DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 15, 2016

Hitachi, Ltd.
% Ms. Angela Van Arsdale
RA/QA Manager
10 Fairfield Boulevard
WALLINGFORD CT 06492

Re: K162902
Trade/Device Name: ARIETTA Prologue Diagnostic Ultrasound System and Transducers
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: October 13, 2016
Received: October 18, 2016

Dear Ms. Van Arsdale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162902

Device Name
ARIETTA Prologue Diagnostic Ultrasound System and Transducers

Indications for Use *(Describe)*

ARIETTA Prologue is intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of following clinical applications: FETAL; ABDOMINAL - (Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis)); INTRA-OPERATIVE (SPEC.) - (Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures)); INTRA-OPERATIVE (NEURO); LAPAROSCOPIC; PEDIATRIC; SMALL ORGAN (SPEC.) - (Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy); NEONATAL CEPHALIC; ADULT CEPHALIC; TRANS-RECTAL - (Includes imaging for guidance of trans-rectal biopsy); TRANS-VAGINAL - (Includes imaging for guidance of trans-vaginal biopsy); TRANS-ESOPHAGEAL (NON-CARDIAC & CARDIAC) - ADULT/PEDIATRIC; MUSCULOSKELETAL (CONVENT./ SUPERFIC.); Other (spec.) -WOUND (Includes imaging for Cavernous/Non-Cavernous wounds); Other (spec) - GYNECOLOGICAL; CARDIAC: ADULT/ PEDIATRIC and PERIPHERAL VESSEL.

The Modes of Operation are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Amplitude Doppler (Color Flow Angiography) and TDI (Tissue Doppler Imaging), Omni Directional M mode.

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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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA Prologue

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
	Neonatal Cephalic	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
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (Wound)	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 K134016, K142368

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

**Power Doppler (Color Flow Angiography), Tissue Doppler Imaging, Free Angular M-mode, Trapezoid 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)

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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)_____

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA Prologue
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 K142368
*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)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA Prologue
Transducer: C251
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	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.)							
	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 K142368
*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), Tissue Doppler Imaging, 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)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA Prologue
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 K142368
*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)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA Prologue
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
	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.)							
	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 K142368
*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), Tissue Doppler Imaging, 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

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA Prologue
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 K142368
*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)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA Prologue
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 K142368
*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)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA Prologue
Transducer: C42K
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.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic	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							
	Other (spec.)							

N = new indication; P = previously cleared in K142368
*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).
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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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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA Prologue
Transducer: L44
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)							
	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 K142368
*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, Trapezoid 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

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA Prologue
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
	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)							
	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 K142368
*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, Trapezoid 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

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA Prologue
Transducer: L44LA
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.)	P	P	P		P	P	P
	Intra-operative (Neuro.)							
	Laparoscopic	P	P	P		P	P	P
	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 K142368
*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, Trapezoid 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

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA Prologue
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* (Spe	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 K142368
*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, Trapezoid 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

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA Prologue
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 K142368
*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, Trapezoid 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

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA Prologue
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
	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 K142368
*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, Trapezoid 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

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA Prologue
Transducer: S211
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 K142368
*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, CFM-B/CW
**Power Doppler (Color Flow Angiography), Tissue Doppler Imaging, 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)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA Prologue
Transducer: S31KP
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.)	P	P	P		P	P	P
	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 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)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ARIETTA Prologue
Transducer: S3ESEL
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 K142368
*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, CFM-B/CW
**Power Doppler (Color Flow Angiography), Tissue Doppler Imaging, 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

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510(k) Summary of Safety and Effectiveness in accordance with 21 CFR Part 807, Subpart E, Section 807.92.

21 CFR 807.92, Subsection a

1. Submitter's Information

Hitachi Aloka Medical America, Inc.
10 Fairfield Boulevard
Wallingford, CT 06492-5903

On behalf of Hitachi, Ltd. Tokyo, Japan

Primary Contact Person: Angela Van Arsdale R.A. / Q.A. Manager
Telephone: (203) 269-5088 Ext: 346
Fax Number: (203) 269-6075

Date Prepared: September 7, 2016

2. Device / Common / Classification Name / Classification / Product Code:

Device Proprietary Name – ARIETTA Prologue Diagnostic Ultrasound system and Transducers
Common name - Diagnostic Ultrasound System and Transducers
Classification name - System, Imaging, Pulsed Doppler, Ultrasonic
Classification: Class II
Product Code: 90-IYN 892.1550 Ultrasonic Pulsed Imaging System
90-IYO 892.1560 Ultrasonic Pulsed Echo Imaging System
90-ITX 892.1570 Diagnostic Ultrasound Transducer

3. Legally Marketed Predicate Device(s): NOBLUS (K142368)

4. Device Description:

An ultrasound diagnostic system with the following features:

- Ultrasound transducer(s) – to generate the transmitted ultrasound energy and detect the reflected echoes
- Ultrasound transducer accessories (standard and optional) - to maximize functional usage of transducer(s) in various modes of operation
- A computer system - to control the transducer and analyze the signals resulting from the reflected echoes
- A video monitor with optional image recorder - to display the computed image or derived Doppler data

5. Indication for Use:

ARIETTA Prologue is intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of following clinical applications: FETAL; ABDOMINAL - (Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis)); INTRA-OPERATIVE (SPEC.) - (Includes imaging of organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures)); INTRA-OPERATIVE (NEURO.); LAPAROSCOPIC; PEDIATRIC; SMALL ORGAN (SPEC.) - (Includes thyroid, parathyroid, breast, scrotum, penis and imaging for guidance of biopsy); NEONATAL CEPHALIC; ADULT CEPHALIC; TRANS-RECTAL - (Includes imaging for guidance of trans-rectal biopsy); TRANS-VAGINAL - (Includes imaging for guidance of trans-vaginal biopsy); TRANS-ESOPHAGEAL (Non-Cardiac & Cardiac) - Adult/Pediatric; MUSCULOSKELETAL (CONVENT./SUPERFIC.); Other (spec.) -WOUND (Includes imaging for Cavernous/Non-Cavernous wounds); Other (spec) - GYNECOLOGICAL; CARDIAC ADULT / PEDIATRIC; PERIPHERAL VESSEL.

