Dear Mr. Job:

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

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

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

Robert Ochs
Director
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure
DO NOT SEND YOUR COMPLETED FORM TO THE FDA STAFF. E-MAIL ADDRESS BELOW.

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Date of Use (signed one or both as applicable) □

The ACCURION 5000 Ultrasound System is intended for the following applications:

- Device Name
  KT63396

- Findings of Use (describes)

Indications For Use

Food and Drug Administration
Department of Health and Human Services

Expiration Date: January 31, 2017
From Approved:OMB NO 0910-0120
## Indications for Use Forms

### Diagnostic Ultrasound Indications for Use Form

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

**Device Name:** ACUSON P500™ Ultrasound System

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

<table>
<thead>
<tr>
<th>Mode of Operation</th>
<th>Clinical Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>B Mode</td>
<td>510(k)</td>
</tr>
<tr>
<td>Power Doppler (Continuous)</td>
<td>510(k)</td>
</tr>
<tr>
<td>Color Doppler</td>
<td>510(k)</td>
</tr>
<tr>
<td>Power Doppler (pulsed)</td>
<td>510(k)</td>
</tr>
<tr>
<td>Color Doppler</td>
<td>510(k)</td>
</tr>
<tr>
<td>M Mode</td>
<td>510(k)</td>
</tr>
<tr>
<td>PW Doppler</td>
<td>510(k)</td>
</tr>
</tbody>
</table>

**Note:**
- For example: abdominal, vascular (upper and lower)
- N = new indication; P = previously cleared

---

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature):

___________________________________________

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature):

___________________________________________

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**Note 1** For example: breast, testes, thyroid, prostate, etc.

**Note 2** Dynamic TCE Technology

**Note 3** Advanced SieClear

**Note 4** eSieImage

**Note 5** For example: abdominal, vascular (upper and lower)

**Note 6** Stress Echo

**Note 7** eSieMeasure

**Note 8** eSieScan

**Note 9** AHP

**Note 10** DTI

**Note 11** Panoramic 2D Imaging (SieScape)

**Note 12** Clarify VE

**Note 13** Needle Visualization

**Note 14** Intracardiac Echocardiography (ICE) Imaging

**Note 15** CARTOSOUND Communication

**Note 16** Probe Saver

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
### Indications for Use Form

**Device Name:** P4-2 Phased Array Transducer for use with ACUSON P500™ Ultrasound System

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

<table>
<thead>
<tr>
<th>Clinical Application</th>
<th>Federated Code (ICD-9)</th>
<th>Other Code (ICD-10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ophthalmic</td>
<td>361</td>
<td></td>
</tr>
<tr>
<td>Fetal</td>
<td>760.4, 760.5</td>
<td>02, 04, 12, 16</td>
</tr>
<tr>
<td>Abdominal</td>
<td>760.4, 760.5</td>
<td>02, 04, 12, 16</td>
</tr>
<tr>
<td>Intra-operative</td>
<td>996</td>
<td>12, 15</td>
</tr>
<tr>
<td>Otorhinolaryngologic</td>
<td>78.08, 78.09</td>
<td></td>
</tr>
<tr>
<td>Pediatric Imaging</td>
<td>79.02, 79.03, 79.05</td>
<td>13, 14</td>
</tr>
<tr>
<td>Small Organ Imaging</td>
<td>751.8, 751.9</td>
<td>13, 14</td>
</tr>
<tr>
<td>Other (Specify)</td>
<td>751.0, 751.1</td>
<td>13, 14</td>
</tr>
<tr>
<td>Cardiac</td>
<td>760.4, 760.5, 760.6</td>
<td>02, 04, 12, 16</td>
</tr>
<tr>
<td>Cardiac Pediatric</td>
<td>760.4, 760.5, 760.6</td>
<td>02, 04, 12, 16</td>
</tr>
<tr>
<td>Intra-vascular</td>
<td>760.0, 760.1, 760.2</td>
<td>02, 04, 12, 16</td>
</tr>
<tr>
<td>Trans-esophageal</td>
<td>760.0, 760.1, 760.2</td>
<td>02, 04, 12, 16</td>
</tr>
<tr>
<td>Intra-cardiac</td>
<td>760.0, 760.1, 760.2</td>
<td>02, 04, 12, 16</td>
</tr>
<tr>
<td>Other (Specify)</td>
<td>760.0, 760.1, 760.2</td>
<td>02, 04, 12, 16</td>
</tr>
<tr>
<td>Peripheral Vessel</td>
<td>741</td>
<td>15</td>
</tr>
<tr>
<td>Vascular</td>
<td>741</td>
<td>15</td>
</tr>
<tr>
<td>Other (Specify)</td>
<td>741</td>
<td>15</td>
</tr>
</tbody>
</table>

**Note:** For example: breast, testes, thyroid, prostate, etc.

**Note 2:** Dynamic TCE Technology

**Note 3:** Advanced SieClear

**Note 4:** eSieImage

**Note 5:** For example: abdominal, vascular (upper and lower)

**Note 6:** Stress Echo

**Note 7:** eSieMeasure

**Note 8:** eSieScan

**Note 9:** AHP

**Note 10:** DTI

**Note 11:** Panoramic 2D Imaging (SieScape)

**Note 12:** Clarify VE

**Note 13:** Needle Visualization

**Note 14:** Intracardiac Echocardiography (ICE) Imaging

**Note 15:** CARTOSOUND Communication

**Note 16:** Probe Saver

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Concurrence of Center for Devices and Radiological Health (CDRH) (Signature):

____________________________________________

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature):

510(k)____________________   Page  3 of 16
# Indications for Use Form

**ACUSON P500™ Ultrasound System**

**Diagnostic Ultrasound Indications for Use Form**

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

**Device Name:** CH5-2 Curved Array Transducer for use with: ACUSON P500™ Ultrasound System

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

### Clinical Application Mode of Operation

- **Ophthalmic**
- **Fetal**
- **Abdominal**
- **Intra-operative (Neuro)**
- **Laparoscopic**
- **Fetal Pediatric Imaging & Other**
- **Small Organ (Note 1)**
- **Neonatal Cephalic**
- **Adult Cephalic**
- **Trans-rectal**
- **Trans-vaginal**
- **Trans-urethral**
- **Trans-esoph. (non-Card.)**
- **Musculo-skel. (Convent.)**
- **Musculo-skel. (Superfic)**
- **Intra-vascular**
- **Other (Specify)**

