



Samsung Medison Co., Ltd.
Ji Yea Lee
Regulatory Affairs Specialist
3366, Hanseo-ro, Nam-myeon,
HONGCHEON-GUN, GANGWON-DO 25108
REPUBLIC OF KOREA

December 4, 2018

Re: K181336

Trade/Device Name: HS50 / HS60 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: November 02, 2018
Received: November 05, 2018

Dear Ji Yea Lee:

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style. To the right of the signature, the word "For" is printed in a small, black, sans-serif font.

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

Indications for Use

510(k) Number (if known)

K181336

Device Name

HS50 / HS60 Diagnostic Ultrasound System

Indications for Use (Describe)

The HS50 / HS60 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 Trans-esophageal(Cardiac), and peripheral vessel.

SAMSUNG

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: HS50/HS60 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)	P	P	P		Note 15	Note 1	Note 2,3,4, 7, 8, 9, 11
	Abdominal (See Note 10)	P	P	P	P	Note 15	Note 1	Note 2,6, 7, 8, 9, 11, 12, 16
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	Note 15	Note 1	Note 2, 6, 7, 8, 9, 11
	Small Organ (See Note 5)	P	P	P		Note 15	Note 1	Note 2, 7, 9, 11, 12
	Neonatal Cephalic	P	P	P	P	Note 15	Note 1	Note 2, 7, 8, 9, 11
	Adult Cephalic	P	P	P	P	Note 15	Note 1	Note 2, 7, 8, 9, 11
	Trans-rectal	P	P	P		Note 15	Note 1	Notes 2, 7, 8, 9, 11, 12
	Trans-vaginal	P	P	P		Note 15	Note 1	Notes 2, 7, 8, 9, 11, 12
	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)	P	P	P		Note 15	Note 1	Notes 2, 7, 8, 9, 11, 12
Cardiac	Cardiac Adult	P	P	P	P	Note 15	Note 1	Note 4, 7, 14, 17
	Cardiac Pediatric	P	P	P	P	Note 15	Note 1	Note 4, 7, 14, 17
	Trans-esophageal (Cardiac)	P	P	P	P	Note 15	Note 1	Note 4, 7, 14, 17
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	Note 15	Note 1	Note 2, 6, 7, 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LA3-14AD for use with HS60/ HS50

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 (<i>See Note 3</i>)							
	Abdominal (<i>See Note 10</i>)							
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)	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 (<i>See Note 13</i>)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		Note 15	Note 1	Note 2, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K170493; 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, 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+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CA1-7AD for use with HS50/HS60

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	Notes 2, 7, 9, 11
	Abdominal (See Note 10)	P	P	P		Note 15	Note 1	Notes 2, 7, 9, 11, 16
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		Note 15	Note 1	Notes 2, 7, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		Note 15	Note 1	Notes 2, 7, 9, 11
	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 K170493; 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CF4-9 for use with HS50/HS60

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	Notes 9, 11
	Abdominal (See Note 10)	P	P	P		Note 15	Note 1	Notes 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		Note 15	Note 1	Notes 6, 9, 11
	Small Organ (See Note 5)							
	Neonatal Cephalic	P	P	P		P	Note 1	Notes 9, 11
	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	P	P	P		Note 15	Note 1	Notes 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K170493; 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: ER4-9 for use with HS50/HS60

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 (<i>See Note 3</i>)	P	P	P		Note 15	Note 1	Notes 2, 7, 9
	Abdominal (<i>See Note 10</i>)							
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		Note 15	Note 1	Notes 2, 7, 9, 12
	Trans-vaginal	P	P	P		Note 15	Note 1	Notes 2, 7, 9, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (<i>See Note 13</i>)	P	P	P		Note 15	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 K170493; 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, 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+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LA3-16A for use with HS50/HS60

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 (See Note 3)							
	Abdominal (See Note 10)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	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, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K170493; 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LA3-16AI for use with HS50/HS60

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 (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	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 7, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		Note 15	Note 1	Note 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 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K170493; 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LA2-9A for use with HS50/HS60

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 2, 7, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)	P	P	P		Note 15	Note 1	Note 2, 7, 9, 11
	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
	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, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K170493; 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: PA3-8B for use with HS50/HS60

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 15	Note 1	Note 7
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	Note 15	Note 1	Note 6, 7
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	Note 15	Note 1	Note 7
	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	P	P	P	P	Note 1	Note 4, 7, 14, 17
	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7, 14, 17
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K170493; 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: PE2-4 for use with HS50/HS60

