatric	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	
	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							
	Trans-vaginal							
	Trans-urethral							
	Trans-esophageal (non-Cardiac)							
	Musculo-skeletal (Conventional)	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology, Gynecology)	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	
Cardiac	Cardiac Adult	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	
	Cardiac Pediatric	N	N	N		N	B+M; B+CD; B+PWD	
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral Vessel	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	
	Other (Carotid)							

N = new indication; P = previously cleared by K180799

Note 1: Needle Enhancement in B-Mode.

Clarius Scanner EC7 HD

DEVICE NAME: CLARIUS SCANNER EC7 HD

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	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Carotid)							

N = new indication; P = previously cleared by K180799

Note 1: Needle Enhancement in B-Mode.

Clarius Scanner L7 HD

DEVICE NAME: CLARIUS SCANNER L7 HD

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	N						
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Intra-operative (Abdominal organs & vascular)	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Laparoscopic							
	Pediatric	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	N		N	N	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)	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Musculo-skeletal (Superficial)	N	N	N	N	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 (specify)							
Peripheral Vessel	Peripheral Vessel	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Other (Carotid)	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	Note 1

N = new indication; P = previously cleared by K180799

Note 1: Needle Enhancement in B-Mode.

Clarius Scanner L15 HD

DEVICE NAME: CLARIUS SCANNER L15 HD

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							
	Abdominal	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Intra-operative (Abdominal organs & vascular)	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Laparoscopic							
	Pediatric	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	N		N	N	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)	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Musculo-skeletal (Superficial)	N	N	N	N	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 (specify)							
Peripheral Vessel	Peripheral Vessel	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Other (Carotid)	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	Note 1

N = new indication; P = previously cleared by K180799

Note 1: Needle Enhancement in B-Mode.

Clarius Scanner PA HD

DEVICE NAME: CLARIUS SCANNER PA HD

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	Note 1
	Abdominal	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Intra-operative (Abdominal organs & vascular)	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Laparoscopic							
	Pediatric	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Small Organ (Thyroid, Prostate, Scrotum, Breast)							
	Neonatal Cephalic							
	Adult Cephalic	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esophageal (non-Cardiac)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology, Gynecology)							
Cardiac	Cardiac Adult	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Cardiac Pediatric	N	N	N	N	N	B+M; B+CD; B+PD; B+PWD	Note 1
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Carotid)							

N = new indication; P = previously cleared by K180799

Note 1: Needle Enhancement in B-Mode.

Clarius Scanner C3

DEVICE NAME: CLARIUS SCANNER C3

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	P	B+M; B+CD; B+PD; B+PWD	
	Abdominal	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	
	Intra-operative (Abdominal organs & vascular)	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	
	Laparoscopic							
	Pediatric	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	
	Small Organ (Thyroid, Prostate, Scrotum, Breast)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	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	P	B+M; B+CD; B+PD; B+PWD	
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology, Gynecology)	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	
Cardiac	Cardiac Adult	P	P	P		P	B+M; B+CD; B+PWD	
	Cardiac Pediatric	P	P	P		P	B+M; B+CD; B+PWD	
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral Vessel	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	
	Other (Carotid)							

N = new indication; P = previously cleared by K180799

Note 1: Needle Enhancement in B-Mode.

Clarius Scanner C7

DEVICE NAME: CLARIUS SCANNER C7

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	P	B+M; B+CD; B+PD; B+PWD	
	Abdominal	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	
	Intra-operative (Abdominal organs & vascular)	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	
	Laparoscopic							
	Pediatric	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	P	P	P	P	P	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	P	B+M; B+CD; B+PD; B+PWD	
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology, Gynecology)	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	
Cardiac	Cardiac Adult	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	
	Cardiac Pediatric	P	P	P		P	B+M; B+CD; B+PWD	
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral Vessel	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	
	Other (Carotid)							

N = new indication; P = previously cleared by K180799

Note 1: Needle Enhancement in B-Mode.

Clarius Scanner EC7

DEVICE NAME: CLARIUS SCANNER EC7

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	P	B+M; B+CD; B+PD; B+PWD	
	Abdominal	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	
	Intra-operative (Abdominal organs & vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	
	Trans-vaginal	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	
	Trans-urethral							
	Trans-esophageal (non-Cardiac)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Urology, Gynecology)	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Carotid)							

N = new indication; P = previously cleared by K180799

Note 1: Needle Enhancement in B-Mode.

Clarius Scanner L7

DEVICE NAME: CLARIUS SCANNER L7

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	P	B+M; B+CD; B+PD; B+PWD	Note 1
	Intra-operative (Abdominal organs & vascular)	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	Note 1
	Laparoscopic							
	Pediatric	P	P	P	P	P	B+M; B+CD; B+PD	Note 1
	Small Organ (Thyroid, Prostate, Scrotum, Breast)	P		P	P	P	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	P	B+M; B+CD; B+PD; B+PWD	Note 1
	Musculo-skeletal (Superficial)	P	P	P	P	P	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 (specify)							
Peripheral Vessel	Peripheral Vessel	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	Note 1
	Other (Carotid)	P	P	P	P	P	B+M; B+CD; B+PD; B+PWD	Note 1

N = new indication; P = previously cleared by K180799

Note 1: Needle Enhancement in B-Mode.

K192107

510(k) Summary

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

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Date Prepared: May 13, 2019

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 Device:

Device Name: Clarius Ultrasound Scanner

510(k) Number: K180799

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 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.

Users will be trained medical professionals (e.g., doctors, nurses, technicians) with previous training in ultrasound.