### Cardiac Mode of Operation

- **Adult**
- **Pediatric**
- **Intra-vascular (Cardiac)**
- **Trans-esophageal (Cardiac)**
- **Intra-cardiac**
- **Other (Specify)**

### Peripheral Vascular Mode of Operation

- **Peripheral vessel (Note 5)**
- **Other (Specify)**

---

**Note 1** For example: breast, testes, thyroid, prostate, etc.

**Note 2** Dynamic TCE Technology

**Note 3** Advanced SieClear

**Note 4** eSieImage

**Note 5** For example: abdominal, vascular (upper and lower)

---

**Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)**

**Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)**

**Page 4 of 16**
### Indications for Use Form

#### Siemens Medical Solutions USA, Inc.

#### ACUSON P500™ Ultrasound System

#### Ultrasound Division 510(k) Submission

#### Indications for Use Forms

**Diagnostic Ultrasound Indications for Use Form**

<table>
<thead>
<tr>
<th>510(k) Number (if known):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Name: VF10-5 Linear Array Transducer for use with ACUSON P500™ Ultrasound System</td>
</tr>
</tbody>
</table>

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

- **Clinical Application Mode of Operation**
  - Other (Specify)
  - Specific (Tracks 1 and 3) B M PWD CWD Power Doppler
  - Combined (Specify)
  - Other (Specify)

- **Ophthalmic**
  - Fetal
  - Abdominal

- **Intra-operative** (Neuro)
  - Laparoscopic

- **Fetal Pediatric Imaging & Other**
  - Small Organ (Note 1) P P P P P BM DC Note 2, 3, 4, 9, 11, 12, 13, 16
  - Neonatal Cephalic
  - Adult Cephalic

- **Trans-rectal**
- **Trans-vaginal**
- **Trans-urethral**
- **Trans-esoph.** (non-Card.)
- **Musculo-skel.** (Convent.) P P P P P BM DC Note 2, 3, 4, 9, 11, 12, 13, 16
- **Musculo-skel.** (Superfic)
- **Intra-vascular**
- **Other** (Specify)

- **Cardiac**
  - Adult
  - Pediatric
  - Intra-vascular (Cardiac)
  - Trans-esophageal (Cardiac)
  - Intra-cardiac

- **Peripheral**
  - Vessel (Note 5) P P P P P BM DC Note 2, 3, 4, 9, 11, 12, 13, 16
  - Other (Specify)

**Note:**
- N = new indication; P = previously cleared K150050
- Note 1 For example: breast, testes, thyroid, prostate, etc.
- Note 2 Dynamic TCE Technology
- Note 3 Advanced SieClear
- Note 4 eSieImage
- Note 5 For example: abdominal, vascular (upper and lower)
- Note 6 Stress Echo
- Note 7 eSieMeasure
- Note 8 eSieScan
- Note 9 AHP
- Note 10 DTI
- Note 11 Panoramic 2D Imaging (SieScape)
- Note 12 Clarify VE
- Note 13 Needle Visualization
- Note 14 Intracardiac Echocardiography (ICE) Imaging
- Note 15 CARTOSOUND Communication
- Note 16 Probe Saver

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**Concurrence of Center for Devices and Radiological Health (CDRH) (Signature):**

____________________________________________

**510(k)____________________   Page  5 of 16**
Indications for Use Forms

Diagnostic Ultrasound Indications for Use Form

EC9-4 Curved Array Transducer for use with ACUSON P500 \textsuperscript{TM} Ultrasound System

Clinical Application

- \textbf{Track 1:}
  - \textbf{BMDC Note 2, 3, 4, 11, 12, 16}
- \textbf{Track 2:}
  - \textbf{BMDC Note 2, 3, 4, 11, 12, 16}
- \textbf{Track 3:}
  - \textbf{BMDC Note 2, 3, 4, 11, 12, 16}
- \textbf{Track 4:}
  - \textbf{BMDC Note 2, 3, 4, 11, 12, 16}
- \textbf{Track 5:}
  - \textbf{BMDC Note 2, 3, 4, 11, 12, 16}
- \textbf{Track 6:}
  - \textbf{BMDC Note 2, 3, 4, 11, 12, 16}

Mode of Operation

- \textbf{P} (Power)
- \textbf{C} (Contrast)
- \textbf{F} (Flow)
- \textbf{R} (Real-time)
- \textbf{D} (Doppler)
- \textbf{E} (Echo)
- \textbf{M} (M-mode)
- \textbf{S} (SonoVue)
- \textbf{V} (Video)
- \textbf{O} (Other)

Diagnostic Imaging of Full View and/or Parts of the Human Body as follows:

- \textbf{Cardiac}
- \textbf{Ophthalmic}
- \textbf{Fetal}
- \textbf{Pediatric}
- \textbf{Imaging}
- \textbf{Musculo-skeletal}
- \textbf{Neuro}
- \textbf{Intra-vascular}
- \textbf{Other}

NOTE:
- \textbf{N = new indication; P = previously cleared K150050}
- \textbf{Note 1} For example: breast, testes, thyroid, prostate, etc.
- \textbf{Note 2} Dynamic TCE Technology
- \textbf{Note 3} Advanced SieClear
- \textbf{Note 4} eSieImage
- \textbf{Note 5} For example: abdominal, vascular (upper and lower)
- \textbf{Note 6} Stress Echo
- \textbf{Note 7} eSieMeasure
- \textbf{Note 8} eSieScan
- \textbf{Note 9} AHP
- \textbf{Note 10} DTI
- \textbf{Note 11} Panoramic 2D Imaging (SieScape)
- \textbf{Note 12} Clarify VE
- \textbf{Note 13} Needle Visualization
- \textbf{Note 14} Intracardiac Echocardiography (ICE) Imaging
- \textbf{Note 15} CARTOSOUND Communication
- \textbf{Note 16} Probe Saver

