DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 17, 2016

Hitachi, Ltd.
% Ms. Angela Van Arsdale
RA/QA Manager
Hitachi Aloka Medical America, Inc.
10 Fairfield Boulevard
WALLINGFORD CT 06492-5903

Re: K162583
Trade/Device Name: ALOKA LISENDO 880
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: September 29, 2016
Received: September 30, 2016

Dear Ms. Van Arsdale:

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

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

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

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

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

Sincerely yours,

For

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K162583

Device Name
ALOKA LISENDO 880

Indications for Use *(Describe)*
ALOKA LISENDO 880 is intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Fetal, Abdominal, Pediatric, Small Organ (Spec.), Intra-operative (Spec.), Neonatal Cephalic, Musculo-skel. (Convent./Superfic.), Peripheral vessel, Cardiac Adult, Cardiac Pediatric, Trans-esoph. (non-Card), Trans-esophageal (card), Adult Cephalic 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, Amplitude Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging.

Type of Use *(Select one or both, as applicable)*

[X] 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 LISENDO 880

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

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

N = new indication; P = previously cleared in K134016, K142368

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

**Power Doppler (Color Flow Angiography), Tissue Doppler Imaging, Free Angular M-mode, 3D Imaging, 4D Imaging

Additional Comments:

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

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

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

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

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

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

Subscript “g”: For Adult and pediatric patients

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

Prescription Use Only (Per 21 CFR 801.109)

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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
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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA LISENDO 880
Transducer: C251
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

Prescription Use Only (Per 21 CFR 801.109)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA LISENDO 880
Transducer: C252
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

Prescription Use Only (Per 21 CFR 801.109)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA LISENDO 880
Transducer: C35
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

Prescription Use Only (Per 21 CFR 801.109)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA LISENDO 880
Transducer: C42K
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

Prescription Use Only (Per 21 CFR 801.109)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA LISENDO 880
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 Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd	Pd	Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P	P	P	P	P
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (Wound)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Adult/Pediatric)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

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

Additional Comments:

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

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA LISENDO 880
Transducer: L441
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N = new indication; P = previously cleared in K134016, K142368
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW
**Power Doppler (Color Flow Angiography), Free Angular M-mode

Additional Comments:

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

Prescription Use Only (Per 21 CFR 801.109)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA LISENDO 880
Transducer: L64
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N = new indication; P = previously cleared in K134016, K142368
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW
**Power Doppler (Color Flow Angiography), Free Angular M-mode

Additional Comments:

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

Prescription Use Only (Per 21 CFR 801.109)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA LISENDO 880
Transducer: MXS1
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA LISENDO 880
Transducer: MXS2ESLL
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N = new indication; P = previously cleared in K134016, K142368
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW
**Power Doppler (Color Flow Angiography), Tissue Doppler Imaging, Free Angular M-mode, 3D Imaging, 4D Imaging

Additional Comments:

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

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA LISENDO 880
Transducer: S121
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA LISENDO 880
Transducer: S31
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA LISENDO 880
Transducer: S3ESEL
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N = new indication; P = previously cleared in K134016, K142368
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW
**Power Doppler (Color Flow Angiography), Tissue Doppler Imaging, Free Angular M-mode

Additional Comments:

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

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA LISENDO 880
Transducer: S42
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA LISENDO 880
Transducer: UST-2265-2
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N = new indication; P = previously cleared in K134016, K142368

Additional Comments:

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

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA LISENDO 880
Transducer: UST-2266-5
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N = new indication; P = previously cleared in K134016

**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

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

21 CFR 807.92, Subsection a

1. Submitter's Information

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

On behalf of:

Hitachi, Ltd.
Healthcare Business Unit
2-16-1, Higashi-Ueno, Taito-ku
Tokyo 110-0015 JAPAN

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

Date Prepared: September 9, 2016

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

Device Proprietary Name – ALOKA LISENDO 880
Common name - Diagnostic Ultrasound System and Transducers
Classification name - System, Imaging, Pulsed Doppler, Ultrasonic
Classification: Class II
Product Code: 90-IYN 892.1550 Ultrasonic Pulsed Imaging System
90-IYO 892.1560 Ultrasonic Pulsed Echo Imaging System
90-ITX 892.1570 Diagnostic Ultrasound Transducer

