



January 28, 2019

Hitachi Healthcare Americas
% Mr. Dennis Domoracki
Senior Regulatory Affairs Specialist
1959 Summit Commerce Park
TWINSBURG OH 44087

Re: K183456

Trade/Device Name: ALOKA ARIETTA 850
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: December 13, 2018
Received: December 13, 2018

Dear Mr. Domoracki:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, appearing to read "Rob 2. Mills", is written over a large, light blue, semi-transparent "FDA" watermark.

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number (if known)

K183456

Device Name

ALOKA ARIETTA 850

Indications for Use (Describe)

The ALOKA ARIETTA 850 is intended for use by trained personnel (doctor, Sonographer, etc.) for the diagnostic ultrasound evaluation of Fetal, Abdominal, Intra-operative (Spec.), Pediatric, Small Organ (Spec.), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Trans-essoph. (non-Card.), Musculo-skel. (Convent.), Musculo-skel. (Superfic.), Wound (Cavernous/Non-Cavernous), Gynecology, Cardiac Adult, Cardiac Pediatric, Trans-esophageal (card.), Peripheral vessel, and gastro-intestinal (GI) endoscopic 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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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

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	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. (Convnt.)	P	P	P	P	P	P	P	
Musculo-skel. (Superfic.)	P	P	P	P	P	P	P	
Other (Wound)	Ph	Ph	Ph	Ph	Ph	Ph	Ph	
Other (Gynecological)	P	P	P		P	P	P	
Other (Endoscopic)	Pi, Pj	Pi, Pj	Pi, Pj		Pi, Pj	Pi, Pj	Pi, Pj	
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	
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P

N = new indication; P = previously cleared in K173739, K140639

*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), Tissue Doppler Imaging, Free Angular M-mode, 3D Imaging, 4D Imaging, Shear Wave Measurement, Contrast imaging, eFocusing, Real time Tissue Elastography, Real time Virtual Sonography, Trapezoid

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 Cavemous/Non-Cavemous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
Transducer: C22K

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.)	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. (Superfc.)								
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)								
Cardiac Adult								
Cardiac Pediatric								
Trans-esophageal (Adult/Pediatric)								
Peripheral Vessel	Peripheral vessel							

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, 3D imaging, Contrast 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 Cavemous/Non-Cavemous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

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.)								
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)								
Cardiac Adult								
Cardiac Pediatric								
Cardiac	Trans-esophageal (Adult/Pediatric)							
Peripheral Vessel	Peripheral vessel							

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, 3D imaging, Contrast Imaging, eFocusing, Real time Virtual Sonography

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 Cavertous/Non-Cavertous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

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	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. (Convant.)								
Musculo-skel. (Superfic.)								
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)								
Cardiac Adult								
Cardiac Pediatric								
Cardiac	Trans-esophageal (Adult/Pediatric)							
Peripheral Vessel	Peripheral vessel							

N = new indication; P = previously cleared in K173739

*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), Tissue Doppler Imaging, Free Angular M-mode, 3D imaging, Shear Wave Measurement, Contrast Imaging, eFocusing, Real time Tissue Elastography, Real time Virtual Sonography

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 Cavertous/Non-Cavertous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: C252

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

General (Track I only)	Specific (Tracks I & III)	Mode of Operation							
		B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)	
Ophthalmic	Ophthalmic								
	Fetal	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	P
	Small Organ (Spec.)	Pd	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.)									
Other (Wound)									
Other (Gynecological)									
Other (Endoscopic)									
Cardiac Adult									
Cardiac Pediatric									
Cardiac	Trans-esophageal (Adult/Pediatric)								
Peripheral Vessel	Peripheral vessel								

N = new indication; P = previously cleared in K173739

*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), Tissue Doppler Imaging, Free Angular M-mode, 3D imaging, Shear Wave Measurement, Contrast Imaging, eFocusing, Real time Tissue Elastography, Real time Virtual Sonography

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 Cavertous/Non-Cavertous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: C25P

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

Clinical Application	Specific (Tracks I & III)	Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)
General (Track I only)	Ophthalmic							
	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							
Fetal Imaging & Other	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (Wound)							
	Other (Gynecological)							
	Other (Endoscopic)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
Peripheral Vessel	Peripheral vessel							

