Samsung Medison Co., Ltd.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN  55313

Re: K172129
Trade/Device Name: HS40 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: July 12, 2017
Received: July 14, 2017

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,

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

Enclosure
Indications for Use

510(k) Number (if known)
K172129

Device Name
HS40 Diagnostic Ultrasound System

Indications for Use (Describe)
The HS40 diagnostic ultrasound system and probes were designed for obtaining ultrasound images and analyzing body fluid.

The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric and Peripheral vessel.

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.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRARestaff@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 STATEMENT

**510(k) No.:**

Device Name: HS40 Diagnostic Ultrasound System

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

<table>
<thead>
<tr>
<th>Clinical Application</th>
<th>Mode of Operation (*includes simultaneous B-mode)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General (Track I only)</td>
<td>B</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Ophthalmic</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Fetal/Ophthalmic (See Note 3)</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Abdominal (See Note 10)</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Intra-operative (See Note 6)</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Intra-operative (Neuro.)</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Laparoscopic</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Pediatric</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Small Organ (See Note 5)</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Neonatal Cephalic</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Adult Cephalic</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Trans-rectal</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Trans-vaginal</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Trans-urethral</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Trans-esoph. (non-Cardiac)</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Musculo-skel. (Convent.)</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Musculo-skel. (Superfic.)</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Intra-luminal</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Other (See Note 13)</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Cardiac Adult</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Cardiac Pediatric</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Trans-esophageal (Cardiac)</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Other (spec.)</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Peripheral vessel</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>Other (spec.)</td>
</tr>
</tbody>
</table>

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

**Additional Comments:**

- Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PPI, B+TD, B+PPI+PW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Other M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organ, renal, gynecology/pelvis
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: MultiVision (Spatial Compound Imaging)
- Note 10: Includes Renal, Gynecology/Pelvis
- Note 11: Panoramic imaging
- Note 12: ElastoScan
- Note 13: Includes Urology/Prostate
- Note 14: Tissue Doppler Imaging (TDI)
- Note 15: Color Doppler includes Power (Amplitude) Doppler
- Note 16: Contrast
- Note 17: Strain

Concurrence of Center for Devices and Radiological Health (CDRH)

Prescription Use (Per 21 CFR 801.109)
## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

### 510(k) No.:
Device Name: LA3-16AD for use with HS40

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

<table>
<thead>
<tr>
<th>Clinical Application</th>
<th>Mode of Operation (*includes simultaneous B-mode)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td></td>
</tr>
<tr>
<td>Fetal Imaging &amp; Other</td>
<td></td>
</tr>
<tr>
<td>Fetal/Obstetrics</td>
<td>N</td>
</tr>
<tr>
<td>Abdominal</td>
<td>N</td>
</tr>
<tr>
<td>Intra-operative</td>
<td>N</td>
</tr>
<tr>
<td>Pediatric</td>
<td>P</td>
</tr>
<tr>
<td>Neonatal Cephalic</td>
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</tr>
<tr>
<td>Adult Cephalic</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-Cardiac)</td>
<td></td>
</tr>
<tr>
<td>Musculo-skel. (Convent.)</td>
<td>P</td>
</tr>
<tr>
<td>Musculo-skel. (Superfic.)</td>
<td>P</td>
</tr>
<tr>
<td>Intra-luminal</td>
<td></td>
</tr>
<tr>
<td>Other (See Note 13)</td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td></td>
</tr>
<tr>
<td>Cardiac Adult</td>
<td></td>
</tr>
<tr>
<td>Cardiac Pediatric</td>
<td></td>
</tr>
<tr>
<td>Trans-esophageal (Cardiac)</td>
<td>P</td>
</tr>
<tr>
<td>Other (spec.)</td>
<td></td>
</tr>
<tr>
<td>Peripheral Vessel</td>
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</tr>
<tr>
<td>Peripheral vessel</td>
<td>P</td>
</tr>
<tr>
<td>Other (spec.)</td>
<td></td>
</tr>
</tbody>
</table>

N = new indication; P = previously cleared by FDA K153408; E = added under Appendix E

