Hitachi Healthcare Americas
℅ Aaron Pierce
Director, RA/QA
1959 Summit Commerce Park
TWINSBURG OH 44087

August 9, 2019

Re: K191233
Trade/Device Name: ARIETTA 750
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: June 11, 2019
Received: June 12, 2019

Dear Aaron Pierce:

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)*
K191233

Device Name
ARIETTA 750

Indications for Use *(Describe)*
The ARIETTA 750 is intended for use by trained personnel (doctor, Sonographer, etc.) for the diagnostic ultrasound evaluation of Fetal, Abdominal, Intra-operative (Spec.), Intra-operative (Neuro.), Laparoscopic, Pediatric, Small Organ (Spec.), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Trans-esoph. (non-Card.), Musculo-skel. (Convent.), Musculo-skel. (Superfic.), Wound (Cavernous/Non-Cavernous), Gynecology, Cardiac Adult, Cardiac Pediatric, Trans-esophageal (card.), Peripheral vessel clinical applications.
The Modes of Operation are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Power Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging.

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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"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 INDICATIONS FOR USE FORM

Device Name: ARIETTA 750

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spe	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)	P	P	P		P	P	P
	Laparoscopic	P	P	P		P	P	P
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd	Pd	Pd	Pd	Pd
	Neonatal Cephalic	P	P	P	P	P	P	P
	Adult Cephalic	P	P	P	P	P	P	P
	Trans-rectal	Pe	Pe	Pe		Pe	Pe	Pe
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							
	Trans-esoph. (non-Card.)	Pg	Pg	Pg	Pg	Pg	Pg	Pg
	Musculo-skel. (Convent.)	P	P	P	P	P	P	P
	Musculo-skel. (Superfic.)	P	P	P	P	P	P	P
	Intra-luminal							
	Other (Wound)	Ph	Ph	Ph	Ph	Ph	Ph	Ph
	Other (Gynecological)	P	P	P		P	P	P
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (Adult/Pediatric)	Pg	Pg	Pg	Pg	Pg	Pg	Pg
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

N = new indication; P = previously cleared in K173739, K160559

*Combination of each operating mode, B, M, PWD, CWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW B/CW, CFM-B/CW

**Power Doppler (Color Flow Angiography), Free Angular M-mode, Tissue Doppler Imaging, Shear Wave Measurement, Real time 3D Imaging, 4D Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript “e”: Includes imaging for guidance of trans-rectal biopsy

Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.

Subscript “g”: For Adult and pediatric patients

Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: C252
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spe	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd	Pd	Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication; P = previously cleared in K173739, K181376
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW B/CW, CFM-B/CW
**Power Doppler (Color Flow Angiography), Free Angular M-mode, Tissue Doppler Imaging, Shear Wave Measurement

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: C253
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spe	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd	Pd	Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication; P = previously cleared in K173739, K181376
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW B/CW, CFM-B/CW
**Power Doppler (Color Flow Angiography), Free Angular M-mode, Tissue Doppler Imaging, Shear Wave Measurement

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: C35
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spe	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd	Pd	Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication; P = previously cleared in K173739, K181376
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW B/CW, CFM-B/CW
**Power Doppler (Color Flow Angiography), Free Angular M-mode, Tissue Doppler Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: C22P
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spe	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication; P = previously cleared in K173739, K181376
*Combination of each operating mode, B, M, PWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW
**Power Doppler (Color Flow Angiography), Free Angular M-mode

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: C25P
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spe	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication; P = previously cleared in K173739, K181376
*Combination of each operating mode, B, M, PWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW
**Power Doppler (Color Flow Angiography), Free Angular M-mode

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: C41V1
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spe	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Pe	Pe	Pe		Pe	Pe	Pe
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)	P	P	P		P	P	P
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication; P = previously cleared in K173739, K181376
*Combination of each operating mode, B, M, PWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW
**Power Doppler (Color Flow Angiography), Free Angular M-mode

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: C41B
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spe	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Pe	Pe	Pe		Pe	Pe	Pe
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)	P	P	P		P	P	P
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication; P = previously cleared in K173739, K181376
*Combination of each operating mode, B, M, PWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW
**Power Doppler (Color Flow Angiography), Free Angular M-mode,