3. Legally Marketed Predicate Device(s): ARIETTA70 (K134016)

4. Device Description:

An ultrasound diagnostic system with the following features:

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

5. Indication for Use:

ALOKA LISENDO 880 is intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Fetal, Abdominal, Pediatric, Small Organ (Spec.), Intra-operative (Spec.), Neonatal Cephalic, Musculo-skel. (Convent. /Superfic.), Peripheral vessel, Cardiac Adult, Cardiac Pediatric, Trans-esoph. (non-Card.), Trans-esophageal (card.), Adult Cephalic 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.

6. Comparison to predicate device:

	SUBJECT DEVICE: ALOKA LISENDO 880	PREDICATE DEVICE: ARIETTA 70 (K134016)
INDICATION FOR USE	ALOKA LISENDO 880 is intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Fetal, Abdominal, Pediatric, Small Organ (Spec.), Intra-operative (Spec.), Neonatal Cephalic, Musculo-skel. (Convent./Superfic.), Peripheral vessel, Cardiac Adult, Cardiac Pediatric, Trans-esoph. (non-Card), Trans-esophageal (card), Adult Cephalic 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, Amplitude Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging.*	The ARIETTA 70/ ARIETTA V70/ ARIETTA S70 is intended for use by trained personnel (doctor, songrapher, etc.) for the diagnostic ultrasound evaluation of Abdominal, Cardiac, Intra-operative, Fetal, Pediatric, Small Organ, Peripheral vessel, Biopsy, Trans-rectal, Trans-vaginal, Musculoskeletal, Neonatal Cephalic, Adult Cephalic, Endloscopy, Intra-luminal, Gynecology, Urology and Laparoscopic clinical applications. *The Modes of Operation are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Amplitude Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging, Real Time Tissue Elastography, and Real Time Virtual Sonography*
TRACK	3	3
PROBE TYPES	Convex, Linear, Sector and Other	Convex, Linear, Sector, 4D and Other
MODES	B, M, PW, CW and combinations of	B, M, PW, CW and combinations of

APPLICABLE SOFTWARE FEATURE COMPARISION

FEATURE:	SUBJECT DEVICE: ALOKA LISENDO 880	PREDICATE DEVICE: ARIETTA 70 (K134016)
PHYSIOLOGICAL SIGNAL DISPLAY	YES	YES
DICOM	YES	YES
DICOM SR	YES	YES
DICOM QR	YES	YES
PICTURE IN PICTURE	YES	YES
FREEHAND 3D	YES	YES
REAL-TIME 3D	YES	YES
3D STIC	YES	YES
AUTOMATED IMT MEASUREMENT	YES	YES
AUTOMATED NT MEASUREMENT	YES	YES
ET (ETRACKING / ECHO TRACKING	YES	YES
FMD (FLOW DILATION)	YES	YES
WI (WAVE INTENSITY)	YES	YES
EFV(EXTENDED FIELD OF VIEW)	YES	YES
STRESS ECHO	YES	YES
HI REZ / AIP	YES	YES
EyeballEF	YES	YES
DSD (DYNAMIC SLOW MOTION DISPLAY)	YES	YES
CHI/CHE	YES	YES
MARKING ASSIST DISPLAY	YES	YES
REAL-TIME DOPPLER AUTO TRACE	YES	YES
SPATIAL COMPOUND	YES	YES
FAM (FREE ANGULAR M-MODE)	YES	YES
MEASUREMENT FUNCTION	YES	YES
DUAL DOPPLER	YES	YES
TRAPEZOID	YES	YES
TDI	YES	YES
COLOR FLOW	YES	YES

21 CFR Part 807.92, Section b

1. Non-clinical Testing

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

2. Clinical testing:

None required

3. Conclusions:

The ALOKA LISENDO 880 Diagnostic Ultrasound scanner is substantially equivalent in safety and effectiveness to the predicate device;

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

END OF SUMMARY