



Hitachi Healthcare Americas Corporation
% Mr. Doug Thistlethwaite
Manager of Regulatory Affairs
1959 Summit Commerce Park
TWINSBURG OH 44087

February 28, 2018

Re: K173739

Trade/Device Name: ALOKA ARIETTA 850
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: February 12, 2018
Received: February 15, 2018

Dear Mr. Thistlethwaite:

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

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

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 blue ink that reads "Michael D. O'Hara". The signature is written over a large, light blue, semi-transparent watermark of the letters "FDA".

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2020

See PRA Statement below.

510(k) Number (if known)
K 173739

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-esoph. (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.)							
	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	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							
Cardiac	Trans-esoph. (non-Card.)	Pg	Pg	Pg	Pg	Pg	Pg	Pg
	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)	P	P	P		P	P	P
	Other (Endoscopic)	Pi	Pi	Pi		Pi	Pi	Pi
	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	P	P	P	P	P	P	P

N = new indication; P = previously cleared in K171708, 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

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:

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	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. (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 K1717078

*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 Cavernous/Non-Cavernous wounds

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

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:

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

N = new indication; P = previously cleared in K171708

*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 Cavernous/Non-Cavernous wounds
- Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

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:

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
		Abdominal	Pa	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								
Fetal Imaging & Other	Fetal Imaging & Other	Trans-essoph. (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 K171708

*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 Cavemous/Non-Cavemous wounds
- Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

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)	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	
		Abdominal	Pa	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 K171708

*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 Cavemous/Non-Cavemous wounds
- Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

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:

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	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							
Cardiac	Cardiac	Trans-esophageal (Adult/Pediatric)								
			Cardiac Adult							
			Cardiac Pediatric							
			Trans-esophageal (Adult/Pediatric)							
			Peripheral Vessel							
			Peripheral vessel							

N = new indication; P = previously cleared in K171708

*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 Cavernous/Non-Cavernous wounds

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

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)	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
			Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
			Intra-operative (Spec.)							
			Intra-operative (Neuro.)							
			Laparoscopic							
			Pediatric	P	P	P	P	P	P	P
			Small Organ (Spec.)	Pd	Pd	Pd	Pd	Pd	Pd	Pd
			Neonatal Cephalic							
			Adult Cephalic							
			Trans-rectal							
			Trans-vaginal							
			Trans-urethral							
			Trans-esoph. (non-Card.)							
			Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)										
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 K171708

*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 Cavernous/Non-Cavernous wounds

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

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:

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	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. (Convant.)											
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 K171708

*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

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:

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	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. (Convant.)											
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 K171708

*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

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:

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								
		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. (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 K171708

*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

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)	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	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. (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 K171708

*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 Cavemous/Non-Cavemous wounds

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

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:

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									
	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. (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 K171708

*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 Cavernous/Non-Cavernous wounds

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

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:

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

N = new indication; P = previously cleared in K171708

*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 Cavemous/Non-Cavemous wounds
- Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

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

N = new indication; P = previously cleared in K171708

*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 Cavemous/Non-Cavemous wounds
- Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

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:

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	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.)									
Cardiac	Cardiac	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)									
Peripheral Vessel	Peripheral vessel	Cardiac Adult									
		Cardiac Pediatric									
		Trans-esophageal (Adult/Pediatric)									
			P	P	P		P	P	P		

N = new indication; P = previously cleared in K171708

*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, serotum, 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

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:

General (Track I only)	Clinical Application	Specific (Tracks I & IID)	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							
Fetal Imaging & Other	Abdominal	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							
Cardiac	Cardiac Adult	Cardiac Pediatric								
			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)							
Peripheral Vessel	Peripheral vessel	Cardiac Pediatric								
			Trans-esophageal (Adult/Pediatric)							
			P	P	P	P	P	P	P	

N = new indication; P = previously cleared in K171708

*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 Cavemous/Non-Cavemous wounds
- Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

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

N = new indication; P = previously cleared in K171708

*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

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:

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								
		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. (Convant.)										
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 K171708

*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 Cavernous/Non-Cavernous wounds

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

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:

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

N = new indication; P = previously cleared in K171708

*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 Cavernous/Non-Cavernous wounds

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

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:

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		
		Abdominal										
		Intra-operative (Spec.)	P	P	P	P		P	P	P	P	
		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	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	P		
Cardiac Pediatric		P	P	P	P		P	P	P	P		
Trans-esophageal (Adult/Pediatric)												
Peripheral Vessel	Peripheral vessel	P	P	P	P		P	P	P	P		