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, 3D imaging, Contrast Imaging, Real time Virtual Sonography

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 Cervical/Non-Cervical wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: C35

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

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

N = new indication; P = previously cleared in K173739

*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, CMM-B/CW

**Power Doppler (Color Flow Angiography), Tissue Doppler Imaging, Free Angular M-mode, 3D imaging, Contrast Imaging, eFocusing, Real time Tissue Elastography, Real time Virtual Sonography

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 Cavertous/Non-Cavertous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

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	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.)								
Other (Wound)								
Other (Gynecological)	P	P	P		P	P	P	
Other (Endoscopic)								
Cardiac Adult								
Cardiac Pediatric								
Cardiac	Trans-esophageal (Adult/Pediatric)							
Peripheral Vessel	Peripheral vessel							

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, Contrast Imaging, eFocusing, Real time Tissue Elastography, Real time Virtual Sonography

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 Cavertous/Non-Cavertous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

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	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							
Fetal Imaging & Other	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (Wound)							
	Other (Gynecological)	P	P	P		P	P	P
	Other (Endoscopic)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (Adult/Pediatric)							
	Peripheral vessel							

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, Contrast Imaging, eFocusing, Real time Tissue Elastography, Real time Virtual Sonography

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 Cavemous/Non-Cavemous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

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* (Spe)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	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							
Cardiac	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convant.)							
	Musculo-skel. (Superfic.)							
	Other (Wound)							
	Other (Gynecological)							
	Other (Endoscopic)							
	Cardiac Adult							
Peripheral Vessel	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Peripheral vessel	P	P	P	P	P	P	P

N = new indication; P = previously cleared in 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, CMM-B/CW

**Power Doppler (Color Flow Angiography), Free Angular M-mode, 3D 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 Cavertous/Non-Cavertous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: C42K

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

Clinical Application	Specific (Tracks I & III)	Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)
General (Track I only)								
Ophthalmic	Ophthalmic							
	Fetal							
Fetal Imaging & Other	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.)								
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)								
Cardiac Adult								
Cardiac Pediatric								
Cardiac	Trans-esophageal (Adult/Pediatric)							
Peripheral Vessel	Peripheral vessel							

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, 3D 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

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: C42T

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							
	Abdominal							
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)	P	P	P		P	P	P
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
Fetal Imaging & Other	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (Wound)							
	Other (Gynecological)							
	Other (Endoscopic)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
Peripheral Vessel	Peripheral vessel							

N = new indication; P = previously cleared in K163505

*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

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

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: CC41R

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

Clinical Application	Specific (Tracks I & III)	Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)
General (Track I only)	Ophthalmic							
	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.)								
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)								
Cardiac Adult								
Cardiac Pediatric								
Trans-esophageal (Adult/Pediatric)								
Peripheral Vessel	Peripheral vessel							

N = new indication; P = previously cleared in KI60559

*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

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 Cervical/Non-Cervical wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: CC41RI

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

General (Track I only)	Specific (Tracks I & III)	Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	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.)								
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)								
Cardiac Adult								
Cardiac Pediatric								
Cardiac	Trans-esophageal (Adult/Pediatric)							
Peripheral Vessel	Peripheral vessel							

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, Contrast Imaging, Real time Tissue Elastography, Real time Virtual Sonography

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 Cervical/Non-Cervical wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: CL4416R

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

Clinical Application	Specific (Tracks I & III)	Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)
General (Track I only)	Ophthalmic							
	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.)								
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)								
Cardiac Adult								
Cardiac Pediatric								
Cardiac	Trans-esophageal (Adult/Pediatric)							
Peripheral Vessel	Peripheral vessel							

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, Trapezoid, Real time Tissue Elastography, Real time Virtual Sonography

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 Cavemous/Non-Cavemous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: L34

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							
	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							
Fetal Imaging & Other	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convant.)	P	P	P	P	P	P	P
	Musculo-skel. (Superfic.)							
	Other (Wound)							
	Other (Gynecological)							
	Other (Endoscopic)							
	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Peripheral Vessel	P	P	P	P	P	P	P
Peripheral vessel								

N = new indication; P = previously cleared in K173739

*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, 3D imaging, Contrast Imaging, eFocusing, Trapezoid, Real time Tissue Elastography

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 Cavertous/Non-Cavertous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: L43K

