



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

August 8, 2017

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,

A handwritten signature in blue ink that reads "Robert Ochs, Ph.D." with a large, stylized "FDA" watermark in the background.

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.

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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:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	N	N	N		Note 15	Note 1	Note 2, 7, 8, 9, 11
	Abdominal (See Note 10)	N	N	N		Note 15	Note 1	Note 2, 7, 8, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		Note 15	Note 1	Note 2, 7, 8, 9, 11
	Small Organ (See Note 5)	N	N	N		Note 15	Note 1	Note 2, 7, 9, 11, 12
	Neonatal Cephalic	N	N	N		Note 15	Note 1	Note 8, 9, 11
	Adult Cephalic	N	N	N	N	Note 15	Note 1	Note 7
	Trans-rectal	N	N	N		Note 15	Note 1	Note 2, 7, 8, 9, 12
	Trans-vaginal	N	N	N		Note 15	Note 1	Note 2, 7, 8, 9, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	N	N	N		Note 15	Note 1	Note 2, 7, 8, 9, 11, 12
	Musculo-skel. (Superfic.)	N	N	N		Note 15	Note 1	Note 2, 7, 9, 11
	Intra-luminal							
Other (See Note 13)	N	N	N		Note 15	Note 1	Note 2, 7, 9, 12	
Cardiac	Cardiac Adult	N	N	N	N	Note 15	Note 1	Note 4, 7, 14, 16
	Cardiac Pediatric	N	N	N	N	Note 15	Note 1	Note 4, 7, 14, 16
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N	N	Note 15	Note 1	Note 2, 7, 8, 9, 11
	Other (spec.)							

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: 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: 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:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 10)	N	N	N		Note 15	Note 1	Note 2, 7, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		Note 15	Note 1	Note 2, 7, 9, 11
	Small Organ (See Note 5)	P	P	P		Note 15	Note 1	Note 2, 7, 9, 11, 12
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		Note 15	Note 1	Note 2, 7, 9, 11, 12
	Musculo-skel. (Superfic.)	P	P	P		Note 15	Note 1	Note 2, 7, 9, 11
Intra-luminal								
Other (See Note 13)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		Note 15	Note 1	Note 2, 5, 7, 9, 11
	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+

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: CA2-8AD for use with HS40

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		Note 15	Note 1	Note 2, 7, 9, 11
	Abdominal (See Note 10)	P	P	P		Note 15	Note 1	Note 2, 7, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		Note 15	Note 1	Note 2, 7, 9, 11
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	N	N	N		Note 15	Note 1	Note 2, 7, 9, 11
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (See Note 13)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N		Note 15	Note 1	Note 2, 7, 9, 11
	Other (spec.)							

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+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: CF4-9 for use with HS40

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		Note 15	Note 1	Note 8, 9, 11
	Abdominal (See Note 10)	P	P	P		Note 15	Note 1	Note 8, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		Note 15	Note 1	Note 8, 9, 11
	Small Organ (See Note 5)							
	Neonatal Cephalic	P	P	P		Note 15	Note 1	Note 8, 9, 11
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	N	N	N		Note 15	Note 1	Note 8, 9, 11
	Musculo-skel. (Superfic.)							
	Intra-luminal							
Other (See Note 13)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		Note 15	Note 1	Note 8, 9, 11
	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+

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: PN2-4 for use with HS40

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	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+

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: EVN4-9 for use with HS40

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)							
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)	
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		Note 15	Note 1	Note 2, 7, 9	
	Abdominal (See Note 10)	P	P	P		Note 15	Note 1	Note 2, 7, 9	
	Intra-operative (See Note 6)								
	Intra-operative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (See Note 5)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal		P	P	P		Note 15	Note 1	Note 2, 7, 9, 12
	Trans-vaginal		P	P	P		Note 15	Note 1	Note 2, 7, 9, 12
	Trans-urethral								
	Trans-esoph. (non-Cardiac)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic.)								
	Intra-luminal								
Other (spec.) (See Note 13)		P	P	P		Note 15	Note 1	Note 2, 7, 9, 12	
Cardiac	Cardiac Adult								
	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+

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: VN4-8 for use with HS40

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		Note 15	Note 1	Note 2, 7, 8, 9, 11
	Abdominal (See Note 10)	P	P	P		Note 15	Note 1	Note 2, 7, 8, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		Note 15	Note 1	Note 2, 7, 8, 9, 11
	Small Organ (See Note 5)							
	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)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