### Additional Comments:
Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PPI, B+TD, B+PPI+PW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: MultiVision (Spatial Compound Imaging)
Note 10: Includes Renal, Gynecology/Pelvis
Note 11: Panoramic imaging
Note 12: ElastoScan
Note 13: Includes Urology/Prostate
Note 14: Tissue Doppler Imaging (TDI)
Note 15: Color Doppler includes Power (Amplitude) Doppler
Note 16: Strain+
**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT**

510(k) No.:
Device Name: CA2-8AD for use with HS40
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

<table>
<thead>
<tr>
<th>General (Track I only)</th>
<th>Specific (Tracks I &amp; III)</th>
<th>B</th>
<th>M</th>
<th>PWD</th>
<th>CWD</th>
<th>Color Doppler*</th>
<th>Combined* (Spec.)</th>
<th>Other (Spec.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ophthalmic</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Fetal Imaging & Other**

- **Fetal/Obstetrics (See Note 3)**
  - B: 1
  - M: 1
  - PWD: 1
  - CWD: 1
  - Color Doppler*: 1
  - Combined*: 1
  - Other: 1

- **Abdominal (See Note 10)**
  - B: 1
  - M: 1
  - PWD: 1
  - CWD: 1
  - Color Doppler*: 1
  - Combined*: 1
  - Other: 1

- **Intra-operative (See Note 6)**
  - B: 1
  - M: 1
  - PWD: 1
  - CWD: 1
  - Color Doppler*: 1
  - Combined*: 1
  - Other: 1

- **Laparoscopic**
  - B: 1
  - M: 1
  - PWD: 1
  - CWD: 1
  - Color Doppler*: 1
  - Combined*: 1
  - Other: 1

- **Pediatric**
  - B: 1
  - M: 1
  - PWD: 1
  - CWD: 1
  - Color Doppler*: 1
  - Combined*: 1
  - Other: 1

- **Small Organ (See Note 5)**
  - B: 1
  - M: 1
  - PWD: 1
  - CWD: 1
  - Color Doppler*: 1
  - Combined*: 1
  - Other: 1

- **Neonatal Cephalic**
  - B: 1
  - M: 1
  - PWD: 1
  - CWD: 1
  - Color Doppler*: 1
  - Combined*: 1
  - Other: 1

- **Adult Cephalic**
  - B: 1
  - M: 1
  - PWD: 1
  - CWD: 1
  - Color Doppler*: 1
  - Combined*: 1
  - Other: 1

- **Trans-rectal**
  - B: 1
  - M: 1
  - PWD: 1
  - CWD: 1
  - Color Doppler*: 1
  - Combined*: 1
  - Other: 1

- **Trans-vaginal**
  - B: 1
  - M: 1
  - PWD: 1
  - CWD: 1
  - Color Doppler*: 1
  - Combined*: 1
  - Other: 1

- **Trans-urethral**
  - B: 1
  - M: 1
  - PWD: 1
  - CWD: 1
  - Color Doppler*: 1
  - Combined*: 1
  - Other: 1

- **Trans-esoph. (non-Cardiac)**
  - B: 1
  - M: 1
  - PWD: 1
  - CWD: 1
  - Color Doppler*: 1
  - Combined*: 1
  - Other: 1

- **Musculo-skel. (Convent.)**
  - B: 1
  - M: 1
  - PWD: 1
  - CWD: 1
  - Color Doppler*: 1
  - Combined*: 1
  - Other: 1

- **Musculo-skel. (Superfic.)**
  - B: 1
  - M: 1
  - PWD: 1
  - CWD: 1
  - Color Doppler*: 1
  - Combined*: 1
  - Other: 1

- **Intra-luminal**
  - B: 1
  - M: 1
  - PWD: 1
  - CWD: 1
  - Color Doppler*: 1
  - Combined*: 1
  - Other: 1

- **Other (See Note 13)**

**Cardiac**

- **Cardiac Adult**
  - B: 1
  - M: 1
  - PWD: 1
  - CWD: 1
  - Color Doppler*: 1
  - Combined*: 1
  - Other: 1

- **Cardiac Pediatric**
  - B: 1
  - M: 1
  - PWD: 1
  - CWD: 1
  - Color Doppler*: 1
  - Combined*: 1
  - Other: 1

- **Trans-esophageal (Cardiac)**
  - B: 1
  - M: 1
  - PWD: 1
  - CWD: 1
  - Color Doppler*: 1
  - Combined*: 1
  - Other: 1