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: C42
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)	Pb	Pb	Pb	Pb	Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd	Pd	Pd	Pd	Pd
	Neonatal Cephalic	P	P	P	P	P	P	P
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

N = new indication; P = previously cleared in K134016
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW B/CW, CFM-B/CW
**Power Doppler (Color Flow Angiography), Free Angular M-mode

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: L441
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spe	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd	Pd	Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P	P	P	P	P
	Musculo-skel. (Superfic.)	P	P	P	P	P	P	P
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

N = new indication; P = previously cleared in K173739, K181376
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW B/CW, CFM-B/CW
**Power Doppler (Color Flow Angiography), Free Angular M-mode

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: L442
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spe	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd	Pd	Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P	P	P	P	P
	Musculo-skel. (Superfic.)	P	P	P	P	P	P	P
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

N = new indication; P = previously cleared in K173739, K181376
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW B/CW, CFM-B/CW
**Power Doppler (Color Flow Angiography), Free Angular M-mode

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: L53K
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication; P = previously cleared in K173739
*Combination of each operating mode, B, M, PWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW
**Power Doppler (Color Flow Angiography), Free Angular M-mode

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: L55
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spe	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (Wound)	Ph	Ph	Ph		Ph	Ph	Ph
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication; P = previously cleared in K173739, K181376
*Combination of each operating mode, B, M, PWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW
**Power Doppler (Color Flow Angiography), Free Angular M-mode, Tissue Doppler Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript "e": Includes imaging for guidance of trans-rectal biopsy
Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.
Subscript "g": For Adult and pediatric patients
Subscript "h" Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: L64
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spe	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd	Pd	Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P	P	P	P	P
	Musculo-skel. (Superfic.)	P	P	P	P	P	P	P
	Intra-luminal							
	Other (Wound)	Ph	Ph	Ph	Ph	Ph	Ph	Ph
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

N = new indication; P = previously cleared in K173739, K181376
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW B/CW, CFM-B/CW
**Power Doppler (Color Flow Angiography), Free Angular M-mode, Shear Wave Measurement

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: R41R
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication; P = previously cleared in K134016
*Combination of each operating mode, B, M, PWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW
**Power Doppler (Color Flow Angiography)

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: R41RL
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication; P = previously cleared in K134016
*Combination of each operating mode, B, M, PWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW
**Power Doppler (Color Flow Angiography)

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: S11
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spe	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	P	P	P	P	P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	P	P
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

N = new indication; P = previously cleared in K173739, K181376
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW B/CW, CFM-B/CW
**Power Doppler (Color Flow Angiography), Free Angular M-mode, Tissue Doppler Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: S121
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spe	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	P	P	P	P	P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	P	P
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

N = new indication; P = previously cleared in K173739, K181376
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW B/CW, CFM-B/CW
**Power Doppler (Color Flow Angiography), Free Angular M-mode, Tissue Doppler Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: S31
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spe	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P	P	P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)							
	Neonatal Cephalic	P	P	P	P	P	P	P
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication; P = previously cleared in K173739, K181376
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW B/CW, CFM-B/CW
**Power Doppler (Color Flow Angiography), Free Angular M-mode, Tissue Doppler Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: S42
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spe	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P	P	P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)							
	Neonatal Cephalic	P	P	P	P	P	P	P
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication; P = previously cleared in K173739, K181376
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW B/CW, CFM-B/CW
**Power Doppler (Color Flow Angiography), Free Angular M-mode, Tissue Doppler Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: S3ESL1
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spe	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	Pg	Pg	Pg	Pg	Pg	Pg	Pg
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)	Pg	Pg	Pg	Pg	Pg	Pg	Pg
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication; P = previously cleared in K173739, K160559
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW B/CW, CFM-B/CW
**Power Doppler (Color Flow Angiography), Free Angular M-mode, Tissue Doppler Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: CC41R
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Pe	Pe	Pe		Pe	Pe	Pe
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication; P = previously cleared in K134016
*Combination of each operating mode, B, M, PWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW
**Power Doppler (Color Flow Angiography), Free Angular M-mode