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

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)
Indications for Use Form

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:
VF13-5 Linear Transducer for use with:
ACUSON P500™ Ultrasound System

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

Clinical Application Mode of Operation

Other (Track 1 Only)
Specific (Tracks 1 & 3) B M P W D C W D Doppler
Power Doppler Combined
Other (Specify)

Clinical Imaging

Ophthalmic Ophthalmic Fetal Abdominal Intra-operative Intra-operative (Neuro)
Laparoscopic Fetal Pediatric Imaging & Other Small Organ (Note 1)
Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.)
Musculo-skel. (Convent.) Musculo-skel. (Superfic) Combined
Intra-vascular Other (Specify)
Cardiac Adult Cardiac Pediatric Intra-vascular (Cardiac) Trans-esophageal (Cardiac) Intra-cardiac Other (Specify)
Peripheral peripheral vessel (Note 5) Combined
Peripheral Other (Specify)

N = new indication;  P = previously cleared K150050

Note 1 For example: breast, testes, thyroid, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 Advanced SieClear
Note 4 eSieImage
Note 5 For example: abdominal, vascular (upper and lower)
Note 6 Stress Echo
Note 7 eSieMeasure
Note 8 eSieScan
Note 9 AHP
Note 10 DTI
Note 11 Panoramic 2D Imaging (SieScape)
Note 12 Clarify VE
Note 13 Needle Visualization
Note 14 Intracardiac Echocardiography (ICE) Imaging
Note 15 CARTOSOUND Communication
Note 16 Probe Saver

(Please do not write below this line; continue on another page if needed)

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

510(k) ___________________ Page 7 of 16
Diagnostic Ultrasound Indications for Use Form

Page 8 of 16

Indications for Use Forms

510(k) Number (if known):
Device Name: VF16-5 Transducer for use with:
ACUSON P500
TM
Ultrasound System

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

Clinical Application Mode of Operation

- Other (Specify)
- Cardiac (Conventional)
- Other (Specify)
- Cardiac (Conventional)
- Trans-esophageal
- Trans-esophageal
- Trans-rectal
- Trans-rectal
- Trans-vaginal
- Trans-vaginal
- Trans-urethral
- Trans-urethral
- Intra-vascular
- Intra-vascular
- Intra-cardiac
- Other (Specify)
- Intra-cardiac
- Other (Specify)
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- Other (Specify)
- Other (Specify)
- Other (Specify)
- Other (Specify)
- Other (Specify)
- Other (Specify)
- Other (Specify)
- Other (Specify)
- Other (Specify)
- Other (Specify)
Indications for Use Form

Page 3 of 16

Diagnostic Ultrasound Indications for Use Form

Device Name: P8-4 Transducer

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

Clinical Application Mode of Operation

Notes:

1. Dynamic TCE Technology
2. Advanced SieClear
3. eSieImage
4. eSieScan
5. For example: abdominal, vascular (upper and lower)
6. Stress Echo
7. eSieMeasure
8. AHP
9. DTI
10. Panoramic 2D Imaging (SieScape)
11. Needle Visualization
12. Clarify VE
13. Intracardiac Echocardiography (ICE) Imaging
14. CARTOSOUND Communication

Note 1 For example: breast, testes, thyroid, prostate, etc.

Note 2 For example: Flo-sonic, Velocysor, upper and lower

Note 3 A new indication; previously cleared by K141846 (K161787)

Note 4 For example: CEC, ICE, etc.

Note 5 For example: abdominal, vascular (upper and lower)

Note 6 For example: CEC, ICE, etc.

Note 7 For example: CEC, ICE, etc.

Note 8 For example: CEC, ICE, etc.

Note 9 For example: CEC, ICE, etc.

Note 10 For example: CEC, ICE, etc.

Note 11 For example: CEC, ICE, etc.

Note 12 For example: CEC, ICE, etc.

Note 13 For example: CEC, ICE, etc.

Note 14 For example: CEC, ICE, etc.

Note 15 For example: CEC, ICE, etc.

Note 16 For example: CEC, ICE, etc.