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 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	P	Note 15	Note 1	Note 7
	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	P	P	P	P	Note 1	Note 4, 7, 14,17
	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7, 14, 17
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K170493; 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CV1-8AD for use with HS50/HS60

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							
	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 K170493; 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: V5-9 for use with HS50/HS60

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, 12
	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 K170493; 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: DP2B for use with HS50/HS60

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 K170493; 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CW6.0 for use with HS50/HS60

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 K170493; 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CA2-9AD for use with HS50/HS60

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	Notes 2, 7, 9, 11
	Abdominal (See Note 12)	P	P	P		Note 15	Note 1	Notes 2, 7, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	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 K170493; 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: EA2-11B for use with HS60

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 12)	P	P	P		Note 15	Note 1	Note 2, 7, 9, 12
	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 (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 K170493; 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LA4-18BD for use with HS60

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)	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, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K170493; 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: PA1-5A for use with HS60

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)	P	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	P	Note 15	Note 1	Note 7
	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	P	P	P	Note 15	Note 1	Note 4, 7, 14, 17
	Cardiac Pediatric	P	P	P	P	Note 15	Note 1	Note 4, 7, 14, 17
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K170493; 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CA3-10A for use with HS60

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, 3, 4, 7, 9,
	Abdominal (See Note 12)	P	P	P		P	Note 1	Notes 2, 6, 7, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 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.)	P	P	P		P	Note 1	Notes 2, 7, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Notes 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		P	Note 1	Notes 2, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K173204, ; 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CA2-6BM for use with HS50/HS60

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)	P	P	P		Note 15	Note 1	Notes 2, 7, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	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)

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: VR5-9 for use with HS60

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, 8, 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, 8, 9, 12
	Trans-vaginal	P	P	P		P	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		P	Note 1	Notes 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 K173513; 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: EVN4-9 for use with HS50

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 12)							
	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 (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:

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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: PA4-12B for use with HS50/HS60

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)	P	P	P	P	P	Note 1	Note 2,15
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	Note 1	Note 2,15
	Small Organ (See Note 5)							
	Neonatal Cephalic	P	P	P	P	P	Note 1	Note 2,15
	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	P	P	P	P	P	Note 1	Note 4, 7,15
	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7,15
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K173204; 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: DP8B for use with HS60

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							
	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 K173204; 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)

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: MMPT3-7 for use with HS50/HS60

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							
	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)	P	P	P	P	P	Note 1	Note 4, 7,14, 17
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K173204; 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)

Note 15: Color Doppler includes Power (Amplitude) Doppler

Note 16: Contrast

Note 17: Strain+



510(K) Summary: K181336

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

1. Date Prepared – November 30, 2018
2. Manufacturer
SAMSUNG MEDISON CO., LTD.
3366, Hanseo-ro, Nam-myeon,
HONGCHEON-GUN, GANGWON-DO 25108
REPUBLIC OF KOREA
3. Primary Contact Person
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4. Proposed Device
 - Proprietary Name: HS50/HS60 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
5. Predicate Device
 - HS50/HS60 Diagnostic Ultrasound System (K170493); primary predicate
 - RS85 Diagnostic Ultrasound System (K173204)
 - WS80A Diagnostic Ultrasound System (K173513)
 - HS40 Diagnostic Ultrasound System (K180409)

The predicates have not been the subject of a design-related recall.

6. Device Description
The HS50 / HS60 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, Dual mode, Quad mode, Combined mode, Simultaneous mode and Zoom mode. The HS50 / HS60 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 HS50 / HS60 have real time acoustic



output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

The HS50 / HS60 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, Trans-esophageal(Cardiac), and Peripheral vessel.

7. Indications for Use

The HS50 / HS60 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 Trans-esophageal(Cardiac), and peripheral vessel.

The indications for use of **the proposed device** is not the same as the primary predicate HS50/HS60 (K170493) due to the additional supporting application of Trans-esophageal (Cardiac). However, the predicate RS85 (K173204) has the same indications for use and is the same submission from which the corresponding TEE probe was migrated. Therefore, **the proposed device** has similar indications for use compared to the predicates that does not raise different questions of safety and effectiveness.

8. Technological Comparison to Predicate Devices

The **proposed HS50/HS60 Diagnostic Ultrasound System** and the currently marketed predicate device(s), HS50/HS60(K170493), RS85(K173204), HS40(K180409) and WS80A(K173513), employ the same fundamental scientific technology. The differences are the addition of software features, transducers and supporting biopsy guides.