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							
Fetal Imaging & Other	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.)								
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)								
Cardiac Adult								
Cardiac Pediatric								
Cardiac	Trans-esophageal (Adult/Pediatric)							
Peripheral Vessel	Peripheral vessel							

N = new indication; P = previously cleared in K163505

*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

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

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: L441

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

General (Track I only)	Specific (Tracks I & III)	Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	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. (Convnt.)	P	P	P	P	P	P	P
Musculo-skel. (Superfic.)	P	P	P	P	P	P	P	
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)								
Cardiac Adult								
Cardiac Pediatric								
Trans-esophageal (Adult/Pediatric)								
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P

N = new indication; P = previously cleared in K173739

*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, 3D imaging, Contrast imaging, eFocusing, Trapezoid, Real time Tissue Elastography

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 Cavertous/Non-Cavertous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: L44K

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							
Fetal Imaging & Other	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.)								
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)								
Cardiac Adult								
Cardiac Pediatric								
Cardiac	Trans-esophageal (Adult/Pediatric)							
Peripheral Vessel	Peripheral vessel							

N = new indication; P = previously cleared in K163505

*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

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 Cervical/Non-Cervical wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

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							
	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							
Fetal Imaging & Other	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (Wound)							
	Other (Gynecological)							
	Other (Endoscopic)							
	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Peripheral Vessel	Peripheral vessel						

N = new indication; P = previously cleared in K163505

*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

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

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: L46K1

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							
Fetal Imaging & Other	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.)								
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)								
Cardiac Adult								
Cardiac Pediatric								
Cardiac	Trans-esophageal (Adult/Pediatric)							
Peripheral Vessel	Peripheral vessel							

N = new indication; P = previously cleared in KI63505

*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

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

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: L51K

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							
Fetal Imaging & Other	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.)								
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)								
Cardiac Adult								
Cardiac Pediatric								
Cardiac	Trans-esophageal (Adult/Pediatric)							
Peripheral Vessel	Peripheral vessel							

N = new indication; P = previously cleared in K163505

*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

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

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: L53K

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

Clinical Application	Specific (Tracks I & III)	Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)
General (Track I only)								
Ophthalmic	Ophthalmic							
	Fetal							
Fetal Imaging & Other	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.)								
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)								
Cardiac Adult								
Cardiac Pediatric								
Cardiac	Trans-esophageal (Adult/Pediatric)							
Peripheral Vessel	Peripheral vessel							

N = new indication; P = previously cleared in K163505

*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

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

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

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							
	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							
Cardiac	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convant.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Other (Wound)	Ph	Ph	Ph		Ph	Ph	Ph
	Other (Gynecological)							
	Other (Endoscopic)							
	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Peripheral Vessel	Peripheral vessel	P	P	P		P	P

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, 3D imaging, Contrast imaging, eFocusing, Trapezoid, Tissue Doppler, Real time Tissue Elastography, Real time Virtual Sonography

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 Cavemous/Non-Cavemous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

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							
	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. (Convant.)	P	P	P	P	P	P	P	
Musculo-skel. (Superfic.)	P	P	P	P	P	P	P	
Other (Wound)	Ph	Ph	Ph	Ph	Ph	Ph	Ph	
Other (Gynecological)								
Other (Endoscopic)								
Cardiac Adult								
Cardiac Pediatric								
Trans-esophageal (Adult/Pediatric)								
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P

N = new indication; P = previously cleared in K173739

*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, 3D imaging, eFocusing, Trapezoid, Real time Tissue Elastography, Real time Virtual Sonography

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 Cavertous/Non-Cavertous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: MXS1

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

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

N = new indication; P = previously cleared in K173739

*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), Tissue Doppler Imaging, Free Angular M-mode, 3D Imaging, 4D Imaging, eFocusing

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 Cavemous/Non-Cavemous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: R41R

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

Clinical Application	Specific (Tracks I & III)	Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)
General (Track I only)								
Ophthalmic	Ophthalmic							
	Fetal							
Fetal Imaging & Other	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.)								
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)								
Cardiac Adult								
Cardiac Pediatric								
Cardiac	Trans-esophageal (Adult/Pediatric)							
Peripheral Vessel	Peripheral vessel							

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), Real time Tissue Elastography