(Continued on another page if needed)
### Indications for Use Form

**Device Name:** L10-5v Transducer for use with: ACUSON P500™ Ultrasound System

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

<table>
<thead>
<tr>
<th>Clinical Application Mode of Operation</th>
<th>Other (Specify)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neuroradiology</td>
<td>Non-invasive vs. inv. (upper and lower)</td>
</tr>
<tr>
<td>Cardiac</td>
<td>Non-invasive (cardiac)</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Non-invasive (ophthalmic)</td>
</tr>
<tr>
<td>Fetal</td>
<td>Non-invasive (fetal)</td>
</tr>
<tr>
<td>Abdominal</td>
<td>Non-invasive (abdominal)</td>
</tr>
<tr>
<td>Intra-operative</td>
<td>Non-invasive (intra-operative)</td>
</tr>
<tr>
<td>Intra-operative (Neuro)</td>
<td>Non-invasive (intra-operative (neuro))</td>
</tr>
<tr>
<td>Laparoscopic</td>
<td>Non-invasive (laparoscopic)</td>
</tr>
<tr>
<td>Fetal Pediatric</td>
<td>Non-invasive (pediatric)</td>
</tr>
<tr>
<td>Imaging &amp; Other</td>
<td>Non-invasive (other)</td>
</tr>
<tr>
<td>Small Organ (Note 1)</td>
<td>Non-invasive (small organ)</td>
</tr>
<tr>
<td>Neonatal Cephalic</td>
<td>Non-invasive (neonatal cephalic)</td>
</tr>
<tr>
<td>Adult Cephalic</td>
<td>Non-invasive (adult cephalic)</td>
</tr>
<tr>
<td>Trans-rectal</td>
<td>Trans-rectal</td>
</tr>
<tr>
<td>Trans-vaginal</td>
<td>Trans-vaginal</td>
</tr>
<tr>
<td>Trans-urethral</td>
<td>Trans-urethral</td>
</tr>
<tr>
<td>Trans-esophageal (non-Card.)</td>
<td>Trans-esophageal (non-cardiac)</td>
</tr>
<tr>
<td>Musculo-skeletal (Convent.)</td>
<td>Musculo-skeletal (conventional)</td>
</tr>
<tr>
<td>Musculo-skeletal (Superfic)</td>
<td>Musculo-skeletal (superficial)</td>
</tr>
<tr>
<td>Intra-vascular</td>
<td>Intra-vascular</td>
</tr>
<tr>
<td>Other (Specify)</td>
<td>Other (Specify)</td>
</tr>
<tr>
<td>Cardiac</td>
<td>Cardiac</td>
</tr>
<tr>
<td>Cardiac Pediatric</td>
<td>Cardiac pediatric</td>
</tr>
<tr>
<td>Intra-vascular (Cardiac)</td>
<td>Intra-vascular (cardiac)</td>
</tr>
<tr>
<td>Trans-esophageal (Cardiac)</td>
<td>Trans-esophageal (cardiac)</td>
</tr>
<tr>
<td>Intra-cardiac</td>
<td>Intra-cardiac</td>
</tr>
<tr>
<td>Other (Specify)</td>
<td>Other (Specify)</td>
</tr>
<tr>
<td>Peripheral vessel (Note 5)</td>
<td>Peripheral vessel (note 5)</td>
</tr>
<tr>
<td>Vessel Other (Specify)</td>
<td>Vessel other (specify)</td>
</tr>
<tr>
<td>Peripheral</td>
<td>Peripheral</td>
</tr>
<tr>
<td>Vessel Other (Specify)</td>
<td>Vessel other (specify)</td>
</tr>
<tr>
<td>N = new indication;  P = previously cleared K161787</td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**

1. For example: breast, testes, thyroid, prostate, etc.
2. Dynamic TCE Technology
3. Advanced SieClear
4. eSieImage
5. For example: abdominal, vascular (upper and lower)
6. Stress Echo
7. eSieMeasure
8. eSieScan
9. AHP
10. DTI
11. Panoramic 2D Imaging (SieScape)
12. Clarify VE
13. Needle Visualization
14. Intracardiac Echocardiography (ICE) Imaging
15. CARTOSOUND Communication
16. Probe Saver

**Conformity of Center for Devices and Radiological Health (CDRH) (Signature):**

______________________________________________

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

ACUSON P500™ Ultrasound System

**Diagnostic Ultrasound Indications for Use Form**

Siemens Medical Solutions USA, Inc.

Ultrasound Division

510(k) Submission

ACUSON P500™ Ultrasound System
Indications for Use Form

ULTRASOUND INDICATIONS FOR USE FORM

ACUSON P500™ Ultrasound System

Ultrasonic Division 510(k) Submission

Indications for Use Forms

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: CW2 Transducer for use with:

ACUSON P500™ Ultrasound System

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

Clinical Application Mode of Operation

- Other (Track1 Only)
- Specific (Tracks 1 & 3) B M PWD CWD Color Doppler
- Power Doppler
- Combined (Specify)
- Other (Specify)

Ophthalmic
- For example: breast, testes, thyroid, prostate, etc.

Fetal
- Dynamic TCE Technology

Abdominal
- Advanced SieClear

Intra-operative
- eSieImage

Laparoscopic
- Note 5 For example: abdominal, vascular (upper and lower)

Fetal Pediatric Imaging
- Stress Echo

Small Organ (Note 1)
- eSieMeasure

Neonatal Cephalic
- eSieScan

Adult Cephalic
- Note 10 DTI

Trans-rectal
- Note 11 Panoramic 2D Imaging (SieScape)

Trans-vaginal
- Clarify VE

Trans-urethral
- Intracardiac Echocardiography (ICE) Imaging

Trans-esoph. (non-Card.)
- CARTOSOUND Communication

Musculo-skel. (Convent.)
- Probe Saver

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

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

510(k)____________________   Page  11 of 16
**Clinical Indications for Use Form**

**ACUSON P500™ Ultrasound System**

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**Indications for Use**

**Device Name:** CW5 Transducer for use with ACUSON P500™ Ultrasound System

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

<table>
<thead>
<tr>
<th>Clinical Application</th>
<th>Mode of Operation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ophthalmic Ophthalmic</td>
<td></td>
</tr>
<tr>
<td>Fetal</td>
<td></td>
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<tr>
<td>Abdominal</td>
<td></td>
</tr>
<tr>
<td>Intra-operative</td>
<td></td>
</tr>
<tr>
<td>Intra-operative (Neuro)</td>
<td></td>
</tr>
<tr>
<td>Laparoscopic</td>
<td></td>
</tr>
<tr>
<td>Fetal Pediatric</td>
<td></td>
</tr>
<tr>
<td>Imaging &amp; Other</td>
<td></td>
</tr>
<tr>
<td>Neonatal Cephalic P</td>
<td></td>
</tr>
<tr>
<td>Adult Cephalic P</td>
<td></td>
</tr>
<tr>
<td>Trans-rectal</td>
<td></td>
</tr>
<tr>
<td>Trans-vaginal</td>
<td></td>
</tr>
<tr>
<td>Trans-urethral</td>
<td></td>
</tr>
<tr>
<td>Trans-esoph. (non-Card.)</td>
<td></td>
</tr>
<tr>
<td>Musculo-skel. (Convent.)</td>
<td></td>
</tr>
<tr>
<td>Musculo-skel. (Superfic)</td>
<td></td>
</tr>
<tr>
<td>Intra-vascular</td>
<td></td>
</tr>
<tr>
<td>Other (Specify)</td>
<td></td>
</tr>
<tr>
<td>Cardiac Cardiac Adult P</td>
<td></td>
</tr>
<tr>
<td>Cardiac Cardiac Pediatric P</td>
<td></td>
</tr>
<tr>
<td>Intra-vascular (Cardiac)</td>
<td></td>
</tr>
<tr>
<td>Trans-esophageal (Cardiac)</td>
<td></td>
</tr>
<tr>
<td>Intra-cardiac</td>
<td></td>
</tr>
<tr>
<td>Other (Specify)</td>
<td></td>
</tr>
</tbody>
</table>