A comparison of the **proposed HS50/HS60 Diagnostic Ultrasound System** to the currently marketed and predicates, HS50/HS60(K170493), RS85(K173204), WS80A(K173513) and HS40(K180409) is provided in the Table below:

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510(k) Premarket Notification – Traditional



Feature	HS50/ HS60 (Proposed Device)	HS50/ HS60 (K170493; Primary Predicate Device)	RS85 (K173204)	WS80A (K173513)	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 - Transesophageal	- 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 - Transesophageal	Same as RS85 (K173204)	Same as HS50/ HS60 (K170493)
Scanhead Types:	Same	- Linear Array - Curved Linear Array - Endocavity - Phased Array - Static Probes	Same	Same	Same
Scanhead Frequency	Same	1.0 ~ 20.0 MHz	Same	Same	Same
Acoustic Output Display & FDA Limits:	Same	- Display Feature for Higher Output–Track3 - MI Output Display	Same	Same	Same

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510(k) Premarket Notification – Traditional



Feature	HS50/ HS60 (Proposed Device)	HS50/ HS60 (K170493; Primary Predicate Device)	RS85 (K173204)	WS80A (K173513)	HS40 (K180409)
Modes of Operation:	Same	- TI Output Display - B-mode - M-mode - Color Doppler - Pulsed wave (PW) Doppler - Continuous wave (CW) Doppler - Power Amplitude Doppler - Elastoscans - 3D imaging - Combination Modes - Pulse Inversion Harmonic Imaging - Tissue Harmonic Imaging	Same	Same	Same
#Transmit Channels	Same as HS50/ HS60 (K170493)	128	192	Same as RS85 (K173204)	64
#Receive Channels	Same as HS50/ HS60 (K170493)	128	192	Same as RS85 (K173204)	64
510(k) Track	Same	Track 3	Same	Same	Same
System Characteristics:	Same as HS50/ HS60 (K170493) with Li-ion Backup Battery and Battery Assist function	- Beamformer 128 - Mobile cart - LCD Monitor - 256 gray shades on monitor	- Beamformer 192 - Mobile cart - LCD Monitor (LED Backlight unit) - 256 gray shades	Same as RS85 (K173204)	Same as HS50/ HS60 (K170493)

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510(k) Premarket Notification – Traditional



Feature	HS50/ HS60 (Proposed Device)	HS50/ HS60 (K170493; Primary Predicate Device)	RS85 (K173204)	WS80A (K173513)	HS40 (K180409)
		- 100-120V, 60 Hz; - 200-240V, 50 Hz	on monitor - 100-240VAC, 1100VA, 50/60Hz		
Functionality	- 3D Imaging	- 3D Imaging	- 3D Imaging	- 3D Imaging	- 3D Imaging
	- 3D image presentation - (3D Cine/4D Cine)	- 3D image presentation - (3D Cine/4D Cine)	- 3D image presentation - (3D Cine/4D Cine)	- 3D image presentation - (3D Cine/4D Cine)	- 3D image presentation - (3D Cine/4D Cine)
	- 3D Rendering (MPR)	- 3D Rendering (MPR)	- 3D Rendering (MPR)	- 3D Rendering (MPR)	- 3D Rendering (MPR)
	- 3D XI - (MSV, Oblique View)	- 3D XI - (MSV, Oblique View)	- 3D XI - (MSV, Oblique View)	- 3D XI - (MSV, Oblique View)	- 3D XI - (MSV, Oblique View)
	- Volume CT	- Volume CT	- Volume CT	- Volume CT	- Volume CT
	- 3D MagiCut	- 3D MagiCut	- 3D MagiCut	- 3D MagiCut	- 3D MagiCut
	- Volume Calculation (VOCAL, XI VOCAL)	- Volume Calculation (VOCAL, XI VOCAL)	- Volume Calculation (VOCAL, XI VOCAL)	- Volume Calculation (VOCAL, XI VOCAL)	- Volume Calculation (VOCAL, XI VOCAL)
	- XI STIC	- XI STIC	- XI STIC	- XI STIC	- XI STIC
	- Quick Scan (Q Scan)	- Quick Scan (Q Scan)	- Quick Scan (Q Scan)	- Quick Scan (Q Scan)	- Quick Scan (Q Scan)
	- ClearVision	- ClearVision	- ClearVision	- ClearVision	- ClearVision
	- MultiVision	- MultiVision	- MultiVision	- MultiVision	- MultiVision
	- Auto IMT+	- Auto IMT+	- Auto IMT+	- Auto IMT+	- Auto IMT+
	- Elastoscan	- Elastoscan	- Elastoscan	- Elastoscan	- Elastoscan
	- Panoramic	- Panoramic	- Panoramic	- Panoramic	- Panoramic
	- Needle Mate+	- Needle Mate+	- Needle Mate+	- Needle Mate+	- Needle Mate+
	- Realistic Vue	- Realistic Vue	- Realistic Vue	- Realistic Vue	- Realistic Vue