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:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)							
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)	
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		Note 15	Note 1	Note 2, 7, 8, 9	
	Abdominal (See Note 10)	P	P	P		Note 15	Note 1	Note 2, 7, 8, 9	
	Intra-operative (See Note 6)								
	Intra-operative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (See Note 5)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal		P	P	P		Note 15	Note 1	Note 2, 7, 8, 9, 12
	Trans-vaginal		P	P	P		Note 15	Note 1	Note 2, 7, 8, 9, 12
	Trans-urethral								
	Trans-esoph. (non-Cardiac)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic.)								
Intra-luminal									
Other (See Note 13)		P	P	P		Note 15	Note 1	Note 2, 7, 8, 9, 12	
Cardiac	Cardiac Adult								
	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+

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: DP2B for use with HS40

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

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

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

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

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

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Data Prepared: Apr 13, 2017

2. Name of the device:

Common/Usual Name:
 Diagnostic Ultrasound System and Accessories
Proprietary Name:
 HS40 Diagnostic Ultrasound System

<u>Classification Names:</u>	<u>FR Number</u>	<u>Product Code</u>
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasound Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX

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.

<Technological Characteristics Comparison Table>

Feature / Characteristics	The subject device	The predicate device.
	HS40	HS50 / HS60 (K170493)
Indications for use		
Fetal/Obstetrics	√	√
Abdominal	√	√
Gynecology	√	√
Pediatric	√	√
Small Organ	√	√
Neonatal Cephalic	√	√
Adult Cephalic	√	√
Trans-rectal	√	√
Trans-vaginal	√	√
Musculo-skeletal (Conventional)	√	√
Musculo-skeletal (Superficial)	√	√
Urology	√	√
Cardiac Adult	√	√
Cardiac Pediatric	√	√
Peripheral vessel	√	√
Scanhead Types		
Linear Array	√	√
Curved Linear Array	√	√

Feature / Characteristics	The subject device	The predicate device.
	HS40	HS50 / HS60 (K170493)
Endocavity	√	√
Phased Array	√	√
Static Probes	√	√
Scanhead Frequency		
1.0 ~ 20.0 MHz	√	√
Modes of Operation		
B-mode	√	√
M-mode	√	√
Pulsed wave (PW) Spectral Doppler	√	√
Continuous wave (CW) Doppler	√	√
Color Doppler	√	√
Power Amplitude Doppler	√	√
Tissue Harmonic Imaging	√	√
3D/4D imaging mode	√	√
Combined modes	√	√
Safety & EMC		
Compliance		
IEC 60601-1 UL 60601-1 CSA C22.2 No.601.1	√	√
IEC 60601-2-37	√	√
IEC 60601-1-2	√	√
Acoustic Output Display Standard		
Track 3	√	√
Patient Contact Materials		
Tested to ISO 10993-1	√	√
Functionality		
Quick Scan (Q Scan)	√	√
ClearVision	√	√
MultiVision	√	√
Needle Mate+	√	√
Auto IMT+	√	√
Strain+	√	√
Elastoscan	√	√
Panoramic	√	√
3D Imaging (Volume Data Acquisition)	√	√
3D Imaging presentation 3D Cine/4D Cine	√	√
3D Rendering MPR	√	√
3D XI	√	√
3D MSV/Oblique View	√	√
3D MXI Volume Slice/Mirror View	√	√
Volume CT	√	√
3D MagiCut	√	√
Volume Calculation (VOCAL, XI VOCAL)	√	√
XI STIC	√	√
Realistic Vue	√	√
Ez Exam+	√	√
5D NT	√	√

Feature / Characteristics	The subject device	The predicate device.
	HS40	HS50 / HS60 (K170493)
5D Follicle	√	√

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:

Reference No.	Title
IEC 60601-1	AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
IEC 60601-1-2	AAMI / ANSI / IEC 60601-1-2:2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)
IEC 60601-2-37	IEC 60601-2-37:2007 Edition 2.0 2007-08, Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
ISO10993-1	AAMI / ANSI / ISO 10993-1:2009/(R)2013, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO14971	ISO 14971:2007, Medical devices - Application of risk management to medical devices
NEMA UD 2-2004	NEMA UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3
NEMA UD 3-2004	NEMA UD 3-2004 (R2009) Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 2

Summary of Clinical 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