The Clarius Ultrasound Scanner product/package components include:

Non-HD Packages

1. Software:
   - The Clarius Ultrasound App (Clarius App) for iOS; and
   - The Clarius Ultrasound App (Clarius App) for Android.
2. Transducers/Scanners:
   - Clarius Scanner C3;
   - Clarius Scanner EC7;
   - Clarius Scanner C7; and
   - Clarius Scanner L7;
3. Accessories:
   - Clarius-Built:
     - Battery Pack (Li-ion);
     - Battery Charger; and
     - Clarius Fan.
   - 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).

HD Packages

1. Software:
   - The Clarius Ultrasound App (Clarius App) for iOS; and
   - The Clarius Ultrasound App (Clarius App) for Android.
2. Transducers/Scanners:
   - Clarius Scanner C3 HD
   - Clarius Scanner L7 HD;
   - Clarius Scanner C7 HD;
   - Clarius Scanner EC7 HD;
   - Clarius Scanner L15 HD; and
   - Clarius Scanner PA HD.
4. Accessories:
   - Clarius-Built:
     - Clarius Battery HD;
     - Clarius Charger HD; and
     - Clarius Fan HD.
   - OEM/Off-the-Shelf Product(s):
     - Medical Power Supply (Off-the-shelf power adaptor from GlobTek, Inc.; Model Number WR9QA3200USBNMEDR6B; approved in the US).

The concept of the Clarius Ultrasound Scanner 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 Scanner is intended for use in professional healthcare environments where healthcare is provided by trained medical professionals.

Changes Implemented

The subject change of this 510(k) is the addition of a new set of transducer models to the Clarius Ultrasound Scanner family. The new set of scanners comprises the Clarius Scanner L7 HD (L7 HD), Clarius Scanner C3 HD (C3 HD), Clarius Scanner C7 HD (C7 HD), Clarius Scanner EC7 HD (EC7 HD), Clarius Scanner L15 HD (L15 HD), and Clarius Scanner PA HD (PA HD). An overview of the changes implemented are provided below:

Changed Specification	Clarius Ultrasound Scanner (Subject 510(k))	Clarius Ultrasound Scanner (K180799)
Models	C3, C7, L7, EC7, C3 HD, L7 HD, C7 HD, EC7 HD, L15 HD, PA HD	C3, C7, L7, EC7
Accessories	Non-HD Scanners: • Battery Pack (Li-ion); • Battery Charger; • Clarius Dock (optional); • Clarius Fan; and • Medical Power Supply. HD Scanners: • Clarius Battery HD • Clarius Charger HD • Clarius Fan HD	Battery Pack (Li-ion); Battery Charger; Clarius Dock (optional); Clarius Fan (optional); Medical Power Supply; and Medical Power Supply for Clarius Dock
Biocompatibility Testing	All models utilize identical materials to the predicate Clarius models.	ISO 10993-5, ISO 10993-10, and ISO 10993-11 for the Clarius Scanner EC7. All other models utilize identical materials to the predicate Clarius models.

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 Device

Equivalent devices are referred to as predicate devices in alignment with the FDA's standard terminology for comparable devices. The predicate device selected to demonstrate equivalence is the Clarius Ultrasound Scanner (K180799).

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Determination of Substantial Equivalence

The Clarius Ultrasound system is a Track 3 system that employs the same fundamental scientific technology as that cleared with K180799. All indications for use introduced by the Clarius Ultrasound Scanner are identical to the predicate device. A comparison table is provided below:

Criteria for Comparison	Clarius Ultrasound Scanner (Subject Device)	Clarius Ultrasound Scanner (K180799)
Portability	Portable ultrasound system	Portable ultrasound system
Power Source	Removable battery (Li-ion)	Removable battery (Li-ion)
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
510(k) Track	Track 3	Track 3
Transducer Types	– Convex Array – Linear Array – Phased Array – Intracavity	– Convex Array – Linear Array – Phased Array – Intracavity
Intended Use	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 – Trans-rectal – Trans-vaginal – Musculo-skel. (Conv.) – Musculo-skel. (Superfic.) – Urology – Gynecology – Cardiac adult – Cardiac pediatric – Peripheral vessel – Carotid – Needle guidance
Modes of Operation	– B-mode – M-mode – Color Doppler – Power Doppler – PWD – Combined (B+M; B+CD; B+PD; B+PWD)	– B-mode – M-mode – Color Doppler – Power Doppler – PWD – Combined (B+M; B+CD; B+PD; B+PWD)

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Nonclinical Performance Data

Nonclinical performance tests show compliance to the following standards:

Standard	Title of Standard
ANSI/AAMI 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)
IEC 60601-1-12 Edition 1.0 2014-06	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 60601-1-2 Edition 4.0 2014-02	Medical Electrical Equipment -- Part 1-2: General Requirements for Basic Safety and Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements and Tests
IEC 60601-1-6 Edition 3.1 2013-10	Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
IEC 60601-2-37 Edition 2.1 2015	Medical Electrical Equipment - Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment
IEC 62133 Edition 2.0 2012-12	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 62304:2006	Medical Device Software - Software Life Cycle Processes
ISO 10993-10 Third Edition 2010-08-01	Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization
ISO 10993-11 Third Edition 2017-09	Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity
ISO 10993-5 Third Edition 2009-06-01	Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
ISO 14971 Second Edition 2007-03-01	Medical Devices - Application of Risk Management to Medical Devices
ISO 15223-1:2012	Medical Devices - Symbols to be Used with Medical Devices Labels, Labeling, and Information to be Supplied - Part 1: General Requirements
UD 2-2004 (R2009)	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 were conformant with FDA Quality System Requirements (QSR) 21 CFR 820.

Conclusion

This device is a modification of an existing licensed device using technologies that exist on the market as of the date of this submission. 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 the predicate device.