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 Cavertous/Non-Cavertous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

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* (Spe)	Other** (Spec.)
Ophthalmic	Ophthalmic							
	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.)								
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)								
Cardiac Adult								
Cardiac Pediatric								
Cardiac	Trans-esophageal (Adult/Pediatric)							
Peripheral Vessel	Peripheral vessel							

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), Real time Tissue Elastography

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 Cavemous/Non-Cavemous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

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	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. (Convant.)								
Musculo-skel. (Superfic.)								
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)								
Cardiac Adult		P	P	P	P	P	P	P
Cardiac Pediatric		P	P	P	P	P	P	P
Trans-esophageal (Adult/Pediatric)								
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P

N = new indication; P = previously cleared in K173739

*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), Tissue Doppler Imaging, Free Angular M-mode, Contrast Imaging, eFocusing

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 Cavertous/Non-Cavertous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: S31

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

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

N = new indication; P = previously cleared in K173739

*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), 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 Cavemous/Non-Cavemous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: S3SEL

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

General (Track I only)	Clinical Application	Specific (Tracks I & III)	Mode of Operation							
			B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)	
Ophthalmic	Ophthalmic	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.)	P _g	P _g	P _g	P _g	P _g	P _g	P _g	P _g
		Musculo-skel. (Convant.)								
		Musculo-skel. (Superfic.)								
Other (Wound)										
Other (Gynecological)										
Other (Endoscopic)										
Cardiac Adult										
Cardiac Pediatric										
Cardiac	Trans-esophageal (Adult/Pediatric)									
Peripheral Vessel	Peripheral vessel	P _g	P _g	P _g	P _g	P _g	P _g	P _g		

N = new indication; P = previously cleared in K173739

*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), 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 Cavertous/Non-Cavertous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: S3ESL1

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

General (Track I only)	Clinical Application	Specific (Tracks I & III)	Mode of Operation							
			B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)	
Ophthalmic	Ophthalmic	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.)	P _g	P _g	P _g	P _g	P _g	P _g	P _g	P _g
		Musculo-skel. (Convant.)								
		Musculo-skel. (Superfic.)								
Other (Wound)										
Other (Gynecological)										
Other (Endoscopic)										
Cardiac Adult										
Cardiac Pediatric										
Cardiac	Trans-esophageal (Adult/Pediatric)									
Peripheral Vessel	Peripheral vessel	P _g	P _g	P _g	P _g	P _g	P _g	P _g		

N = new indication; P = previously cleared in K173739

*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), 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 Cavertous/Non-Cavertous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: S42

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

General (Track I only)	Clinical Application	Specific (Tracks I & III)	Mode of Operation							
			B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)	
Ophthalmic	Ophthalmic	Fetal								
		Abdominal	P	P	P	P		P		P
		Intra-operative (Spec.)								
		Intra-operative (Neuro.)								
		Laparoscopic								
		Pediatric	P	P	P	P		P		P
		Small Organ (Spec.)								
		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.)										
Other (Wound)										
Other (Gynecological)										
Other (Endoscopic)										
Cardiac Adult		P	P	P	P		P		P	
Cardiac Pediatric		P	P	P	P		P		P	
Cardiac										
Cardiac		Trans-esophageal (Adult/Pediatric)								
Peripheral Vessel		Peripheral vessel								

N = new indication; P = previously cleared in K173739

*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), 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 Cavemous/Non-Cavemous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: SML44

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

General (Track I only)	Clinical Application	Specific (Tracks I & III)	Mode of Operation							
			B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)	
Fetal Imaging & Other	Ophthalmic	Ophthalmic								
		Fetal								
		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. (Convnt.)	P	P	P		P	P	P			
Musculo-skel. (Superfic.)	P	P	P		P	P	P			
Other (Wound)										
Other (Gynecological)										
Other (Endoscopic)										
Cardiac Adult										
Cardiac Pediatric										
Trans-esophageal (Adult/Pediatric)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		

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, 3D imaging, eFocusing, Trapezoid, Real time Tissue Elastography, Real time Virtual Sonography

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 Cavertous/Non-Cavertous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: UST-2265-2

