Samsung Medison Co., Ltd.
Jee Young Ju
Regulatory Affairs Specialist
3366, Hanseo-ro, Nam-myeon,
Hongcheon-gun, Gangwon-do 25108,
REPUBLIC OF KOREA

January 8, 2019

Re: K182632
Trade/Device Name: HS30 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: December 7, 2018
Received: December 10, 2018

Dear Jee Young Ju:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182632

Device Name
HS30 Diagnostic Ultrasound System

Indications for Use *(Describe)*
The HS30 Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.
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
PRAStaff@fda.hhs.gov

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

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: HS30 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		N	Note 1	Note 2, 7, 8, 9, 11
	Abdominal *(See Note 10)*	N	N	N	N	N	Note 1	Note 2, 7, 8, 9, 10, 11
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2, 7, 8, 9, 11
	Small Organ *(See Note 5)*	N	N	N		N	Note 1	Note 2, 7, 9, 11, 12
	Neonatal Cephalic	N	N	N		N	Note 1	Note 8, 9, 11
	Adult Cephalic	N	N	N	N	N	Note 1	Note 7
	Trans-rectal	N	N	N		N	Note 1	Note 2, 7, 9, 12, 13
	Trans-vaginal	N	N	N		N	Note 1	Note 2, 7, 9, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	N	N	N		N	Note 1	Note 2, 7, 8, 9, 11, 12
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Note 2, 7, 9, 11
	Intra-luminal							
	Other (*See Note 13)*	N	N	N		N	Note 1	Note 2, 7, 9, 12
Cardiac	Cardiac Adult	N	N	N	N	N	Note 1	Note 4, 7, 14
	Cardiac Pediatric	N	N	N	N	N	Note 1	Note 4, 7, 14
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N	N	N	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:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E
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)

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 HS30
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		P	Note 1	Notes 7, 8, 9, 11
	Abdominal *(See Note 10)*	P	P	P		P	Note 1	Notes 7, 8, 9, 11
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 7, 8, 9, 11
	Small Organ *(See Note 5)*							
	Neonatal Cephalic	P	P	P		P	Note 1	Notes 7, 8, 9, 11
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Notes 7, 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		P	Note 1	Notes 7, 8, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K180409; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E
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)

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 HS30
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		P	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		P	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		P	Note 1	Note 4, 7, 14
	Cardiac Pediatric	P	P	P		P	Note 1	Note 4, 7, 14
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K180409; 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)

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 HS30
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		P	Note 1	Note 2, 7, 9
	Abdominal *(See Note 10)*							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 9, 12, 13
	Trans-vaginal	P	P	P		P	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		P	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 K180409; 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)

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 HS30
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 12)*							
	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 K180409; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E
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)

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: C2-8 for use with HS30
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		P	Note 1	Notes 2, 4, 7,8, 9, 11
	Abdominal *(See Note 10)*	P	P	P		P	Note 1	Notes 2, 6, 7, 8, 9,10, 11
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 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 FDA K180409; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E
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)

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: C2-5 for use with HS30
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		P	Note 1	Notes 2, 4, 7, 8, 9, 11
	Abdominal *(See Note 10)*	P	P	P		P	Note 1	Notes 2, 6, 7, 8, 9, 10, 11
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 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 FDA K180409; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E
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)

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: LN5-12 for use with HS30
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	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 11
	Small Organ *(See Note 5)*	P	P	P		P	Note 1	Notes 2, 5, 7, 8, 9, 11
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Notes 2, 7, 8, 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		P	Note 1	Notes 2, 7, 8, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K180409; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E
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)

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: L5-12/50 for use with HS30
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	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 11
	Small Organ *(See Note 5)*	P	P	P		P	Note 1	Notes 2, 5, 7, 8, 9, 11
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Notes 2, 7, 8, 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		P	Note 1	Notes 2, 7, 8, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K180409; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E
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)

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: ER4-9 for use with HS30
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		P	Note 1	Notes 2, 7, 8
	Abdominal *(See Note 10)*							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Notes 2, 7, 9, 12, 13
	Trans-vaginal	P	P	P		P	Note 1	Notes 2, 7, 9, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (*See Note 13)*	P	P	P		P	Note 1	Notes 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 K180409; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E
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)

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

5. 510(K) Summary: K182632

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. Date Prepared – December 07, 2018

2. Manufacturer
   SAMSUNG MEDISON CO., LTD.
   3366, Hanseo-ro, Nam-myeon,
   Hongcheon-gun, Gangwon-do 25108,
   REPUBLIC OF KOREA

3. Primary Contact Person
   Jee Young Ju
   Regulatory Affairs Specialist
   Phone: +82.2.2194.0861
   Fax: +82.31.8017.9573
   Email: jee.ju@samsungmedison.com

