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

October 31, 2017

Re: K171708
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: October 24, 2017
Received: October 25, 2017

Dear Mr. Thistlethwaite:

This letter corrects our substantially equivalent letter of October 31, 2017.

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.

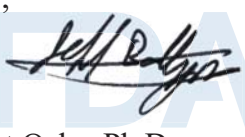
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (DICE) 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 (DICE) 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,



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)*

K171708

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-esophageal (non-Card.), Musculo-skel. (Convent.), Musculo-skel. (Superfic.), Wound (Cavernous/Non-Cavernous), Gynecology, Cardiac Adult, Cardiac Pediatric, Trans-esophageal (card.), and Peripheral vessel clinical applications.

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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Department of Health and Human Services
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Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: 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* (Spec.) | 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 | Pe | Pe | Pe | | Pe | Pe | Pe |
| | Trans-vaginal | Pf | Pf | Pf | | Pf | Pf | Pf |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | Pg | Pg | Pg | Pg | Pg | Pg | Pg |
| | Musculo-skel. (Convent.) | P | P | P | P | P | P | P |
| | Musculo-skel. (Superfic.) | P | P | P | P | P | P | P |
| | Intra-luminal | | | | | | | |
| | Other (Wound) | Ph | Ph | Ph | Ph | Ph | Ph | Ph |
| | Other (Gynecological) | P | P | P | | P | P | P |
| Cardiac | Cardiac Adult | P | P | P | P | P | P | P |
| | Cardiac Pediatric | P | P | P | P | P | P | P |
| | Trans-esophageal (Adult/Pediatric) | Pg | Pg | Pg | Pg | Pg | Pg | Pg |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | P | P | P | P | P | P | P |
| | Other (spec.) | | | | | | | |

N = new indication; P = previously cleared in K134016, K160559 and K153421

*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

Additional Comments:

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

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

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

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

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

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

Subscript “g”: For Adult and pediatric patients

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

*Prescription Use Only (Per 21 CFR 801.109)*

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
Transducer: C22K
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|---|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler | Combined* (Spec.) | Other** (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | |
| | Abdominal | Pa | Pa | Pa | | Pa | Pa | Pa |
| | Intra-operative (Spec.) | Pb | Pb | Pb | | Pb | Pb | Pb |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (Spec.) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (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 K160559
*Combination of each operating mode, B, M, PWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW
**Power Doppler (Color Flow Angiography), Free Angular M-mode, 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

*Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
Transducer: C22P
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

*Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
Transducer: C251
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|---|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler | Combined* (Spec.) | 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 K1162583
*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

Additional Comments:

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

*Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
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* (Spec.) | 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 K162583
*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

Additional Comments:

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

*Prescription Use Only (Per 21 CFR 801.109)*

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
Transducer: C25P
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

*Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
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* (Spec.) | 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 K162583
*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

Additional Comments:

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

*Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
Transducer: C41V1
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

*Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
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* (Spec.) | Other** (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (Spec.) | Pb | Pb | Pb | | Pb | Pb | Pb |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (Spec.) | 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 K162583
*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

*Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
Transducer: CC41R1
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

*Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
Transducer: CL4416R
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

*Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
Transducer: L34
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|---|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler | Combined* (Spec.) | 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 K162583
*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

Additional Comments:

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

*Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
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* (Spec.) | 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 K162583
*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

Additional Comments:

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

*Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
Transducer: L55
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

*Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
Transducer: L64
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N = new indication; P = previously cleared in K162583
*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

Additional Comments:

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

*Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
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* (Spec.) | 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 K162583
*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

Additional Comments:

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

*Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
Transducer: R41R
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

*Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
Transducer: R41RL
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

*Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
Transducer: S121
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|---|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler | Combined* (Spec.) | 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 K162583
*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 Cavernous/Non-Cavernous wounds

*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:

| Clinical Application | | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|---|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler | Combined* (Spec.) | Other** (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | |
| | Abdominal | 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 K162583
*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 Cavernous/Non-Cavernous wounds

*Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
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* (Spec.) | Other** (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (Spec.) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (Spec.) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | 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 K162583
*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 Cavernous/Non-Cavernous wounds

*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:

| Clinical Application | | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|---|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler | Combined* (Spec.) | Other** (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (Spec.) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (Spec.) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | 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 K160559
*Combination of each operating mode, B, M, PWD, CWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW B/CW, CFM-B/CW
**Power Doppler (Color Flow Angiography), 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)*

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:

| Clinical Application | | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|---|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler | Combined* (Spec.) | Other** (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | |
| | Abdominal | 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 K162583
*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 Cavernous/Non-Cavernous wounds

*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:

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

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

*Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
Transducer: UST-2265-2
Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|---|
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler | Combined* (Spec.) | Other** (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (Spec.) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (Spec.) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | 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 K162583

Additional Comments:

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

*Prescription Use Only (Per 21 CFR 801.109)*

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: ALOKA ARIETTA 850
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* (Spec.) | Other** (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | |
| | Abdominal | | | | | | | |
| | Intra-operative (Spec.) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (Spec.) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | 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 K162583

**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

*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:

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

N = new indication; P = previously cleared in K134016
*Combination of each operating mode, B, M, PWD and Color Doppler. B/B, B/M, B/PW, CFM-B/CFM-B, CFM-B/CFM-M, CFM-B/PW
**Power Doppler (Color Flow Angiography), Free Angular M-mode, 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
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Subscript “h” Includes imaging for Cavernous/Non-Cavernous wounds