- **Other (spec.)**

**Peripheral Vessel**

- **Peripheral vessel**
  - B: 1
  - M: 1
  - PWD: 1
  - CWD: 1
  - Color Doppler*: 1
  - Combined*: 1
  - Other: 1

- **Other (spec.)**

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**Additional Comments:**

- Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PPI, B+TD, B+PPI+PW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: MultiVision (Spatial Compound Imaging)
- Note 10: Includes Renal, Gynecology/Pelvis
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- Note 12: ElastoScan
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- Note 14: Tissue Doppler Imaging (TDI)
- Note 15: Color Doppler includes Power (Amplitude) Doppler
- Note 16: Strain+

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Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)

Indication for use
### DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

**510(k) No.:**

Device Name: CF4-9 for use with HS40

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

<table>
<thead>
<tr>
<th>Clinical Application</th>
<th>Mode of Operation (*includes simultaneous B-mode)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General (Track I only)</td>
<td>B M PWD CWD Color Doppler* Combined* Other</td>
</tr>
<tr>
<td>Specific (Tracks I &amp; III)</td>
<td>Note 15 Note 1 Note 8, 9, 11</td>
</tr>
</tbody>
</table>

- **Ophthalmic**
  - Fetal/Ophthalmic (See Note 3)
  - Abdominal (See Note 10)
  - Intra-operative (See Note 6)
  - Laparoscopic
  - Pediatric
  - Neonatal Cephalic
  - Adult Cephalic
  - Trans-rectal
  - Trans-vaginal
  - Trans-urethral
  - Trans-esoph. (non-Cardiac)
  - Musculo-skel. (Convent.)
  - Musculo-skel. (Superfic.)
  - Intra-luminal
  - Other (See Note 13)

- **Fetal Imaging & Other**
  - Cardiac Adult
  - Cardiac Pediatric
  - Trans-esophageal (Cardiac)
  - Other (spec.)

- **Perivascular**
  - Peripheral vessel
  - Other (spec.)

- **Cardiac**
  - Cardiac Adult
  - Cardiac Pediatric
  - Trans-esophageal (Cardiac)
  - Other (spec.)

**N= new indication; P= previously cleared by FDA K133505; E= added under Appendix E**

**Additional Comments:**

- Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PPI, B+TD, B+PPI+PW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
- Note 2: Includes imaging for guidance of biopsy
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- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
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- Note 10: Includes Renal, Gynecology/Pelvis
- Note 11: Panoramic imaging
- Note 12: ElastoScan
- Note 13: Includes Urology/Prostate
- Note 14: Tissue Doppler Imaging (TDI)
- Note 15: Color Doppler includes Power (Amplitude) Doppler
- Note 16: Strain+
## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

### 510(k) No.: PN2-4 for use with HS40

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

<table>
<thead>
<tr>
<th>Clinical Application</th>
<th>Mode of Operation (*includes simultaneous B-mode)</th>
</tr>
</thead>
</table>
| General (Track I only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler* | Combined* | Other | (
| Ophthalmic | Ophthalmic | |
| Fetal Imaging & Other | | Fetal/Obstetrics (See Note 3) | P | P | P | Note 15 | Note 1 | Note 7 |
| | Abdominal (See Note 10) | P | P | P | Note 15 | Note 1 | Note 7 |
| | Intra-operative (See Note 6) | |
| | Intra-operative (Neuro.) | |
| | Laparoscopic | |
| | Pediatric | |
| | Small Organ (See Note 5) | |
| | Neonatal Cephalic | |
| | Adult Cephalic | P | P | P | Note 15 | Note 1 | Note 7 |
| | Trans-rectal (See Note 13) | |
| | Trans-vaginal (See Note 13) | |
| | Trans-urethral | |
| | Trans-esoph. (non-Cardiac) | |
| | Musculo-skel. (Convent.) | |
| | Musculo-skel. (Superfic.) | |
| | Intra-luminal | |
| | Other (See Note 13) | |
| Cardiac | Cardiac Adult | P | P | P | Note 15 | Note 1 | Note 4, 7, 14, 16 |
| | Cardiac Pediatric | P | P | P | Note 15 | Note 1 | Note 4, 7, 14, 16 |
| | Trans-esophageal (Cardiac) | |
| | Other (spec.) | |
| Peripheral Vessel | Peripheral vessel | |
| | Other (spec.) | |