4. Secondary Contact Person
   Roberto Cunha
   Director of Regulatory & Quality
   Phone: +1.978.564.8503
   Email: rcunha@samsungneurologica.com

5. Proposed Device
   - Proprietary Name: HS30 Diagnostic Ultrasound System
   - Common Name: System, Imaging, Pulsed Doppler, Ultrasonic
   - System, Imaging, Pulsed Echo, Ultrasonic
   - Transducer, Ultrasonic, Diagnostic

   - Classification : 21 CFR 892.1550 Ultrasonic pulsed doppler imaging system
     21 CFR 892.1560 Ultrasonic pulsed echo imaging system
     21 CFR 892.1570 Diagnostic ultrasonic transducer
   - Product Code(s): IYN, IYO, ITX

6. Predicate Device
   - HS40 Diagnostic Ultrasound System (K180409)

   The predicate has not been the subject of a design-related recall.

7. Device Description
   The HS30 is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as 2D mode, M mode, Color Doppler imaging, Power Doppler imaging (including Directional Power Doppler mode; S-Flow), PW Spectral Doppler mode, CW Spectral Doppler mode, Harmonic imaging(S-Harmonic), Tissue Doppler imaging, Tissue Doppler Wave, Panoramic Imaging, Freehand 3D, Elastoscan Mode or as a combination of these modes. The HS30 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 HS30 has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

   The HS30 uses digital multi-beam forming technology and supports a variety of Linear, Convex, Phased, Static and Volume probes for a wide variety of applications. It is an ultrasound scanner, which provides high resolution, high penetration performance, and various measurement functions. Probes are supported in frequencies from 1.0 MHz to 20.0 MHz. These probes can be applied to a variety of clinical applications such as 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.

8. Indications for Use

The HS30 Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

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.

The indications for use of the proposed device are the same as the predicate HS40 (K180409) except Intra-Operative application.

Since the proposed device HS30 does not support the Intra-Operative application for any of the transducers, it does not raise new questions of safety and effectiveness.

9. Technological Comparison to Predicate Devices

The **proposed HS30 Diagnostic Ultrasound System** and the currently marketed predicate device HS40 (K180409), employ the same fundamental scientific technology as all of the features are migrated from the predicate.

A comparison of the **proposed HS30 Diagnostic Ultrasound System** to the currently marketed and predicates HS40 (K180409) is provided in the Table below:

Feature	**HS30 (Under Review)**	**HS40 (K180409)**
Indication for Use	- Fetal/Obstetrics - Abdominal - Gynecology - Pediatric - Small Organ - Neonatal Cephalic - Adult Cephalic - Trans-rectal - Trans-vaginal - Musculo-skel. (Conventional) - Musculo-skel. (Superficial) - Urology - Cardiac Adult - Cardiac Pediatric - Peripheral vessel	- Fetal/Obstetrics - Abdominal - Gynecology - Pediatric - Small Organ - Neonatal Cephalic - Adult Cephalic - Trans-rectal - Trans-vaginal - Musculo-skel. (Conventional) - Musculo-skel. (Superficial) - Urology - Cardiac Adult - Cardiac Pediatric - Peripheral vessel - Intra-Operative
Scanhead Types:	- Linear Array - Curved Linear Array - Endocavity - Phased Array - Static Probes	- Linear Array - Curved Linear Array - Endocavity - Phased Array - Static Probes
Scanhead Frequency	1.0 ~ 20.0 MHz	1.0 ~ 20.0 MHz
Acoustic Output Display & FDA Limits:	- Display Feature for Higher Output–Track3 - MI Output Display - TI Output Display	- Display Feature for Higher Output–Track3 - MI Output Display TI Output Display
Modes of Operation:	- B-mode - M-mode - Color Doppler - Pulsed wave (PW) Doppler - Continuous wave (CW) Doppler	- B-mode - M-mode - Color Doppler - Pulsed wave (PW) Doppler - Continuous wave (CW) Doppler