**Peripheral: Peripheral vessel**

**Concurrence of Center for Devices and Radiological Health (CDRH)**

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Please do not write below this line; continue on another page if needed.
## Indications for Use Form

### Diagnostic Ultrasound Indications for Use Form

**Device Name:** AcuNav 8F Transducer for use with: ACUSON P500™ Diagnostic Ultrasound System

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

<table>
<thead>
<tr>
<th>Mode of Operation</th>
<th>Clinical Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vein (popliteal system)</td>
<td>P = previously cleared K141846</td>
</tr>
<tr>
<td>Other</td>
<td>(Specify)</td>
</tr>
<tr>
<td>2D</td>
<td>(Specify)</td>
</tr>
<tr>
<td>B Mode</td>
<td>(Specify)</td>
</tr>
<tr>
<td>Doppler (Color)</td>
<td>(Specify)</td>
</tr>
<tr>
<td>Other</td>
<td>(Specify)</td>
</tr>
<tr>
<td>Anterior</td>
<td>(Specify)</td>
</tr>
<tr>
<td>Intra-cardiac</td>
<td>(Specify)</td>
</tr>
<tr>
<td>Trans-esophageal (non-Card.)</td>
<td>(Specify)</td>
</tr>
<tr>
<td>Musculo-skeletal</td>
<td>(Specify)</td>
</tr>
<tr>
<td>Trans-motion</td>
<td>(Specify)</td>
</tr>
<tr>
<td>Intra-vascular</td>
<td>(Specify)</td>
</tr>
<tr>
<td>Other</td>
<td>(Specify)</td>
</tr>
</tbody>
</table>

**Note 1** For example: breast, testes, thyroid, prostate, etc.

**Note 2** Dynamic TCE Technology

**Note 3** Advanced SieClear

**Note 4** eSieImage

**Note 5** For example: abdominal, vascular (upper and lower)

**Note 6** Stress Echo

**Note 7** eSieMeasure

**Note 8** eSieScan

**Note 9** AHP

**Note 10** DTI

**Note 11** Panoramic 2D Imaging (SieScape)

**Note 12** Clarify VE

**Note 13** Needle Visualization

**Note 14** Intracardiac Echocardiography (ICE) Imaging

**Note 15** CARTOSOUND Communication

**Note 16** Probe Saver

---

**Please do NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED**

<table>
<thead>
<tr>
<th>N = new indication; P = previously cleared K141846</th>
</tr>
</thead>
</table>

---

**Concurrence of Center for Devices and Radiological Health (CDRH) (Signature):**

__________________________

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**Page 13 of 16**
Indications for Use Form

Device Name: AcuNav 10F Transducer for use with:
ACUSON P500™ Diagnostic Ultrasound System

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

- Clinical Application Mode of Operation
- Other

- Specific (Tracks 1 & 3) BM PW Doppler
- Combined (Specify)
- Other (Specify)
- Ophthalmic Ophthalmic
- Fetal
- Abdominal
- Intra-operative
- Intra-operative (Neuro)
- Laparoscopic
- Other Pediatric Imaging
- & Other
- Small Organ (Note 1)
- Neonatal Cephalic
- Adult Cephalic
- Trans-rectal
- Trans-vaginal
- Trans-urethral Trans-esoph. (non-Card.)
- Musculo-skel. (Convent.)
- Musculo-skel. (Superfic)
- Intra-vascular
- Other (Specify)
- Cardiac Adult Cardiac
- Cardiac Pediatric
- Intra-vascular (Cardiac)
- Trans-esophageal (Cardiac)
- Intra-cardiac
- Other (Specify)
- Peripheral Peripheral vessel (Note 5)
- Other (Specify)

N = new indication; P = previously cleared K141846

Note 1 For example: breast, testes, thyroid, prostate, etc.

Note 2 Dynamic TCE Technology

Note 3 Advanced SieClear

Note 4 eSieImage

Note 5 For example: abdominal, vascular (upper and lower)

Note 6 Stress Echo

Note 7 eSieMeasure

Note 8 eSieScan

Note 9 AHP

Note 10 DTI

Note 11 Panoramic 2D Imaging (SieScape)

Note 12 Clarify VE

Note 13 Needle Visualization

Note 14 Intracardiac Echocardiography (ICE) Imaging

Note 15 CARTOSOUND Communication

Note 16 Probe Saver

(Please do not write below this line. Continue on another page if needed.)

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

510(k) ___________________ Page 14 of 16
## Diagnostic Ultrasound Indications for Use Form