N = new indication; P = previously cleared in K171708

*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 Cavemous/Non-Cavemous wounds

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

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.)		
Fetal Imaging & Other		Ophthalmic									
		Fetal									
		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	P	P	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	P		
Cardiac Pediatric		P	P	P	P		P	P	P		
Trans-esophageal (Adult/Pediatric)											
Peripheral Vessel	Peripheral vessel										

N = new indication; P = previously cleared in K171708

*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

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										
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 K171708

*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

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 & IID)	Mode of Operation							
			B	M	PWD	CWD	Color Doppler	Combined* (Spe)	Other** (Spec.)	
Fetal Imaging & Other	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								
Cardiac	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									
	Trans-esophageal (Adult/Pediatric)	P _g	P _g	P _g	P _g	P _g	P _g	P _g	P _g	
	Peripheral Vessel	Peripheral vessel								

N = new indication; P = previously cleared in K171708

*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

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. (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		
Trans-esophageal (Adult/Pediatric)											
Peripheral Vessel	Peripheral vessel										

N = new indication; P = previously cleared in K171708

*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

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									
		Fetal									
		Abdominal	P	P	P		P	P		P	
		Intra-operative (Spec.)									P
		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									
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)									
		Other (Gynecological)									
		Other (Endoscopic)									
Peripheral Vessel		Cardiac Adult									
		Cardiac Pediatric									
		Trans-esophageal (Adult/Pediatric)									
		Peripheral vessel	P	P	P		P	P		P	

N = new indication; P = previously cleared in K171708

*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 Cavemous/Non-Cavemous wounds

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

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:

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									
			Fetal								
			Abdominal								
			Intra-operative (Spec.)								
			Intra-operative (Neuro.)								
			Laparoscopic								
			Pediatric								
			Small Organ (Spec.)								
			Neonatal Cephalic								
			Adult Cephalic								
			Trans-rectal								
			Trans-vaginal								
			Trans-urethral								
			Trans-esoph. (non-Card.)								
			Musculo-skel. (Convent.)								
Musculo-skel. (Superfic.)											
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 K171708

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, serotum, 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

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:

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									
	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										
Cardiac Pediatric							P			
Trans-esophageal (Adult/Pediatric)										
Peripheral Vessel	Peripheral vessel						P			

N = new indication; P = previously cleared in K171708

**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 Cavernous/Non-Cavernous wounds
- Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

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.)	
Fetal Imaging & Other	Ophthalmic	Ophthalmic								
		Fetal	P	P	P		P	P	P	
		Abdominal	P	P	P		P	P	P	
		Intra-operative (Spec.)								
		Intra-operative (Neuro.)								
		Laparoscopic								
		Pediatric	P	P	P		P	P	P	
		Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc	
		Neonatal Cephalic								
		Adult Cephalic								
		Trans-rectal								
		Trans-vaginal								
		Trans-urethral								
		Trans-esoph. (non-Card.)								
Musculo-skel. (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 K171708

*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 Cavernous/Non-Cavernous wounds

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

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.)	
Fetal Imaging & Other	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.)		Pg	Pg	Pg		Pg	Pg	Pg
Musculo-skel. (Convant.)										
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 K171708, 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 Cavernous/Non-Cavernous wounds

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

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:

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								
		Fetal								
		Abdominal								
		Intra-operative (Spec.)								
		Intra-operative (Neuro.)								
		Laparoscopic								
		Pediatric								
		Small Organ (Spec.)								
		Neonatal Cephalic								
		Adult Cephalic								
		Trans-rectal								
		Trans-vaginal								
		Trans-urethral								
		Trans-esoph. (non-Card.)		Pg	Pg	Pg		Pg	Pg	Pg
Musculo-skel. (Convant.)										
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 K171708, 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 Cavernous/Non-Cavernous wounds
- Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

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.)		
Fetal Imaging & Other	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.)	Pg	Pg	Pg		Pg	Pg	Pg	
Musculo-skel. (Convant.)											
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 K171708, 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), 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 Cavernous/Non-Cavernous wounds

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

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								
		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								
		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 K1171708, 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, 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 Cavernous/Non-Cavernous wounds

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

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:

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								
		Small Organ (Spec.)								
		Neonatal Cephalic								
		Adult Cephalic								
		Trans-rectal								
		Trans-vaginal								
		Trans-urethral								
		Trans-esoph. (non-Card.)	Pg	Pg	Pg		Pg	Pg	Pg	
		Musculo-skel. (Convant.)								
		Musculo-skel. (Superfic.)								
		Other (Wound)								
		Other (Gynecological)								
		Other (Endoscopic)	Pi	Pi	Pi		Pi	Pi	Pi	
		Cardiac Adult								
Cardiac		Cardiac Pediatric								
		Trans-esophageal (Adult/Pediatric)								
Peripheral Vessel		Peripheral vessel								

N = new indication; P = previously cleared in K171708, 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, 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 Cavernous/Non-Cavernous wounds
- Subscript "i": Includes imaging for Gastrointestinal Tract and Surrounding Organs

Prescription Use Only (Per 21 CFR 801.109)

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

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

Submitter Information

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Date:	April 18, 2017

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

Main Predicate Device:	ALOKA ARIETTA 850 (K171708)
Regulation Number:	21 CFR 892.1550
Regulation Name:	Diagnostic Ultrasound System and Accessories
Product Code	90-IYN, 21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System 90-IYO, 21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System 90-ITX, 21 CFR 892.1570 Diagnostic Ultrasonic Transducer
Class	II
Panel	Radiology
Reference Devices	PROSOUND F75 (K140639)

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.), 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, 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.

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

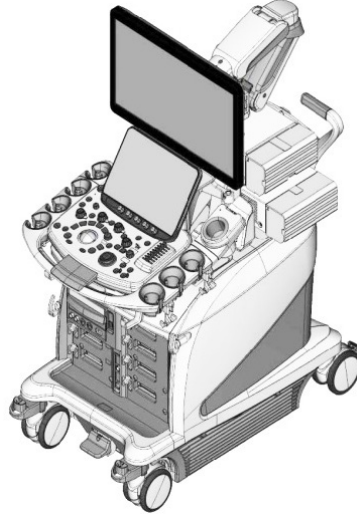
Device Technological Characteristics

The technological characteristics differences between the ALOKA ARIETTA 850 and the predicate device ALOKA ARIETTA 850 (K171708) are:

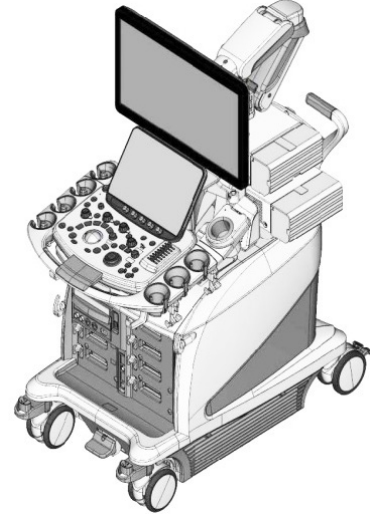
- Physical characteristics of the system

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

ALOKA ARIETTA 850



Predicate Device



- Additional New Probes

New Probe	Previously Cleared Device
C41B	ARIETTA Prologue (K162902)
GF-UCT140-AL5	Prosound F75 (K140639)
GF-UC140P-AL5	Prosound F75 (K140639)
GF-UE160-AL5	Prosound F75 (K140639)
GF-UCT180	Prosound F75 (K140639)
TGF-UC180 J	Prosound F75 (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 ALOKA ARIETTA 850 has no additional issues with safety and effectiveness
Probes	Based on that there are no significant differences from the predicate device. All additional probes (C41B, GF-UCT140-AL5, GF-UC140P-AL5, GF-UE160-AL5, GF-UCT180, and TGF-UC180 J) have been cleared 510(k) in the previous submissions, Hitachi judges that the ALOKA ARIETTA 850 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 ALOKA ARIETTA 850 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 ALOKA ARIETTA 850 has no additional issues with safety and effectiveness
Features (All)	Based on that there are no differences from the predicate device, Hitachi judges that the ALOKA ARIETTA 850 has no additional issues with safety and effectiveness

Based on analysis of the above-mentioned comparison, Hitachi has judged the ALOKA ARIETTA 850 to have the equivalent safety and effectiveness of the predicate device, ALOKA ARIETTA 850 (K171708).

Summary of Non-Clinical Testing

The ALOKA ARIETTA 850 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 are substantially equivalent to the predicate device. The subject device software features, intended use, materials, and diagnostic capabilities have been taken from the predicate device. In addition, we have concluded that the subject device and predicate device is substantially equivalent with respect to safety, effectiveness, and functionality.