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Feature	HS50/ HS60 (Proposed Device)	HS50/ HS60 (K170493; Primary Predicate Device)	RS85 (K173204)	WS80A (K173513)	HS40 (K180409)
	- 5D Follicle	- 5D Follicle	- 5D Follicle	- 5D Follicle	- 5D Follicle
	- 5D NT	- 5D NT	- 5D NT	- 5D NT	- 5D NT
	- Strain +	- Strain +	- Strain +	- MPI	- Strain +
	- CEUS+	- CEUS+	- CEUS+	- ADVR	-
	- E-Strain	-	- E-Strain	- E-Strain	-
	- Stress Echo	-	- Stress Echo	-	-
	- 2D NT	-	- 2D NT	- 2D NT	-
	- Crystal Vue	-	-	- Crystal Vue	-
	- 5D Heart Color	-	-	- 5D Heart Color	-
	- BiometryAssist	-	-	- BiometryAssist	-
	- HQ Vision	-	- HQ Vision	- E-Cervix	-
	- S-Detect for Breast (Lite)	-	- S-Detect for Breast (Lite)	- S-Detect for Breast (Lite)	-
Transducer	[Linear array] - LA3-14AD - LA2-9A - LA4-18BD - LA3-16A - LA3-16AI	[Linear array] - LA3-14AD - LA2-9A - LA3-16AI - LA4-18BD - LA3-16A	[Linear array] - L3-12A - LA2-9A - LA3-16A - LA3-16AI - LA4-18B - LM4-15B -	[Linear array] - L3-12A - L5-13 - LA2-9A - LA3-16A - LA3-16AI - LA4-18B - LM4-15B	[Linear array] - LA3-16AD - LN5-12 - L5-12/50
	[Curved array] - CA1-7AD - CA2-9AD - CF4-9 - - CA3-10A - CA2-6BM	[Curved array] - CA1-7AD - CA2-9AD - - CF4-9	[Curved array] - CA1-7A - CA2-8A - CF4-9 - - CA3-10A	[Curved array] - C2-6 - CA1-7A - CA2-8A - CA2-9A - CA3-10A - CF4-9,	[Curved array] - CA2-8AD - CF4-9 - C2-8 - C2-5 - CA2-6BM

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Feature	HS50/ HS60 (Proposed Device)	HS50/ HS60 (K170493; Primary Predicate Device)	RS85 (K173204)	WS80A (K173513)	HS40 (K180409)
				- SC1-6	
	[Phased array] - PE2-4 - PA1-5A - PA4-12B - PA3-8B	[Phased array] - PE2-4 - PA1-5A - - PA3-8B	[Phased array] - PM1-6A - PA3-8B - PA4-12B -	[Phased array] - PA3-8B - PE2-4 - PM1-6A - PA4-12B	[Phased array] PN2-4
	[Endo Cavity] - EA2-11B - ER4-9 - VR5-9 - EVN4-9	[Endo Cavity] - EA2-11B - ER4-9 -	[Endo Cavity] - E3-12A - EA2-11B	[Endo Cavity] - E3-12A - VR5-9 - - EA2-11B	[Endo Cavity] - - - - EVN4-9
	[3D] - CV1-8AD - V5-9	[3D] - CV1-8AD - V5-9	[3D] - V5-9 - LV3-14A - CV1-8A - EV3-10B	[3D] - CV1-8A - LV3-14A - V4-8 - V5-9 - EV3-10B	[3D] - VN4-8
	[Pencil] - DP2B - CW6.0 - DP8B	[Pencil] - DP2B - CW6.0	[Pencil] - DP2B - CW6.0 - DP8B	[Pencil] -	[Pencil] - DP2B -
	[TEE] - MMPT3-7	-	[TEE] - MMPT3-7	-	-
Biopsy guides	- BP-KIT-024-3 - BP-KIT-029 - BP-KIT-054 [BP-KIT-054-NG] - BP-KIT-055 [BP-KIT-055-NG] - BP-KIT-060	- BP-KIT-024-3 - BP-KIT-029 - BP-KIT-054 [BP-KIT-054-NG] - BP-KIT-055 [BP-KIT-055-NG] - BP-KIT-060	- BP-KIT-029 - BP-KIT-030 - BP-KIT-043 - BP-KIT-053 - BP-KIT-054 - BP-KIT-055	- BP-KIT-009 - BP-KIT-012 - BP-KIT-028 - BP-KIT-029 - BP-KIT-030 - BP-KIT-041	- BP-KIT-024 - BP-KIT-029 - BP-KIT-049 [BP-KIT-049-NG] - BP-KIT-054 [BP-KIT-054-NG] - BP-KIT-055 [BP-

