K121646



# SECTION 12
# 510(k) Summary

JUN 22 2012

1. Sponsor: Siemens Medical Solutions USA, Inc.,
Ultrasound Division
685 East Middlefield Road
Mountain View, California 94043

2. Contact Person: Shelly Pearce
Title: Regulatory Affairs Specialist
Telephone: (650) 694 5988
Fax: (650) 694 5580

3. Submission Date: May 14, 2012

4. Device Name: ACUSON X150™ Diagnostic Ultrasound System
SONOVISTA X150 Diagnostic Ultrasound System
(K081121)

5. Common Name: Diagnostic Ultrasound System with Accessories

6. Classification:

| | |
|---|---|
| Regulatory Class: | II |
| Review Category: | Tier II |
| Classification Panel: | Radiology |

| | | |
|---|---|---|
| Ultrasonic Pulsed Doppler Imaging System | FR # 892.1550 | Product Code 90-IYN |
| Ultrasonic Pulsed Echo Imaging System | FR # 892.1560 | Product Code 90-IYO |
| Diagnostic Ultrasound Transducer | FR # 892.1570 | Product Code 90-ITX |

A. Legally Marketed Predicate Devices

The Siemens ACUSON X150 Diagnostic Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to the current product that is already cleared for USA distribution under the following 510(k) PreMarket Notification number:

- K081121, ACUSON X150™ Diagnostic Ultrasound System, SONOVISTA X150 Diagnostic Ultrasound System
- K113179, ACUSON SC2000™ Diagnostic Ultrasound System
- K101091, ZONARE z.one Ultra Ultrasoud System
- K113690, GE LOGIQ i, LOGIQ e, Vivid e
- K014206, GE LogiqBooK XP
- K101757, Sonosite M-turbo

B. Device Description:

The Siemens ACUSON X150 Diagnostic Ultrasound System is a multi-purpose mobile, software controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging and 3D Imaging on a Flat Panel Display.

C. Intended Use

The Siemens Acuson X150 ultrasound imaging system is intended for the following applications: General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Neonatal/Adult Cephalic, Cardiac, Transesophageal, Pelvic, Transcranial, OB/GYN, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

D. Substantial Equivalence

The submission device is substantially equivalent to the predicate with regard to both intended use and technological characteristics.

E. Performance Data

The modifications to the Siemens ACUSON X150 Diagnostic Ultrasound System are verified and validated according to the company's design control process.

F. A brief discussion of nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence.

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and has been found to conform with applicable medical device safety standards. The system complies with the following voluntary standards:

UL 60601-1, Safety Requirements for Medical Equipment

IEC 60601-2-37 Diagnostic Ultrasound Safety Standards

CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment

AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound

93/42/EEC Medical Devices Directive

Safety and EMC Requirements for Medical Equipment

EN/IEC 60601-1

EN/IEC 60601-1-1

EN/IEC 60601-1-2

IEC 1157 Declaration of Acoustic Power

ISO 10993-1 Biocompatibility

Cleared patient contact materials, electrical and mechanical safety are unchanged.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Siemens Medical Solutions USA, Inc. Ultrasound Group
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

JUN 22 2012

Re: K121646
Trade/Device Name: ACUSON X150™ Diagnostic Ultrasound System
SONOVISTA X150 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: June 4, 2012
Received: June 5, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the ACUSON X150™ Diagnostic Ultrasound System, SONOVISTA X150 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

P4-2 Phased Sector Array
CH5-2 Convex Array
VF10-5 Linear Array
EC9-4 Convex Array Endocavity
EV9-4 Convex Array
VF13-5 Linear Array
P8-4 Phased Array
L9-5 Linear Array
P4-2 Litho Phased Sector Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. 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); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

If you have any questions regarding the content of this letter, please contact Joshua Nipper at (301) 796-6524.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

# SECTION 6
# Indications for Use Forms

**Indications for Use Statement**

510(k) Number (if known):