The Modes of Operation are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Amplitude Doppler (Color Flow Angiography) and TDI (Tissue Doppler Imaging), Omni Directional M mode.

6. Comparison to predicate device:

		Subject: ARIETTA Prologue Diagnostic system and Transducers	Predicate: Noblus [K14268]
CLINICAL APPLICATIONS:		Fetal; Abdominal; Intra-operative (Spec.); Intra-operative (Neuro.); Laparoscopic; Pediatric; Small Organ (Spec.); Neonatal Cephalic; Adult Cephalic; Trans-rectal; Trans-Vaginal; Trans-esophageal (Non-Cardiac & Cardiac) - Adult/Pediatric; Musculoskeletal (Convent./Superfic.); Wound (Cavernous/Non-Cavernous); Gynecological; Cardiac Adult / Pediatric and Peripheral Vessel	Fetal; Abdominal; Intra-operative (Spec.); Laparoscopic; Pediatric; Small Organ (Spec.); Neonatal Cephalic; Adult Cephalic; Trans-rectal; Trans-vaginal; Trans-esophageal (Non-Cardiac & Cardiac) - Adult/Pediatric; Musculoskeletal (Convent./Superfic.);Wound (Cavernous/Non-Cavernous); Gynecology; Cardiac; Peripheral vessel, Biopsy, Endoscopy, Intra-luminal, Urology
TRACK		3	3
PROBE TYPES		Convex, Linear, Sector	Convex, Linear, Sector, 4D, Other, EUS, Broncho
TRANSMIT	Transmit channel	64	64
	Transmit power level	0 ~ 100% (1% steps)	5 ~ 100% (5% steps)
	Transmit frequency	Selectable in 4 steps	Selectable in 5 steps
	Transmit focus	Max 8 steps electric focusing	Max 10 steps electric focusing
RECEIVE	Number of receive beam	2 beam	2 beam (as 64 channels)
	Receive focus	Continuously variable aperture	Continuously variable aperture
		dynamic focus	dynamic focus
DISPLAY MODES		B, M, PW, CW and combinations	B, M, PW, CW and combinations
Physiological signal display		N/A	Applicable
DICOM		Applicable	Applicable
DICOM SR		Applicable	Applicable
DICOM QR		Applicable	Applicable
Automated IMT Measurement		Applicable	Applicable
Automated NT Measurement *(Cleared via K140639, K140443, K134016)*		Applicable	N/A
EFV (Extended Field of View)		Applicable	Applicable (Wide View function)
HI REZ / AIP		Applicable (AIP/SIP)	Applicable (HI REZ)
DSD (Dynamic Slow Motion Display) *(Cleared via K140639, K140443, K134016)*		Applicable	N/A
Real-Time Doppler Auto Trace		Applicable	Applicable
Spatial Compound		Applicable	Applicable
FAM (Free Angular M-mode)		Applicable	Applicable (ODM function)
Measurement Function		Applicable	Applicable
Trapezoid		Applicable	Applicable
TDI		Applicable	Applicable
Color Flow	Reference frequency	2.0~8MHz	2.0~10MHz
	PRF	120Hz~20kHz	120Hz~20kHz
	Linear oblique scan angle	0°, ±10°, ±15°, ±20° (depending probe)	0°, ±10°, ±15°, ±20° (depending probe)
	Color Flow Angiography	Available	Available
Built-in Battery		Applicable	Applicable
Wireless equipment		Applicable	N/A
Monitor		11.6 inch LCD	15 inch LCD

21 CFR Part 807.92, Section b

1. Non-clinical Testing

No new hazards were identified with the subject device. 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.

2. Clinical testing:

None required

3. Conclusions:

The Hitachi, Ltd. ARIETTA Prologue Diagnostic Ultrasound system and Transducers is substantially equivalent in safety and effectiveness to the predicate device;

- The subject and predicate device(s) are both indicated for diagnostic ultrasound imaging and fluid flow analysis.
- The subject and predicate device(s) have the same gray scale and Doppler capabilities.
- The subject and predicate device(s) have the same essential technology for imaging, Doppler functions, and signal processing.
- The subject and predicate device(s) have acoustic level below the Track 3 FDA limits.
- The subject and predicate device(s) are manufactured in accordance to FDA 21 CFR 820 Quality System Regulations.
- The subject and predicate device(s) are designed and manufactured to the same electrical and physical safety standards.
- The subject and predicate device(s) are manufactured with materials that have been tested in accordance to ISO 10993-1; all biocompatibility testing has been conducted in accordance to each component material characterization, type of body contact, and duration contact risk profile.
- The subject and predicate device(s) are designed to be re-usable and provide instructions for cleaning, disinfection, and sterilization in the Ultrasound system and transducer manuals.

END OF SUMMARY