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Feature	HS50/ HS60 (Proposed Device)	HS50/ HS60 (K170493; Primary Predicate Device)	RS85 (K173204)	WS80A (K173513)	HS40 (K180409)
	- BP-KIT-061 - BP-KIT-068 [BP-KIT-068-NG] - BP-KIT-043 - BP-KIT-053 [BP-KIT-053-NG] - BP-KIT-058 [BP-KIT-058-NG] - BP-KIT-059 [BP-KIT-059-NG] - BP-KIT-065 - BP-KIT-066 - BP-KIT-069	- BP-KIT-061 - BP-KIT-068 [BP-KIT-068-NG] - BP-KIT-043 - BP-KIT-053 [BP-KIT-053-NG] - BP-KIT-058 [BP-KIT-058-NG] - BP-KIT-059 [BP-KIT-059-NG] - BP-KIT-065 - BP-KIT-066 - BP-KIT-069 -	- BP-KIT-057 - BP-KIT-058 - BP-KIT-059 - BP-KIT-060 - BP-KIT-067 - BP-KIT-068 - BP-KIT-069 - BP-KIT-071 - BP-KIT-075	- BP-KIT-043 - BP-KIT-052 - BP-KIT-053 - BP-KIT-054 - BP-KIT-055 - BP-KIT-057 - BP-KIT-058 - BP-KIT-059 - BP-KIT-060 - BP-KIT-065 - BP-KIT-066 - BP-KIT-068 - BP-KIT-069 - BP-KIT-071 - BP-KIT-075	- KIT-055-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)	- 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)	- Digital B/W Video Printer - Digital Color Video Printer - USB Printer - DVD recorder (DVR)
Etc.	- Digital Storage/Transfer Station	- Digital Storage/Transfer Station	- Digital Storage/Transfer Station	- Digital Storage/Transfer Station	- Digital Storage/Transfer Station
	- Foot Switch - ECG - Gel Warmer	- Foot Switch - ECG - Gel Warmer	- Foot Switch - ECG - Gel Warmer - Clear Track/Virtual Track	- Foot Switch - ECG - Gel Warmer - WLAN Card	- Foot Switch - ECG - Gel Warmer

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			System Stand -WLAN Card		

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



9. Summary of Non-Clinical Testing

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.

All transducers proposed in the present submission were migrated from previously cleared systems. Therefore, additional biocompatibility testing and reprocessing validation was not needed.

Test	Standards and FDA Guidance
Risk Management	ISO 14971 Second edition 2007 Medical devices - Application of risk management to medical devices
Electrical Safety	The HS50/HS60 Ultrasound System with Li-ion backup battery and Battery Assist feature and 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. IEC 60601-2-18: 2009: Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
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
Software/Firmware-driven Functionality	Migrated probes and software functionality including E-Strain, Stress Echo, 2D NT, Crystal Vue, 5D Heart Color, BiometryAssist, HQ Vision, and S-Detect for Breast Lite were evaluated using the same test criteria as the predicates for all applicable imaging modes to ensure that migration from a 192-channel system to 128-channel system did not compromise image quality with respect to the intended use of each feature. Clinical applications of E-strain were expanded to include breast, prostate, small organs, and musculoskeletal with a restriction on use for evaluating bone. The Battery Assist function was tested to ensure that the system enters and promptly exits from a sleep state enabled by the software and Li-ion backup battery.



	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

10. Summary of Clinical Tests

The proposed device HS50 / HS60 Ultrasound System, did not require clinical studies to demonstrate substantial equivalence.

11. Conclusion

Since the predicate devices 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 HS50 / HS60 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(s) that are currently marketed for the same intended use.

- END of 510(K) Summary