<table>
<thead>
<tr>
<th>N. 16</th>
<th>NEW/REVISED</th>
<th>DIAGNOSTIC ULS</th>
<th>New/Rev.</th>
<th>V. 0</th>
<th>D. 02</th>
<th>E. 01</th>
<th>F. 04</th>
<th>G. 01</th>
<th>H. 04</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO16</td>
<td>Paper_shear</td>
<td>CAROTID</td>
<td>Yes</td>
<td>No 2</td>
<td>No 4</td>
<td>No 6</td>
<td>No 7</td>
<td>No 8</td>
<td>No 9</td>
</tr>
<tr>
<td>NO15</td>
<td>Carotid</td>
<td>Yes</td>
<td>No 2</td>
<td>No 4</td>
<td>No 6</td>
<td>No 7</td>
<td>No 8</td>
<td>No 9</td>
<td>No 10</td>
</tr>
<tr>
<td>NO14</td>
<td>Brachiocephalic &amp; subclavian</td>
<td>Yes</td>
<td>No 2</td>
<td>No 4</td>
<td>No 6</td>
<td>No 7</td>
<td>No 8</td>
<td>No 9</td>
<td>No 10</td>
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<tr>
<td>NO13</td>
<td>Upper extremity</td>
<td>Yes</td>
<td>No 2</td>
<td>No 4</td>
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<td>No 8</td>
<td>No 9</td>
<td>No 10</td>
</tr>
<tr>
<td>NO12</td>
<td>Lower extremity</td>
<td>Yes</td>
<td>No 2</td>
<td>No 4</td>
<td>No 6</td>
<td>No 7</td>
<td>No 8</td>
<td>No 9</td>
<td>No 10</td>
</tr>
<tr>
<td>NO11</td>
<td>Peripheral</td>
<td>Yes</td>
<td>No 2</td>
<td>No 4</td>
<td>No 6</td>
<td>No 7</td>
<td>No 8</td>
<td>No 9</td>
<td>No 10</td>
</tr>
<tr>
<td>NO10</td>
<td>Upper extremity</td>
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<td>No 2</td>
<td>No 4</td>
<td>No 6</td>
<td>No 7</td>
<td>No 8</td>
<td>No 9</td>
<td>No 10</td>
</tr>
<tr>
<td>NO9</td>
<td>Lower extremity</td>
<td>Yes</td>
<td>No 2</td>
<td>No 4</td>
<td>No 6</td>
<td>No 7</td>
<td>No 8</td>
<td>No 9</td>
<td>No 10</td>
</tr>
<tr>
<td>NO8</td>
<td>Upper extremity</td>
<td>Yes</td>
<td>No 2</td>
<td>No 4</td>
<td>No 6</td>
<td>No 7</td>
<td>No 8</td>
<td>No 9</td>
<td>No 10</td>
</tr>
<tr>
<td>NO7</td>
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<td>Yes</td>
<td>No 2</td>
<td>No 4</td>
<td>No 6</td>
<td>No 7</td>
<td>No 8</td>
<td>No 9</td>
<td>No 10</td>
</tr>
<tr>
<td>NO6</td>
<td>Upper extremity</td>
<td>Yes</td>
<td>No 2</td>
<td>No 4</td>
<td>No 6</td>
<td>No 7</td>
<td>No 8</td>
<td>No 9</td>
<td>No 10</td>
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<tr>
<td>NO5</td>
<td>Lower extremity</td>
<td>Yes</td>
<td>No 2</td>
<td>No 4</td>
<td>No 6</td>
<td>No 7</td>
<td>No 8</td>
<td>No 9</td>
<td>No 10</td>
</tr>
</tbody>
</table>

**Intended Use:**
Diagnosis of lesions or flow abnormalities of the human body as follows:

ACUSON P500 Ultrasound System

**Device Name:**
ACUSON P500 Ultrasound System

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

**Note:**
- For example: breast, testes, thyroid, prostate, etc.
- Dynamic TCE Technology
- Advanced SieClear
- eSieImage
- For example: abdominal, vascular (upper and lower)
- Stress Echo
- eSieMeasure
- eSieScan
- AHP
- DTI
- Panoramic 2D Imaging (SieScape)
- Clarify VE
- Needle Visualization
- Intracardiac Echocardiography (ICE) Imaging
- CARTOSOUND Communication
- Probe Saver

**PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.**
### Diagnostic Ultrasound Indications for Use Form

#### Indications for Use Forms

**Diagnostic Ultrasound Indications for Use Form**

**Device Name:** Soundstar eco 8F Transducer for use with: ACUSON P500™ Diagnostic Ultrasound System

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

<table>
<thead>
<tr>
<th>Clinical Application</th>
<th>Mode of Operation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ophthalmic</td>
<td>Standard</td>
</tr>
<tr>
<td>Fetal</td>
<td>Standard</td>
</tr>
<tr>
<td>Abdominal</td>
<td>Standard</td>
</tr>
<tr>
<td>Intra-operative</td>
<td>Standard</td>
</tr>
<tr>
<td>Intra-operative (Neuro)</td>
<td>Standard</td>
</tr>
<tr>
<td>Laparoscopic</td>
<td>Standard</td>
</tr>
<tr>
<td>Fetal Pediatric Imaging &amp; Other</td>
<td>Standard</td>
</tr>
<tr>
<td>Neonatal Cephalic</td>
<td>Standard</td>
</tr>
<tr>
<td>Adult Cephalic</td>
<td>Standard</td>
</tr>
<tr>
<td>Trans-rectal</td>
<td>Standard</td>
</tr>
<tr>
<td>Trans-vaginal</td>
<td>Standard</td>
</tr>
<tr>
<td>Trans-urethral</td>
<td>Standard</td>
</tr>
<tr>
<td>Trans-esoph. (non-Card.)</td>
<td>Standard</td>
</tr>
<tr>
<td>Musculo-skel. (Convent.)</td>
<td>Standard</td>
</tr>
<tr>
<td>Musculo-skel. (Superfic)</td>
<td>Standard</td>
</tr>
<tr>
<td>Intra-vascular</td>
<td>Standard</td>
</tr>
<tr>
<td>Other (Specify)</td>
<td>Standard</td>
</tr>
<tr>
<td>Cardiac Adult</td>
<td>Standard</td>
</tr>
<tr>
<td>Cardiac</td>
<td>Standard</td>
</tr>
<tr>
<td>Pediatric</td>
<td>Standard</td>
</tr>
<tr>
<td>Intra-vascular (Cardiac)</td>
<td>Standard</td>
</tr>
<tr>
<td>Trans-esophageal (Cardiac)</td>
<td>Standard</td>
</tr>
<tr>
<td>Intra-cardiac</td>
<td>Standard</td>
</tr>
<tr>
<td>Other (Specify)</td>
<td>Standard</td>
</tr>
<tr>
<td>Peripheral vessel (Note 5)</td>
<td>Standard</td>
</tr>
<tr>
<td>Vessel Other (Specify)</td>
<td>Standard</td>
</tr>
</tbody>
</table>