N= new indication; P= previously cleared by FDA K133505; E= added under Appendix E

### Additional Comments:

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PPI, B+TD, B+PPI+PW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Note 14: Tissue Doppler Imaging (TDI)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Strain+
## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

### 510(k) No.:
Device Name: EVN4-9 for use with HS40

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

<table>
<thead>
<tr>
<th>Clinical Application</th>
<th>Mode of Operation (*includes simultaneous B-mode)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
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<tr>
<td><strong>General</strong> (Track I only)</td>
<td></td>
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<tr>
<td><strong>Specific</strong> (Tracks I &amp; III)</td>
<td></td>
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<tr>
<td><strong>Ophthalmic</strong></td>
<td>Ophthalmic</td>
</tr>
<tr>
<td><strong>Fetal Imaging</strong> &amp; Other</td>
<td></td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>P</td>
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<tr>
<td>Abdominal (See Note 10)</td>
<td>P</td>
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<tr>
<td>Intra-operative (See Note 6)</td>
<td></td>
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<tr>
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<tr>
<td>Laparoscopic</td>
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<tr>
<td>Pediatric</td>
<td></td>
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<tr>
<td>Small Organ (See Note 5)</td>
<td></td>
</tr>
<tr>
<td>Neonatal Cephalic</td>
<td></td>
</tr>
<tr>
<td>Adult Cephalic</td>
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<tr>
<td>Trans-rectal</td>
<td>P</td>
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<td>Trans-vaginal</td>
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<tr>
<td>Trans-urethral</td>
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<tr>
<td>Trans-esoph. (non-Cardiac)</td>
<td></td>
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<tr>
<td>Musculo-skel. (Convent.)</td>
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<td>Musculo-skel. (Superfic.)</td>
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<tr>
<td>Intra-luminal</td>
<td></td>
</tr>
<tr>
<td>Other (spec.) (See Note 13)</td>
<td>P</td>
</tr>
</tbody>
</table>

- **Cardiac** |      |      |      |      |                   |                   |               |
- **Cardiac Pediatric** |      |      |      |      |                   |                   |               |
- **Trans-esophageal (Cardiac)** |      |      |      |      |                   |                   |               |
- **Other (spec.)** |      |      |      |      |                   |                   |               |

- **Peripheral Vessel** |      |      |      |      |                   |                   |               |
- **Peripheral vessel** |      |      |      |      |                   |                   |               |
- **Other (spec.)** |      |      |      |      |                   |                   |               |

N= new indication; P= previously cleared by FDA K153408; E= added under Appendix E

### Additional Comments:
- Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PPI, B+TD, B+PPI+PW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D Imaging
- Note 9: MultiVision (Spatial Compound Imaging)
- Note 10: Includes Renal, Gynecology/Pelvis
- Note 11: Panoramic Imaging
- Note 12: ElastoScan
- Note 13: Includes Urology/Prostate
- Note 14: Tissue Doppler Imaging (TDI)
- Note 15: Color Doppler includes Power (Amplitude) Doppler
- Note 16: Strain+
### DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

#### 510(k) No.:
- Device Name: VN4-8 for use with HS40

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

<table>
<thead>
<tr>
<th>Clinical Application</th>
<th>Mode of Operation (*includes simultaneous B-mode)</th>
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<tbody>
<tr>
<td></td>
<td>B</td>
</tr>
<tr>
<td>General (Track I only)</td>
<td>B</td>
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<tr>
<td>Ophthalmic</td>
<td></td>
</tr>
</tbody>
</table>

#### Fetal Imaging & Other

- **Fetal/Obstetrics (See Note 3)**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Abdominal (See Note 10)**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Intra-operative (See Note 6)**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Intra-operative (Neuro.)**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Laparoscopic**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Pediatric (See Note 5)**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Small Organ (See Note 5)**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Neonatal Cephalic**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Adult Cephalic**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Trans-rectal**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Trans-vaginal**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Trans-urethral**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Trans-esoph. (non-Cardiac)**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Musculo-skel. (Convent.)**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Musculo-skel. (Superfic.)**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Intra-luminal**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Other (See Note 13)**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

#### Cardiac

- **Cardiac Adult**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Cardiac Pediatric**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Trans-esophageal (Cardiac)**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Other (spec.)**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