Device Name: ACUSON X150™ Diagnostic Ultrasound System
SONOVISTA X150 Diagnostic Ultrasound System

Indications For Use:

The Siemens Acuson X150 ultrasound imaging system is intended for the following applications: General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Neonatal/Adult Cephalic, Cardiac, Transesophageal, Pelvic, Transcranial, OB/GYN, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Devices

510(k) K121646

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **ACUSON X150 Diagnostic Ultrasound System**

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

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Abdominal | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Intraoperative (Note 6) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Small Organ (Note 1) | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Neonatal Cephalic | | P | P | P | P | P | P | | BMDC | Note 3 |
| Adult Cephalic | | P | P | P | P | P | P | | BMDC | Note 2 |
| Cardiac | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Transesophageal | | | | | | | | | | |
| Transrectal | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Transvaginal | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Musculo-skeletal Superficial | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K070576; K081121 E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

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## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **P4-2** Phased Sector Array Transducer for use with:
**ACUSON X150 Diagnostic Ultrasound Systems**

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

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Abdominal | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Intraoperative (Note 6) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Small Organ (Note 1) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Cardiac | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K070576; K081121 E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

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**Diagnostic Ultrasound Indications for Use Form**

510(k) Number (if known):

Device Name: **CH5-2** Convex Array Transducer for use with:
**ACUSON X150 Diagnostic Ultrasound Systems**

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

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Abdominal | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Intraoperative (Note 6) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Small Organ (Note 1) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K070576; K081121 E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

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510(k) K121646

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VF10-5** Linear Array Transducer for use with:
**ACUSON X150 Diagnostic Ultrasound Systems**

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

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Intraoperative (Note 6) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Small Organ (Note 1) | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Neonatal Cephalic | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Musculo-skeletal Superficial | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K070576; K081121 E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

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510(k) K121646

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **EC9-4** Convex Array Endocavity Transducer for use with:
**ACUSON X150 Diagnostic Ultrasound Systems**

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

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Abdominal | | | | | | | | | | |
| Intraoperative (Note 6) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (Note 1) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Transvaginal | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K070576; K081121 E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

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## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **EV9-4** Convex Array Transducer for use with:
**ACUSON X150 Diagnostic Ultrasound Systems**

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

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Abdominal | | | | | | | | | | |
| Intraoperative (Note 6) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (Note 1) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Transvaginal | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K070576; K081121 E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

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Office of In Vitro Diagnostic Devices

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## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VF13-5** Linear Array Transducer for use with:
**ACUSON X150 Diagnostic Ultrasound Systems**

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

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative (Note 6) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Small Organ (Note 1) | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Neonatal Cephalic | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Musculo-skeletal Superficial | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K070576; K081121 E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

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510(k) K121646

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **P8-4** Phase Array Transducer for use with:
**ACUSON X150 Diagnostic Ultrasound Systems**

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

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Abdominal | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Intraoperative (Note 6) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Small Organ (Note 1) | | | | | | | | | | |
| Neonatal Cephalic | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K070576; K081121 E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

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510(k) K121646

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **L9-5** Linear Array Transducer for use with:
**ACUSON X150 Diagnostic Ultrasound Systems**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Intraoperative (Note 6) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Small Organ (Note 1) | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Neonatal Cephalic | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Musculo-skeletal Superficial | | P | P | P | | P | P | | BMDC | Note 2,3 |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by K070576; K081121 E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

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510(k) K121640

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **P4-2 Litho** Phased Sector Array Transducer for use with:
**ACUSON X150 Diagnostic Ultrasound Systems**

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

| Clinical Application | Mode of Operation | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (Specify) | Other (Specify) |
| Ophthalmic | | | | | | | | | | |
| Fetal | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Abdominal | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Intraoperative (Note 6) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Small Organ (Note 1) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Cardiac | | P | P | P | P | P | P | | BMDC | Note 2,3 |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K070576, K081211

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

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510(k) K121646