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: C41L47RP
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spe	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Pe	Pe	Pe		Pe	Pe	Pe
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication; P = previously cleared in K173739, K160559
*Combination of each operating mode, B, M, PWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW
**Power Doppler (Color Flow Angiography), Free Angular M-mode

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: VC35
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	P	P	P		P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication; P = previously cleared in K134016
*Combination of each operating mode, B, M, PWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW
**Power Doppler (Color Flow Angiography), Free Angular M-mode, Tissue Doppler Imaging 3D Imaging, 4D Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: VC41V
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	P	P
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)	P	P	P		P	P	P
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication; P = previously cleared in K134016
*Combination of each operating mode, B, M, PWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW
**Power Doppler (Color Flow Angiography), Free Angular M-mode, 3D Imaging, 4D Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA 750
Transducer: UST-2265-2
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spe	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel				P			
	Other (spec.)							

N = new indication; P = previously cleared in K173739, K181376

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).
Subscript "b": Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).
Subscript “c”: Includes thyroid, parathyroid, breast, scrotum, and penis.
Subscript “d”: Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.
Subscript “e”: Includes imaging for guidance of trans-rectal biopsy
Subscript “f”: Includes imaging for guidance of trans-vaginal biopsy.
Subscript “g”: For Adult and pediatric patients
Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

Prescription Use Only (Per 21 CFR 801.109)

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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k) K191233

Section 5
510(k) Summary

K191233

Submitter Information

Submitter:	Hitachi Healthcare Americas 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371
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Date:	January 18, 2019

Subject Device Name

Trade/Proprietary Name:	ARIETTA 750
Regulation Number:	21 CFR 892.1550
Regulation Name:	Diagnostic Ultrasound System and Accessories
Product Code	90-IYN, 21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System 90-IYO, 21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System 90-ITX, 21 CFR 892.1570 Diagnostic Ultrasonic Transducer
Class	II
Panel	Radiology

Predicate Device Name

Predicate Device(s):	ALOKA ARIETTA 850 (K183456)
Regulation Number:	21 CFR 892.1550
Regulation Name:	Diagnostic Ultrasound System and Accessories
Product Code	90-IYN, 21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System 90-IYO, 21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System 90-ITX, 21 CFR 892.1570 Diagnostic Ultrasonic Transducer
Class	II
Panel	Radiology
Reference Devices	• ARIETTA 70 Diagnostic Ultrasound Scanner (K134016) • ARIETTA 65 Diagnostic Ultrasound Scanner (K181376) • Intra-operative Ultrasound Transducer, PROSOUND ALPHA 7 Diagnostic Ultrasound System, ARIETTA 70 Diagnostic Ultrasound System (K142618)

Indications for Use

The ARIETTA 750 is intended for use by trained personnel (doctor, Sonographer, etc.) for the diagnostic ultrasound evaluation of Fetal, Abdominal, Intra-operative (Spec.), Intra-operative (Neuro.), Laparoscopic, Pediatric, Small Organ (Spec.), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Trans-esoph. (non-Card.), Musculo-skel. (Convent.), Musculo-skel. (Superfic.), Wound (Cavernous/Non-Cavernous), Gynecology, Cardiac Adult, Cardiac Pediatric, Trans-esophageal (card.), Peripheral vessel clinical applications.

The Modes of Operation are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Power Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging.

Device Description

Function

The ARIETTA 750 is a multi-functional ultrasound diagnostic scanner in which Doppler, Color Flow Mapping, etc. are provided and all circuits related to image quality are fully digitalized. This device can be utilized with linear, convex, radial and phased array scan type probes for usage with a variety of clinical applications.

The ARIETTA 750 can be used for individual or combined display in the image display model listed below.

- B mode is a display mode in which the tomographic image is formed with plural ultrasound beams by the methods mentioned above. During the process of creating the tomographic image, adaptive filters (HI REZ) that modify the characteristics of each echo filter are used to produce a clear image.
- M mode is a display mode of ultrasound beams received sequentially and repeatedly on the screen from the same direction. It indicates these reflected echoes in one direction from the interior of the patient's body's on time-series scale.
- There are two types of D (Doppler) mode: PW Doppler mode and CW Doppler mode. PW Doppler mode displays bloodstream information consecutively at a sample point that is detected by pulsed Doppler sonography. CW Doppler mode displays bloodstream information continuously in the single-direction ultrasound beam that is detected by the CW Doppler method.
- Color Doppler mode receives ultrasound from the same direction and detects any changes that occur over time to identify three types of bloodstream information: its direction, its speed, and its inconsistency. The mode then colors that information and displays it as an overlay on B mode or M mode. Color Flow Mode, Power Doppler Mode, High-Resolution Power Doppler (eFlow) Mode can be used with this instrument according to need.