#### Peripheral

- **Peripheral**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

- **Vessel**
  - B
  - P
  - P
  - P
  - Note 15
  - Note 1
  - Note 2, 7, 8, 9, 11

---

N= new indication; P= previously cleared by K153408; E= added under Appendix E

#### Additional Comments:
- **Note 1:** B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PPI, B+TD, B+PPI+PW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
- **Note 2:** Includes imaging for guidance of biopsy
- **Note 3:** Includes infertility monitoring of follicle development
- **Note 4:** Color M-mode
- **Note 5:** For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- **Note 6:** Abdominal organs and peripheral vessel
- **Note 7:** Tissue Harmonic Imaging (THI)
- **Note 8:** 3D imaging
- **Note 9:** MultiVision (Spatial Compound Imaging)
- **Note 10:** Includes Renal, Gynecology/Pelvis
- **Note 11:** Panoramic imaging
- **Note 12:** ElastoScan
- **Note 13:** Includes Urology/Prostate
- **Note 14:** Tissue Doppler Imaging (TDI)
- **Note 15:** Color Doppler includes Power (Amplitude) Doppler
- **Note 16:** Strain+

---

Concurrence of Center for Devices and Radiological Health (CDRH)
Prescription Use (Per 21 CFR 801.109)
### DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

**510(k) No.:**  
Device Name: V5-9 for use with HS40  
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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<tr>
<th>Clinical Application</th>
<th>Mode of Operation (*includes simultaneous B-mode)</th>
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<tbody>
<tr>
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<tr>
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<td>Abdominal (See Note 10)</td>
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<td>Intra-operative (See Note 6)</td>
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<tr>
<td>Intra-operative (Neuro.)</td>
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<td>Laparoscopic</td>
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<tr>
<td>Pediatric</td>
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<tr>
<td>Small Organ (See Note 5)</td>
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<tr>
<td>Neonatal Cephalic</td>
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<tr>
<td>Adult Cephalic</td>
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<tr>
<td>Trans-rectal</td>
<td>P</td>
</tr>
<tr>
<td>Trans-vaginal</td>
<td>P</td>
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<td>Trans-urethral</td>
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<td>Trans-esoph. (non-Cardiac)</td>
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<tr>
<td>Musculo-skel. (Convent.)</td>
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<tr>
<td>Musculo-skel. (Superfic.)</td>
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<tr>
<td>Intra-luminal</td>
<td></td>
</tr>
<tr>
<td>Other (See Note 13)</td>
<td>P</td>
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<tr>
<td>Cardiac</td>
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<tr>
<td>Cardiac Adult</td>
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<td>Cardiac Pediatric</td>
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<tr>
<td>Trans-esophageal (Cardiac)</td>
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<td>Other (spec.)</td>
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<tr>
<td>Peripheral vessel</td>
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<td>Other (spec.)</td>
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</tbody>
</table>

N= new indication; P= previously cleared by FDA K153408; E= added under Appendix E  

**Additional Comments:**  
Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PPI, B+TD, B+PPI+PW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)  
Note 2: Includes imaging for guidance of biopsy  
Note 3: Includes infertility monitoring of follicle development  
Note 4: Color M-mode  
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients  
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Note 7: Tissue Harmonic Imaging (THI)  
Note 8: 3D imaging  
Note 9: MultiVision (Spatial Compound Imaging)  
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Note 11: Panoramic imaging  
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Note 13: Includes Urology/Prostate  
Note 14: Tissue Doppler Imaging (TDI)  
Note 15: Color Doppler includes Power (Amplitude) Doppler  
Note 16: Strain+

Concurrence of Center for Devices and Radiological Health (CDRH)  
Prescription Use (Per 21 CFR 801.109)
**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT**

510(k) No.: DP2B for use with HS40

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

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<td>Trans-esoph. (non-Cardiac)</td>
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<td>Musculo-skel. (Convent.)</td>
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<td>Musculo-skel. (Superfic.)</td>
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<tr>
<td>Cardiac Adult</td>
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<td>Trans-esophageal (Cardiac)</td>
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<tr>
<td>Other (spec.)</td>
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<tr>
<td>Peripheral Vessel</td>
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<tr>
<td>Peripheral vessel</td>
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N= new indication; P= previously cleared by FDA K143264; E= added under Appendix E