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

Clinical Application	Specific (Tracks I & III)	Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)
General (Track I only)	Ophthalmic							
	Ophthalmic							
	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. (Convant.)								
Musculo-skel. (Superfic.)								
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)								
Cardiac Adult					P			
Cardiac Pediatric					P			
Trans-esophageal (Adult/Pediatric)								
Peripheral Vessel	Peripheral vessel				P			

N = new indication; P = previously cleared in K173739

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 Cavemous/Non-Cavemous wounds
 - Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs
 - Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.
- Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: UST-2266-5

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

Clinical Application	Specific (Tracks I & III)	Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)
General (Track I only)								
Ophthalmic	Ophthalmic							
	Fetal							
Fetal Imaging & Other	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.)								
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)								
Cardiac Adult								
Cardiac Pediatric								
Cardiac	Trans-esophageal (Adult/Pediatric)							
Peripheral Vessel	Peripheral vessel							
					P			

N = new indication; P = previously cleared in K173739

*Power Doppler (Color Flow Angiography), Tissue Doppler Imaging, Free Angular M-mode, 3D 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 Cavemous/Non-Cavemous wounds
 - Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs
 - Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.
- Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: VC34

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

General (Track I only)	Clinical Application	Specific (Tracks I & III)	Mode of Operation							
			B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)	
Ophthalmic	Ophthalmic	Fetal								
			P	P	P		P	P	P	
			P	P	P		P	P	P	
Fetal Imaging & Other	Abdominal	Intra-operative (Spec.)								
			P	P	P		P	P	P	
Cardiac	Cardiac Adult	Trans-esophageal (Adult/Pediatric)								
Peripheral Vessel	Peripheral vessel									

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, 3D imaging, 4D imaging, eFocusing, 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 Cervical/Non-Cervical wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: VC35

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

General (Track I only)	Clinical Application	Specific (Tracks I & III)	Mode of Operation								
			B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)		
Ophthalmic	Ophthalmic	Fetal	P	P	P			P		P	
		Abdominal	P	P	P			P		P	
		Intra-operative (Spec.)									
		Intra-operative (Neuro.)									
		Laparoscopic									
		Pediatric	P	P	P				P		P
		Small Organ (Spec.)	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.)											
Other (Wound)											
Other (Gynecological)											
Other (Endoscopic)											
Cardiac Adult											
Cardiac Pediatric											
Cardiac											
Trans-esophageal (Adult/Pediatric)											
Peripheral Vessel											
Peripheral vessel											

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, 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 Cavemous/Non-Cavemous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: VC41V

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

Clinical Application	Specific (Tracks I & III)	Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)
General (Track I only)	Ophthalmic							
	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							
Fetal Imaging & Other	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (Wound)							
	Other (Gynecological)							
	Other (Endoscopic)							
	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Peripheral Vessel	Peripheral vessel						

N = new indication; P = previously cleared in K142618

*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

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 Cavemous/Non-Cavemous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: BF-UC180 F

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

Clinical Application	Specific (Tracks I & III)	Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)
General (Track I only)								
Ophthalmic	Ophthalmic							
	Fetal							
Fetal Imaging & Other	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.)	P _g	P _g	P _g		P _g	P _g	P _g
	Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)								
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)	P _j	P _j	P _j		P _j	P _j	P _j	
Cardiac Adult								
Cardiac Pediatric								
Cardiac	Trans-esophageal (Adult/Pediatric)							
Peripheral Vessel	Peripheral vessel							

N = new indication; P = previously cleared in K140639

*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, Real time Tissue Elastography

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 Cavertous/Non-Cavertous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: GF-UCT140-AL5

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

General (Track I only)	Clinical Application	Specific (Tracks I & III)	Mode of Operation							
			B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)	
Ophthalmic	Ophthalmic	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.)		P _g	P _g	P _g		P _g	P _g	P _g
Musculo-skel. (Convent.)										
Musculo-skel. (Superfic.)										
Other (Wound)										
Other (Gynecological)										
Other (Endoscopic)		Pi	Pi	Pi		Pi	Pi	Pi		
Cardiac Adult										
Cardiac Pediatric										
Cardiac		Trans-esophageal (Adult/Pediatric)								
Peripheral Vessel		Peripheral vessel								

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, Real time Tissue Elastography

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 Cavertous/Non-Cavertous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: GF-UC140P-AL5