*Prescription Use Only (Per 21 CFR 801.109)*

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

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

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

## Submitter Information

| | |
|---|---|
| Submitter: | Hitachi Healthcare Americas<br>1959 Summit Commerce Park<br>Twinsburg, Ohio 44087-2371 |
| Contact: | Douglas J. Thistlethwaite |
| Telephone number: | 330-425-1313 |
| Telephone number: | 330-963-0749 |
| E-mail: | thistlethwaited@hitachihealthcare.com |
| 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<br>90-IYO, 21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System<br>90-ITX, 21 CFR 892.1570 Diagnostic Ultrasonic Transducer |
| Class | II |
| Panel | Radiology |

## Predicate Device Name

| | |
|---|---|
| Main Predicate Device: | ARIETTA 70 (K134016) |
| 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<br>90-IYO, 21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System<br>90-ITX, 21 CFR 892.1570 Diagnostic Ultrasonic Transducer |
| Class | II |
| Panel | Radiology |
| Reference Devices | • ALOKA LISENDO 880 (K162583)<br>• Noblus (K160559)<br>• HI VISION Ascendus (K153421) |

## 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-esophageal (non-Card.), Musculo-skel. (Convent.), Musculo-skel. (Superfic.), Wound (Cavernous/Non-Cavernous), Gynecology, Cardiac Adult, Cardiac Pediatric, Trans-esophageal (card.), and Peripheral vessel clinical applications.

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

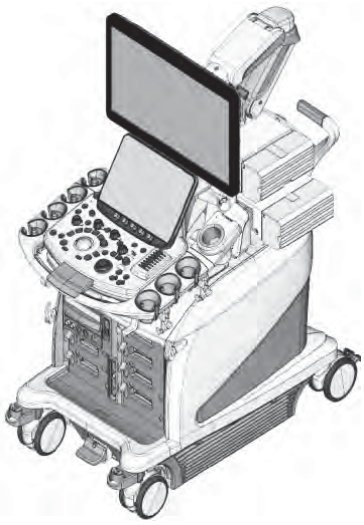
No new hazards were identified with the ALOKA ARIETTA 850. The subject device and its transducers have been evaluated for acoustic output, biocompatibility, cleaning & disinfection effectiveness, electromagnetic compatibility, as well as electrical and mechanical safety, and have been found to conform 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 ARIETTA 70 (K134016) are:

| | |
|---|---|
| • Physical characteristics of the system | There are differences in appearance, weight, size, and hardware from the predicate device.<br>ALOKA ARIETTA 850<br>  <br>Predicate Device<br>  |
| • Body Motion Tracking Feature | The Body Motion Tracking is an additional function to Real-time Virtual Sonography (RVS) software. It consists of a magnetic sensor manufactured by Hitachi and a omniTrax bracket manufactured by CIVCO (K143396).<br>The Body Motion Tracking facilitates automatic registration of fused images when used at the time of CT/MR image acquisition; with the synchronized status being updated when small movements in the patient position are detected during the RVS examination. |
| • Needle Tracking Feature | The Needle Tracking is an additional function to Real-time Virtual Sonography (RVS) software. It consists of a magnetic sensor manufactured by Hitachi and a VirtuTrax bracket manufactured by CIVCO (092619).<br>The Needle Tracking function can track and display the needle tip location on an ultrasound image. |
| • Volume Data Extension Feature | The Volume Data Extension is a function which imports and displays parts regions (ex. liver, blood vessel and tumor). The regions are extracted from CT images in advance and displayed on the images as easily viewable color regions. A data format of the parts regions includes pairs of part index and pixel positions. |
| • 3D Sim-Navigator Feature | 3D Sim-Navigator is an additional function to Real-time Virtual Sonography (RVS) software which helps to simulate puncture and plan the layout of multiple needles three dimensionally. |
| • E-field Simulator Feature | The E-field Simulator is an additional function to 3D Sim-Navigator function. The E-field Simulator calculates the electric field (based on the position of the electrodes of the RFA treatment device being used in combination with RVS), and displays it on the virtual sonography image (CT/MR image) as an E-Field image |

<table>
<tr><td>• Automated FHR Measurement Feature</td><td>In B mode, specifies a measurement ROI on the tomographic image of the fetal heart to measure heart rate automatically from continuous frames</td></tr>
<tr><td>• Additional new probes (CC41R1, CL4416R, SML44)</td><td><table>
<tr><th>New Probe</th><th>Predicate Probe</th><th>Predicate/Reference System</th></tr>
<tr><td>CC41R1</td><td>CC41R</td><td>K160559 (Noblus)</td></tr>
<tr><td>CL4416R</td><td>C41L47RP</td><td>K160559 (Noblus)</td></tr>
<tr><td>SML44</td><td>L64</td><td>K160559 (Noblus)</td></tr>
</table></td></tr>
</table>

## 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 significant differences in size, weight, connections, and Track 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 and all probes 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 significant 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 significant 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 significant 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 this device to have the equivalent safety and effectiveness of the predicate device, ARIETTA 70 (K134016).

## 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 l 0993-10:20lO/(R)2014

  Biological evaluation of medical devices - part l 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