Feature	HS30 (Under Review)	HS40 (K180409)
	- Power Amplitude Doppler - Elastoscan - Combination Modes - S-Harmonic (Pulse Inversion Harmonic Imaging) - Tissue Harmonic Imaging - 3D imaging	- Power Amplitude Doppler - Elastoscan - Combination Modes - Pulse Inversion Harmonic Imaging - Tissue Harmonic Imaging - 3D imaging
#Transmit Channels	64	64
#Receive Channels	64	64
510(k) Track	Track 3	Track 3
System Characteristics:	- Beamformer 128 - Mobile cart - LED Monitor - 256 gray shades on monitor - 100-120V, 60 Hz; - 200-240V, 50 Hz	- Beamformer 128 - Mobile cart - LED Monitor - 256 gray shades on monitor - 100-120V, 60 Hz; - 200-240V, 50 Hz
Functionality	- DICOM - Quick Scan (Q Scan) - ClearVision - MultiVision - Auto IMT+ - Elastoscan - Panoramic - Needle Mate+ - Strain + - EZ-Exam+ - Mobile Export - 3D Imaging (Freehand 3D) - 3D Rendering (MPR) - 3D MagiCut	- DICOM - Quick Scan (Q Scan) - ClearVision - MultiVision - Auto IMT+ - Elastoscan - Panoramic - Needle Mate+ - Strain + - EZ-Exam+ - Mobile Export - 3D Imaging (Freehand 3D) - 3D Rendering (MPR) - 3D MagiCut Volume Calculation (VOCAL, XI VOCAL) - 3D XI (MSV, Oblique View) - 5D Folicle - 5D NT - Realistic Vue - XI-STIC
Transducers	[Linear array] -LN5-12 -L5-12/50	[Linear array] -LN5-12 -L5-12/50 -LA3-16AD
	[Curved array] -CF4-9 -C2-8 -C2-5	[Curved array] -CF4-9 -C2-8 -C2-5 -CA2-8AD -CA2-6BM
	[Endo Cavity] -EVN4-9 -ER4-9	[Endo Cavity] -EVN4-9 -ER4-9
	[Phased array] PN2-4	[Phased array] PN2-4
	[CW]	[CW]

Feature	HS30 (Under Review)	HS40 (K180409)
	DP2B	DP2B
		[3D] VN4-8 V5-9
Biopsy guides	- BP-KIT-024 - BP-KIT-035 [BP-KIT-035-NG] - BP-KIT-040 [BP-KIT-040-NG] - BP-KIT-045 [BP-KIT-045-NG] - BP-KIT-047 [BP-KIT-047-NG] - BP-KIT-061	- BP-KIT-024 - BP-KIT-029 - BP-KIT-035 [BP-KIT-035-NG] - BP-KIT-040 [BP-KIT-040-NG] - BP-KIT-045 [BP-KIT-045-NG] - BP-KIT-047 [BP-KIT-047-NG] - BP-KIT-049 [BP-KIT-049-NG] - BP-KIT-054 [BP-KIT-054-NG] - BP-KIT-060 - BP-KIT-061 - BP-KIT-068 [BP-KIT-068-NG]
On board optional devices	- Digital B/W Video Printer - Digital Color Video Printer - USB Printer - DVD recorder (DVR)	- Digital B/W Video Printer - Digital Color Video Printer - USB Printer - DVD recorder (DVR)
Etc.	- Digital Storage/ Transfer Station	- Digital Storage/ Transfer Station
	- Foot Switch - ECG - Gel Warmer	- Foot Switch - ECG - Gel Warmer

Throughout the comparison to the predicate, the differences in technological characteristics of the proposed device do not raise different questions of safety and effectiveness.

10. Summary of Non-Clinical Test

The device has been evaluated for acoustic output and software function as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform with applicable FDA guidance and medical device safety standards.

Test	Standards and FDA Guidance
Risk Management	ISO 14971 Second edition 2007 Medical devices - Application of risk management to medical devices
Electrical Safety	The HS30 Ultrasound System with defibrillation-proof ECG electrode was evaluated per the following standards. ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010 /(R)2012 Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance.
Electromagnetic Compatibility	IEC60601-1-2: 2014(4th Edition) Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
Biocompatibility	ISO 10993-1 Fourth edition 2009-10-15 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
Reprocessing Medical Devices	FDA Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling issued on March 17, 2015, revised June 9, 2017.
Software/Firmware-driven Functionality	All migrated probes and software functionality were evaluated using the same test criteria as the predicate for all applicable imaging modes to ensure that migration into a new system design did not compromise image quality with respect to the intended use of each feature. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued on May 11, 2005
Ultrasound Safety	Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers issued September 9, 2008
	IEC60601-2-37:2007 + A1:2015, Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
	NEMA UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3
	NEMA UD 3-2004 (R2009)

	Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 2

11. Summary of Clinical Tests
    The proposed device HS30 Diagnostic Ultrasound System did not require clinical studies to demonstrate substantial equivalence.

12. Conclusion
    Since the predicate device and subject device have a similar intended use and key technological features, the non-clinical data support the safety of the device and demonstrate that the HS30 Diagnostic Ultrasound System should perform as intended in the specified use conditions. Therefore, SAMSUNG MEDISON CO., LTD. concludes that the performance of the subject device is as safe and effective, and is therefore substantially equivalent, to the predicate device that is currently marketed for the same intended use.