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

Clinical Application	Specific (Tracks I & III)	Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)
General (Track I only)								
Ophthalmic	Ophthalmic							
	Fetal							
Fetal Imaging & Other	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.)	P _g	P _g	P _g		P _g	P _g	P _g
	Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)								
Other (Wound)								
Other (Gynecological)								
Other (Endoscopic)	Pi	Pi	Pi		Pi	Pi	Pi	
Cardiac Adult								
Cardiac Pediatric								
Cardiac	Trans-esophageal (Adult/Pediatric)							
Peripheral Vessel	Peripheral vessel							

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, Real time Tissue Elastography

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 Cavertous/Non-Cavertous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: GF-UE160-AL5

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

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

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), Contrast Imaging, Real time Tissue Elastography

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).

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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 Cervical/Non-Cervical wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: GF-UCT180

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

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

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, eFocusing, Contrast Imaging, Real time Tissue Elastography

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 Cavertous/Non-Cavertous wounds

Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.

Prescription Use Only (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850

Transducer: TGF-UC180 J

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.)
Fetal Imaging & Other	Ophthalmic							
	Fetal							
	Abdominal	P	P	P		P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
Cardiac	Trans-esoph. (non-Card.)	P _g	P _g	P _g		P _g	P _g	P _g
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Other (Wound)							
	Other (Gynecological)							
	Other (Endoscopic)	P _i	P _i	P _i		P _i	P _i	P _i
	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Peripheral Vessel	Peripheral vessel						

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, Contrast Imaging, Real time Tissue Elastography

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.
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 - Subscript "e": Includes imaging for guidance of trans-rectal biopsy.
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 - Subscript "g": For Adult and pediatric patients
 - Subscript "h": Includes imaging for Cervical/Non-Cervical wounds
 - Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs
 - Subscript "j": Includes imaging for Intraluminal ultrasound for airways and tracheobronchial tree.
- Prescription Use Only (Per 21 CFR 801.109)*

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

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) K183456

Section 5
 510(k) Statement or Summary

K183456

Submitter Information

Submitter:	Hitachi Healthcare Americas 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371
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Date:	November 30, 2018

Subject Device Name

Trade/Proprietary Name:	ALOKA ARIETTA 850
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 (K173739)
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

Device Intended Use

The ALOKA ARIETTA 850 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, Endoscopy 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 ALOKA ARIETTA 850 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 ALOKA ARIETTA 850 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 beam 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 generation of an ultrasound wave pulses with an electric signal applied to a transducer, direction of the resulting ultrasound wave into the tissue of the body, and reception and analysis of the echoes reflected back to the same or an adjacent transducer from the various tissues along the path of the ultrasound wave. The ultrasound waves comprising a beam travel in as straight line in homogeneous media. When an ultrasound wave reaches an interface between two media of different impedances, a portion of the beam energy may pass through the boundary (transmission), and a portion may be reflected. The direction of propagation of the transmitted beam is determined by the angle of incidence of the incident beam upon the boundary, and differences (if any) in the speed of sound in the two media. The direction of reflection is determined solely by the angle of incidence upon the boundary. The relative strength of the reflected wave depends upon the differences in the impedances between the two media. Reflection at a boundary between soft tissue and bone, as an example, involves a large impedance difference, and results in a relatively strong reflected echo. Reflection at a boundary between two soft tissue-types with a relatively small impedance difference, on the other hand, results in a relatively weak reflected echoed. The workstation is based on current PC technology using the Windows™ operating system.

Physical and Performance Characteristics

Analysis confirms the performance characteristics of the ALOKA ARIETTA 850 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 ALOKA ARIETTA 850. 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 ALOKA ARIETTA 850 is substantially equivalent to the predicate.
Performance Testing - Clinical	None required

The analysis confirms the performance characteristics of the ALOKA ARIETTA 850 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 ALOKA ARIETTA 850 and the predicate device ALOKA ARIETTA 850 (K173739) are:

<ul style="list-style-type: none"> Physical characteristics of the system 	<p>There are no differences in appearance, weight, size, hardware, transmit/receive parameters, modes of operation, and features from the predicate device.</p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> <p>ALOKA ARIETTA 850 Subject Device</p>  </div> <div style="text-align: center;"> <p>ALOKA ARIETTA 850 Predicate Device</p>  </div> </div>																																							
<ul style="list-style-type: none"> Additional/New Probes 	<table border="1"> <thead> <tr> <th>Probe</th> <th colspan="2">Previously Cleared Device</th> </tr> </thead> <tbody> <tr> <td>C42</td> <td>C42</td> <td>NOBLUS™ Ultrasound Diagnostic System K160559</td> </tr> <tr> <td>C42T</td> <td>C42T</td> <td>ARIETTA Precision K163505</td> </tr> <tr> <td>L43K</td> <td>L43K</td> <td>ARIETTA Precision K163505</td> </tr> <tr> <td>L44K</td> <td>L44K</td> <td>ARIETTA Precision K163505</td> </tr> <tr> <td>L53K</td> <td>L53K</td> <td>ARIETTA Precision K163505</td> </tr> <tr> <td>L46K1</td> <td>L46K1</td> <td>ARIETTA Precision K163505</td> </tr> <tr> <td>L51K</td> <td>L51K</td> <td>ARIETTA Precision K163505</td> </tr> <tr> <td>L44LA</td> <td>L44LA</td> <td>ARIETTA Precision K163505</td> </tr> <tr> <td>VC35</td> <td>VC34</td> <td>ALOKA ARIETTA 850 K173739</td> </tr> <tr> <td>VC41V</td> <td>VC41V</td> <td>ARIETTA 70 K134016</td> </tr> <tr> <td>CC41R</td> <td>CC41R</td> <td>NOBLUS™ Ultrasound Diagnostic System K160559</td> </tr> <tr> <td>BF-UC180F</td> <td>BF-UC180F</td> <td>PROSOUND F75 Diagnostic Ultrasound System K140639</td> </tr> </tbody> </table>	Probe	Previously Cleared Device		C42	C42	NOBLUS™ Ultrasound Diagnostic System K160559	C42T	C42T	ARIETTA Precision K163505	L43K	L43K	ARIETTA Precision K163505	L44K	L44K	ARIETTA Precision K163505	L53K	L53K	ARIETTA Precision K163505	L46K1	L46K1	ARIETTA Precision K163505	L51K	L51K	ARIETTA Precision K163505	L44LA	L44LA	ARIETTA Precision K163505	VC35	VC34	ALOKA ARIETTA 850 K173739	VC41V	VC41V	ARIETTA 70 K134016	CC41R	CC41R	NOBLUS™ Ultrasound Diagnostic System K160559	BF-UC180F	BF-UC180F	PROSOUND F75 Diagnostic Ultrasound System K140639
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BF-UC180F	BF-UC180F	PROSOUND F75 Diagnostic Ultrasound System K140639																																						

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.

Item	Overall Rationale Analysis
System Configuration	Based on that there are no differences from the predicate device, Hitachi judges that the subject device has no additional issues with safety and effectiveness
Probes	Based on that there are no significant differences from the predicate device. The additional probes (C42, C42T, CC41R, L43K, L44K, L44LA, L46K1, L51K, L53K, VC34, VC41V, BF-UC180 F) have been cleared 510(k) in the previous submissions. The VC35 probe has been judged to be substantially equivalent to the cleared VC34 probe. Therefore, Hitachi judges that the subject device has no additional issues with safety and effectiveness.
Transmit/Receive Parameters	Based on that there are no differences from the predicate device, Hitachi judges that the subject device has no additional issues with safety and effectiveness
Modes of Operation	Based on that there are no differences from the predicate device, Hitachi judges that the subject

Item	Overall Rationale Analysis
	device has no additional issues with safety and effectiveness
Features (All)	The 2 new features are enhancements to existing features. Therefore, based on that there are no significant differences from the predicate device, Hitachi judges that the subject device 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 ALOKA ARIETTA 850 V3.0 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 2.0 2007
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 3: 2007-03
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 0993-10:2010/(R)2014
Biological evaluation of medical devices - part I 0: tests for irritation and skin sensitization. (Biocompatibility)
- NEMA UD 2-2004 (R2009)
Acoustic output measurement standard for diagnostic ultrasound equipment - revision 3. (Radiology)
- NEMA UD 3-2004 (R2009)
Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 2

Summary of Clinical Testing

Clinical testing was not required.

Conclusions

It is the opinion of Hitachi, Ltd. that the ALOKA ARIETTA 850 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.