The 5 methods of electronic scanning are as follows.

- Linear Scanning Method:

  By this method, the ultrasound beam from the ultrasound probe is emitted in a straight line (linearly) and draws a tomographic image of the test subject.
- Convex Scanning Method:

  By this method, the ultrasound beam from the ultrasound probe is emitted radially and draws a tomographic image of the test subject.
- Sector Scanning Method:

  By this method, the ultrasound beam from the ultrasound probe is emitted in a fan shape (sector) and draws a tomographic image of the test subject.
- Radial Scanning Method:

  By this method, the ultrasound probe emits a 360 degree (radial) ultrasound beam and draws a tomographic image of the test subject.
- Trapezoidal Scanning Method:

  By this method, the ultrasound beam from the ultrasound probe is emitted radially without regard to the form of the probe head and draws a tomographic image of the patient.

Scientific Concepts

The principle of operation of ultrasound imaging involves a number of transducers of multiple available transducers form a block that almost simultaneously transmit and receive ultrasound waves. The ultrasound waves generated by each transducer combine to form one ultrasound wave with the same effect as a single ultrasound beam emitted from the center of these transducers. When the first beam has been sent and received, transducers adjacent to the transducers in the first block start sending and receiving ultrasound waves to form the second ultrasound beam. The center of the second ultrasound beam is shifted from the center of the first ultrasound by one transducer. In this manner, different blocks of transducers are used each time to create multiple ultrasound beams with a slightly different center and form a scan plane. Also, the beams can be focused together by adding a time difference to the transmission and reception that creates the beams, to join them in an acoustic focus. Continuously setting the focal time difference according to the ultrasonic wave arrival time can obtain a beam that is joined in overall focus.

This instrument can also revise the time difference between ultrasonic waves that arrive at different times due to different speeds within the patient or diagnostic region.

The ultrasound beams obtained as explained above are converted to video signals with the digital scanning converter, and are displayed on the viewing monitor.

Physical and Performance Characteristics

Analysis confirms the performance characteristics of the ARIETTA 750 are comparable to the predicate device and support our conclusion that the subject system is substantially equivalent.

Performance Comparison

No new hazards were identified with the ARIETTA 750. The subject device and its transducers have been evaluated for acoustic output, biocompatibility, cleaning & disinfection effectiveness, electromagnetic compatibility, as well as electrical and mechanical safety, and have been found to conform to applicable medical device safety standards.

Testing Type	Rationale Analysis
Performance Testing - Bench	Hitachi judged that ARIETTA 750 is substantially equivalent to the predicate.
Performance Testing - Clinical	None required

The analysis confirms the performance characteristics of the ARIETTA 750 are comparable to the predicate device and support our conclusion that the subject device is substantially equivalent.

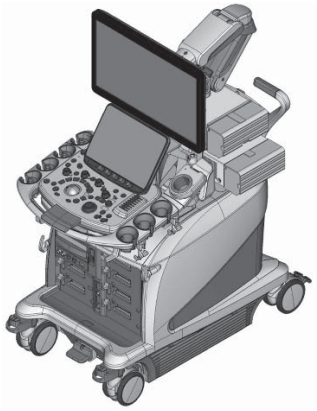
Device Technological Characteristics

The technological characteristics differences between the ARIETTA 750 and the predicate device ALOKA ARIETTA 850 (K183456) are:

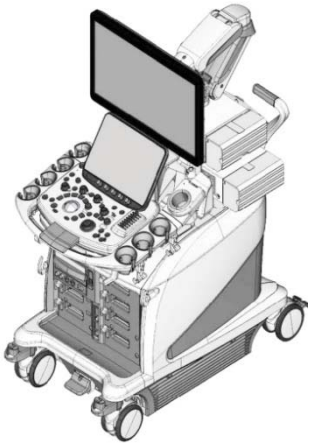
- Physical characteristics of the system

There are no significant differences in appearance, weight, size, hardware, transmit/receive parameters, modes of operation, and features from the predicate device.