**Note:**
- For example: breast, testes, thyroid, prostate, etc.
- Dynamic TCE Technology
- Advanced SieClear
- eSieImage
- For example: abdominal, vascular (upper and lower)
- Stress Echo
- eSieMeasure
- eSieScan
- AHP
- DTI
- Panoramic 2D Imaging (SieScape)
- Clarify VE
- Needle Visualization
- Intracardiac Echocardiography (ICE) Imaging
- CARTOSOUND Communication
- Probe Saver

**Concurrence of Center for Devices and Radiological Health (CDRH):**

**Signature:**

---

**Page 15 of 16**
**Indications for Use Form**

**Device Name:** Soundstar eco 10F Transducer for use with ACUSON P500™ Ultrasound System

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

<table>
<thead>
<tr>
<th>Clinical Application</th>
<th>Mode of Operation</th>
<th>Diagnostic Ultrasound Indications for Use Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ophthalmic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ophthalmic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intra-operative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intra-operative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Neuro)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laparoscopic</td>
<td></td>
<td></td>
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**Note:**
- For example: breast, testes, thyroid, prostate, etc.
- Dynamic TCE Technology
- Advanced SiClear
- eSieImage
- For example: abdominal, vascular (upper and lower)
- Stress Echo
- eSieMeasure
- eSieScan
- AHP
- DTI
- Panoramic 2D Imaging (SieScape)
- Clarify VE
- Needle Visualization
- Intracardiac Echocardiography (ICE) Imaging
- CARTOSOUND Communication
- Probe Saver

**Concurrence of Center for Devices and Radiological Health (CDRH) (Signature):**

____________________________________________

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

Page 16 of 16
510(k) Summary
Prepared October 24, 2016

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

Manufacturing Facility
Siemens Healthcare Ltd.
2nd -3rd floor, 143, Sunhwan-ro,
Jungwon-gu, Seongnam-si, Gyeonggi-do,
Republic of Korea

Contact Person: Shelly Pearce
Telephone: (650) 279-0134
Fax: (650) 694-5580

Device Name: ACUSON P500™ Ultrasound System

Common Name: Diagnostic Ultrasound System with Accessories

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

Device | 21 CFR section | Product Code
--- | --- | ---
Ultrasonic Pulsed Doppler Imaging System | 892.1550 | 90-IYN
Ultrasonic Pulsed Echo Imaging System | 892.1560 | 90-IYO
Diagnostic Ultrasound Transducer | 892.1570 | 90-ITX
Diagnostic Intravascular Catheter | 870.1200 | 90-OBJ

A. Legally Marketed Predicate Devices
The ACUSON P500™ Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to our current product, the
B. Device Description:
The ACUSON P500™ 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 harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Color M mode, Tissue Doppler Image, Power (Amplitude) Doppler Mode and a combination of modes on a Flat Panel Display.

C. Intended Use
The ACUSON P500 ultrasound imaging system is intended for the following applications:
Fetal, Abdominal (including liver), Pediatric, Small Parts, Transcranial, OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures), Pelvic, Neonatal, Cardiac, IntraCardiac, Vascular (including Peripheral Vessel), Musculoskeletal, Superficial Musculoskeletal, and Urology applications.

The system also provides the ability to measure anatomical structures fetal, abdominal, small organ, transrectal, transvaginal, cardiovascular, peripheral vessel, musculoskeletal (conventional), and musculoskeletal (superficial) and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system.

This feature should be utilized according to the “ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Society of Echocardiography Carotid Intima-Media Thickness Task Force. Endorsed by the Society for Vascular Imaging.”

The ACUSON Acunav Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

D. Substantial Equivalence
The ACUSON P500™ Ultrasound System is substantially equivalent to the ACUSON P500 (K150050), ACUSON X700 (K141846), ACUSON SC2000 (K162221), ACUSON NX2 (K161787), ACUSON Freestyle (K162417) and Vivid i&q (K121062). All systems transmit
ultrasonic energy into patients, then perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

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

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### Features:

| Feature                                                                 | 3D Imaging (3-Scape) | 3D Measurements | 4D Basic Imaging (fourSight 4D) | Panoramic 2D Imaging (SieScape) | Cardiac Imaging physiological signal display multiplane TEE fourSight TEE Imaging | Dual-Beam Processing | Quad-Beam Processing | SynAps | Clip Capture | Tissue Grayscale Optimization (TGO) | Spectral DTI | Syngo Auto OB | Stress Echo | 2D(color) DTI | DIMAQ (PIMS Workplace) | Vascular Enhancement (Clarify VE) | eSieImage | Advance SieClear | Multiple Frequency Imaging(MultiHertz) | Digital Architecture | DICOM SR Vascular | DICOM SR OB/GYN | DICOM SR Cardiac | Dynamic TCE | Syngo AHP | eSieMeasure | eSieScan |
|------------------------------------------------------------------------|----------------------|-----------------|--------------------------------|---------------------------------|---------------------------------------------------------------------------------|---------------------|-------------------------|--------|-------------|-------------------------------------|----------------|----------------|-------------|--------------|-----------------------------|----------------------|-----------|-----------------|------------------------|---------------|--------------|--------------|--------------|--------------|-------------|---------|
| 3D Imaging (3-Scape)                                                  | -                    | -               | -                              | -                               | -                                                                               | -                   | -                       | -      | -            | -                                                      | -               | -            | -            | -            | -              | -            | -        |
| 3D Measurements                                                       | -                    | -               | ✓                              | ✓                               | ✓                                                                               | ✓                   | ✓                       | ✓       | ✓            | ✓                                                      | -               | -            | -            | -            | -              | -            | -        |
| 4D Basic Imaging (fourSight 4D)                                       | -                    | -               | ✓                              | -                               | ✓                                                                               | -                   | -                       | -       | -            | -                                                      | -               | -            | -            | -            | -              | -            | -        |
| Panoramic 2D Imaging (SieScape)                                       | -                    | -               | ✓                              | -                               | ✓                                                                               | -                   | -                       | -       | -            | -                                                      | -               | -            | -            | -            | -              | -            | -        |
| Cardiac Imaging physiological signal display multiplane TEE fourSight TEE Imaging | -                    | -               | ✓                              | ✓                               | ✓                                                                               | -                   | -                       | -       | -            | -                                                      | -               | -            | -            | -            | -              | -            | -        |
| Dual-Beam Processing                                                  | -                    | -               | ✓                              | ✓                               | ✓                                                                               | ✓                   | ✓                       | ✓       | ✓            | ✓                                                      | -               | -            | -            | -            | -              | -            | -        |
| Quad-Beam Processing                                                  | -                    | -               | ✓                              | ✓                               | ✓                                                                               | ✓                   | ✓                       | ✓       | ✓            | ✓                                                      | -               | -            | -            | -            | -              | -            | -        |
| SynAps                                                               | -                    | -               | ✓                              | -                               | ✓                                                                               | -                   | -                       | -       | -            | -                                                      | -               | -            | -            | -            | -              | -            | -        |
| Clip Capture                                                         | -                    | ✓               | ✓                              | ✓                               | ✓                                                                               | ✓                   | ✓                       | ✓       | ✓            | ✓                                                      | -               | -            | -            | -            | -              | -            | -        |
| Tissue Grayscale Optimization (TGO)                                   | -                    | -               | ✓                              | -                               | ✓                                                                               | -                   | -                       | -       | -            | -                                                      | -               | -            | -            | -            | -              | -            | -        |
| Spectral DTI                                                         | -                    | -               | ✓                              | ✓                               | ✓                                                                               | ✓                   | -                       | -       | -            | -                                                      | -               | -            | -            | -            | -              | -            | -        |
| Syngo Auto OB                                                        | -                    | -               | ✓                              | -                               | ✓                                                                               | -                   | -                       | -       | -            | -                                                      | -               | -            | -            | -            | -              | -            | -        |
| Stress Echo                                                          | -                    | -               | ✓                              | ✓                               | ✓                                                                               | -                   | -                       | -       | -            | -                                                      | -               | -            | -            | -            | -              | -            | -        |
| 2D(color) DTI                                                        | -                    | -               | ✓                              | ✓                               | ✓                                                                               | ✓                   | -                       | -       | -            | -                                                      | -               | -            | -            | -            | -              | -            | -        |
| DIMAQ (PIMS Workplace)                                                | -                    | -               | ✓                              | -                               | ✓                                                                               | ✓                   | ✓                       | ✓       | ✓            | ✓                                                      | -               | -            | -            | -            | -              | -            | -        |
| Vascular Enhancement (Clarify VE)                                     | -                    | -               | ✓                              | ✓                               | ✓                                                                               | ✓                   | -                       | -       | -            | -                                                      | -               | -            | -            | -            | -              | -            | -        |
| eSieImage                                                            | -                    | -               | -                              | -                               | -                                                                               | ✓                   | ✓                       | ✓       | ✓            | ✓                                                      | -               | -            | -            | -            | -              | -            | -        |
| Advance SieClear                                                     | -                    | -               | ✓                              | ✓                               | ✓                                                                               | ✓                   | ✓                       | ✓       | ✓            | ✓                                                      | -               | -            | -            | -            | -              | -            | -        |
| Multiple Frequency Imaging(MultiHertz)                               | -                    | ✓               | ✓                              | ✓                               | ✓                                                                               | ✓                   | ✓                       | ✓       | ✓            | ✓                                                      | -               | -            | -            | -            | -              | -            | -        |
| Digital Architecture                                                 | -                    | ✓               | ✓                              | ✓                               | ✓                                                                               | ✓                   | ✓                       | ✓       | ✓            | ✓                                                      | -               | -            | -            | -            | -              | -            | -        |
| DICOM SR Vascular                                                    | -                    | -               | ✓                              | ✓                               | ✓                                                                               | ✓                   | ✓                       | ✓       | ✓            | ✓                                                      | -               | -            | -            | -            | -              | -            | -        |
| DICOM SR OB/GYN                                                      | -                    | -               | ✓                              | ✓                               | ✓                                                                               | ✓                   | ✓                       | ✓       | ✓            | ✓                                                      | -               | -            | -            | -            | -              | -            | -        |
| DICOM SR Cardiac                                                     | -                    | -               | ✓                              | ✓                               | ✓                                                                               | ✓                   | -                       | ✓       | -            | -                                                      | -               | -            | -            | -            | -              | -            | -        |
| Dynamic TCE                                                          | -                    | -               | ✓                              | ✓                               | ✓                                                                               | ✓                   | ✓                       | ✓       | ✓            | ✓                                                      | -               | -            | -            | -            | -              | -            | -        |
| Syngo AHP                                                            | -                    | -               | ✓                              | ✓                               | ✓                                                                               | ✓                   | -                       | -       | -            | -                                                      | -               | -            | -            | -            | -              | -            | -        |
| eSieMeasure                                                          | -                    | -               | -                              | -                               | -                                                                               | ✓                   | -                       | -       | -            | -                                                      | -               | -            | -            | -            | -              | -            | -        |
| eSieScan                                                             | -                    | -               | -                              | -                               | ✓                                                                               | -                   | -                       | -       | -            | -                                                      | -               | -            | -            | -            | -              | -            | -        |
### E. 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:

- ANSI/AAMI ES 60601-1, 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
- IEC 62359, Test methods for the determination of thermal and mechanical indices
- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-2-18
- IEC 60601-2-37
- ISO 10993-1

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

### F. A summary discussion of the clinical tests submitted, referenced, or relied on for a determination of substantial equivalence.

Since the ACUSON P500™ Ultrasound System uses the same technology and principles as existing devices, clinical data is not required.
G. Summary

Intended uses and other key features are consistent with traditional clinical practice and FDA guidelines. The design and development process of the manufacturer conforms with 21 CFR 820 Quality System Regulation and ISO 13485:2003 quality system standards. The product is designed to conform with applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of Siemens Medical Solutions USA, Inc that the ACUSON P500™ Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

The ACUSON P500™ Ultrasound System is verified and validated according to the company’s design control process.