Additional Comments:

Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+Elastoscan, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, B+PPI, B+TD, B+TD+PW, B+PDI, B+TD, B+TD+PW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Note 14: Tissue Doppler Imaging (TDI)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Strain+
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1. **Submitter’s Information: 21 CFR 807.92(a)(1)**

   SAMSUNG MEDISON CO., LTD.
   42, Teheran-ro 108-gil, Gangnam-gu,
   Seoul, Korea

   **Contact Person:**
   Jiyeon, Cho
   Regulatory Affairs Specialist

   **Telephone:**  82.2.2194.5431
   **Facsimile:**   82.2.556.3974

   **Data Prepared:** Apr 13, 2017

2. **Name of the device:**

   **Common/Usual Name:**
   Diagnostic Ultrasound System and Accessories

   **Proprietary Name:**
   HS40 Diagnostic Ultrasound System

   **Classification Names:**
<table>
<thead>
<tr>
<th>Classification Names</th>
<th>FR Number</th>
<th>Product Code</th>
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<tbody>
<tr>
<td>Ultrasonic Pulsed Doppler Imaging System</td>
<td>892.1550</td>
<td>IYN</td>
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<tr>
<td>Ultrasound Pulsed Echo Imaging System</td>
<td>892.1560</td>
<td>IYO</td>
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<tr>
<td>Diagnostic Ultrasound Transducer</td>
<td>892.1570</td>
<td>ITX</td>
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</tbody>
</table>

3. **Identification of the predicate or legally marketed device:**

   - HS50 / HS60 Diagnostic Ultrasound System (K170493)
4. Device Description:

The HS40 is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as B mode, M mode, Color M mode, Anatomical mode, Color Doppler mode, Pulsed Wave (PW) Spectral Doppler mode, Continuous Wave (CW) Doppler mode, Tissue Doppler Imaging (TDI) mode, Tissue Doppler Wave (TDW) mode, Power Doppler (PD) mode, ElastoScan Mode, 3D/4D/XI STIC imaging mode, Freehand 3D mode, Dual mode, Dual live mode, Quad mode, Combined mode, Simultaneous mode and Zoom mode. The HS40 also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information that is used to make a diagnosis by competent health care professionals. The HS40 have real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

5. Intended Uses:

The HS40 diagnostic ultrasound system and probes were designed for obtaining ultrasound images and analyzing body fluid.

The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric and Peripheral vessel.

6. Technological Characteristics:

The HS40 are substantially equivalent with respect to safety, effectiveness, and functionality to the HS50 / HS60 (K170493). There is no new functionality that of predicate device of HS40.

All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All system allow for specialized measurements of structures and flow, and calculations.

<table>
<thead>
<tr>
<th>Feature / Characteristics</th>
<th>The subject device</th>
<th>The predicate device.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HS40</td>
<td>HS50 / HS60 (K170493)</td>
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<tr>
<td>Indications for use</td>
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<td>Feature / Characteristics</td>
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<tr>
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<td>Needle Mate+</td>
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<td>3D XI</td>
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<td>3D MSV/Oblique View</td>
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<td>3D MXI Volume Slice/Mirror View</td>
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</table>
7. A brief discussion of the bench and non-clinical tests conducted on the subject device

The device has been evaluated for acoustic output, biocompatibility effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and has been found to conform to applicable medical device safety standards.

The HS40 and their applications comply with voluntary standards as below:

<table>
<thead>
<tr>
<th>Reference No.</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO14971</td>
<td>ISO 14971:2007, Medical devices - Application of risk management to medical devices</td>
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<tr>
<td>NEMA UD 3-2004</td>
<td>NEMA UD 3-2004 (R2009) Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 2</td>
</tr>
</tbody>
</table>

Summary of Clinical Tests:
Not applicable. The subject of this submission, HS40, did not require clinical studies to support substantial equivalence.

8. Conclusion

Intended uses and other key features are consistent with traditional clinical practices and FDA guidelines. The design, development and quality process of the manufacturer confirms with 21 CFR 820 and ISO 13485. The device is designed to conform to applicable medical device safety standards and compliance. Therefore, SAMSUNG MEDISON CO., LTD. considers the HS40 to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

END of 510(K) Summary