ARIETTA 750
Subject Device



ARIETTA 850
Predicate Device



- Probes

AVAILABLE PROBE	PREVIOUS CLEARANCE
C22P	ALOKA ARIETTA 850 K173739
C25P	ALOKA ARIETTA 850 K173739
C252	ALOKA ARIETTA 850 K173739
C253	ARIETTA 65 K181376
C35	ALOKA ARIETTA 850 K173739
C41V1	ALOKA ARIETTA 850 K173739
C41B	ALOKA ARIETTA 850 K173739
C42	NOBLUS K160559
CC41R	NOBLUS K160559
C41L47RP	NOBLUS K160559
L441	ALOKA ARIETTA 850 K173739
L442	ARIETTA 65 K181376
L53K	ARIETTA Precision K163505
L55	ALOKA ARIETTA 850 K173739
L64	ALOKA ARIETTA 850 K173739
R41R	ALOKA ARIETTA 850 K173739
R41RL	ALOKA ARIETTA 850 K173739
S11	ARIETTA 65 K181376
S121	ALOKA ARIETTA 850 K173739
S31	ALOKA ARIETTA 850 K173739
S42	ALOKA ARIETTA 850 K173739
S3ESL1	ALOKA ARIETTA 850 K173739
VC35	ALOKA ARIETTA 850 K173739
VC41V	ARIETTA 70 K134016
UST-2265-2	ALOKA ARIETTA 850 K173739

Substantial Equivalence

A summary decision was based on a thorough analysis and comparison of the functions, scientific concepts, physical and performance characteristics, performance comparison and technological characteristics.

System Configuration	
01	Based on that there are no significant differences in size, weight, connections, and Track from the predicate device, Hitachi judges that the ARIETTA 750 has no additional issues with safety and effectiveness.
Probes	
02	The 25 probes for the system meet user requirements in regards to indications for use and have no effect on the safety and effectiveness of the device. These probes have been cleared by previous 510(k) submissions. See Probe Comparison Chart below.
Transmit/Receive Parameters	
03	Based on that there are no significant differences from the predicate device, Hitachi judges that the ARIETTA 750 has no additional issues with safety and effectiveness.
Modes of Operation	
04	The ARIETTA 750 has no significant differences in the modes that are available on both systems. Therefore, Hitachi judges that the ARIETTA 750 has no additional issues with safety and effectiveness.
Features	
05	The ARIETTA 750 has no significant differences in the features that are available on both systems. Therefore, Hitachi judges that the ARIETTA 750 has no additional issues with safety and effectiveness.

Based on analysis of the above-mentioned comparison, Hitachi has judged the subject device to have the equivalent safety and effectiveness of the predicate device.

Summary of Non-Clinical Testing

The ARIETTA 750 system is in conformance with the applicable parts of the following standards:

- AAMI ANSI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- 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. (Radiology)
- 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 compatibility - requirements and tests. (General II (ES/EMC))
- AAMI I ANSI I ISO 10993-1:2009/(R)2013
  Biological evaluation of medical devices - part I: evaluation and testing within a risk management process. (Biocompatibility)
- AAMI I ANSI I ISO 10993-5:2009/(R)2014
  Biological evaluation of medical devices - part 5: tests for in vitro cytotoxicity. (Biocompatibility)
- AAMI I ANSI I ISO I 0993-10: 2002 + am1 2006
  Biological evaluation of medical devices - part I 0: tests for irritation and skin sensitization. (Biocompatibility)

Summary of Clinical Testing

Clinical testing was not required.

Conclusions

It is the opinion of Hitachi, Ltd. that the ARIETTA 750 Ultrasound Diagnostic scanner and transducers is substantially equivalent to the predicate devices. The subject device software features, intended use, materials, and diagnostic capabilities have been taken from the predicate devices. In addition, we have concluded that the subject device and predicate devices are substantially equivalent with respect to safety, effectiveness, and functionality.