



SAMSUNG MEDISON Co., Ltd.
% Ji Yea Lee
Regulatory Affairs Specialist
42, Teheran-ro 108-gil, Gangnam-gu
Seoul, 06176
KOREA

March 8, 2018

Re: K173713
Trade/Device Name: HS70A Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: February 26, 2018
Received: March 1, 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. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 black ink that reads "Robert Ochs". The signature is written in a cursive style. In the background, there is a large, light blue watermark of the letters "FDA".

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

Enclosure

Indications for Use

510(k) Number (if known)

K173713

Device Name

HS70A Diagnostic Ultrasound System

Indications for Use (Describe)

The HS70A 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, Intra-operative, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Trans-esoph. (non-Cardiac), Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric, 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: HS70A 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		P	Note 1	Notes 2 ,3, 4, 5, 6, 7, 8, 9, 11
	Abdominal (See Note 10)	P	P	P	P	P	Note 1	Notes 2, 4, 6, 7, 8, 9, 11, 12, 13
	Intra-operative (See Note 6)	P	P	P		P	Note 1	Notes 7, 9, 11
	Intra-operative (Neuro.)	P	P	P		P	Note 1	Notes 7, 9, 11
	Laparoscopic							
	Pediatric	P	P	P	P	P	Note 1	Notes 2, 4, 6, 7, 8, 9, 11
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11, 12
	Neonatal Cephalic	P	P	P	P	P	Note 1	Notes 2, 7, 8, 9, 11
	Adult Cephalic	P	P	P	P	P	Note 1	Notes 7
	Trans-rectal	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 12
	Trans-vaginal	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)	P	P	P	P	P	Note 1	Notes 4, 7
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Notes 2, 5, 6, 7, 8, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Notes 2, 5, 6, 7, 8, 9, 11
Intra-luminal								
Other (See Note 13)	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 12	
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	Notes 2, 4, 7
	Cardiac Pediatric	P	P	P	P	P	Note 1	Notes 2, 4, 7
	Trans-esophageal (Cardiac)	P	P	P	P	P	Note 1	Notes 4, 7
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	Note 1	Note 2, 5, 6, 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



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CA1-7A for use with HS70A

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, 11, 12
	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.)	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							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K152962; 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



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CA2-8A for use with HS70A

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, 4, 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 K152962; 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



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CF4-9 for use with HS70A

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	Notes 8, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 8, 9, 11
	Small Organ (See Note 5)							
	Neonatal Cephalic	P	P	P		P	Note 1	Notes 8, 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		P	Note 1	Notes 8, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K152962; 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



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: E3-12A for use with HS70A

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, 9	
	Abdominal (See Note 10)	P	P	P		P	Note 1	Notes 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		P	Note 1	Notes 2, 7, 8, 9, 12
	Trans-vaginal		P	P	P		P	Note 1	Notes 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 K152962; 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



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: VR5-9 for use with HS70A

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)	P	P	P		P	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		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 K152962; 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



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: L3-12A for use with HS70A

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, 5, 6, 7, 9, 11
	Abdominal (See Note 10)	P	P	P		P	Note 1	Notes 2, 4, 6, 7, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 4, 6, 7, 9, 11
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 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	Note 2, 5, 6, 7, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 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	Note 2, 5, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K152962; 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



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LA3-16A for use with HS70A

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		P	Note 1	Note 2, 5, 6, 7, 9, 11, 12
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 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	Note 2, 5, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K152962; 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



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LA3-16AI for use with HS70A

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)	P	P	P		P	Note 1	Note 7, 9, 11
	Intra-operative (Neuro.)	P	P	P		P	Note 1	Note 7, 9, 11
	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		P	Note 1	Note 7, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	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		P	Note 1	Note 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K152962; 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



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LA2-9A for use with HS70A

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 2, 5, 6, 7, 8, 9,
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9,
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9,
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9,
	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	Note 2, 5, 6, 7, 8, 9,
	Other (spec.)							

N= new indication; P= previously cleared by FDA K152962; 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



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: PE2-4 for use with HS70A

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

N= new indication; P= previously cleared by FDA K152962; 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

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: PA3-8B for use with HS70A

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

N= new indication; P= previously cleared by FDA K152962; 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

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: CV1-8A for use with HS70A

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, 4, 7, 8, 9,
	Abdominal (See Note 10)	P	P	P		P	Note 1	Note 2, 7, 8, 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 K152962; 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

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: LV3-14A for use with HS70A

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

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

N= new indication; P= previously cleared by FDA K152962; 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

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



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: V5-9 for use with HS70A

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)	P	P	P		P	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		P	Note 1	Note 2, 7, 8, 9
	Trans-vaginal		P	P	P		P	Note 1	Note 2, 7, 8, 9
	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	
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Trans-esophageal (Cardiac)								
	Other (spec.)								
Peripheral Vessel	Peripheral vessel								
	Other (spec.)								

N= new indication; P= previously cleared by FDA K152962; 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



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: DP2B for use with HS70A

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 K152962; 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

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: CW4.0 for use with HS70A

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				P			
	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 K152962; 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

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: CW6.0 for use with HS70A

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					P		
	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 K152962; 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



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CA3-10A for use with HS70A

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, 8,
	Abdominal (See Note 12)	P	P	P		P	Note 1	Notes 2, 6, 7, 8, 9,
	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	P	P	P		P	Note 1	Notes 2, 7, 8, 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		P	Note 1	Notes 2, 7, 8, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K153529, K163691; 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

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



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CA2-9A for use with HS70A

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 12)	P	P	P		P	Note 1	Notes 2, 4, 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 K153529, K163691; 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

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: EA2-11B for use with HS70A

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 12)	P	P	P		P	Note 1	Note 2, 6, 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		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	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 K153529, K163691 ; 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

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: LA4-18B for use with HS70A

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		P	Note 1	Note 2, 5, 6, 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	Note 2, 5, 6, 7, 8, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 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	Note 2, 5, 6, 7, 8, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K162094, K163691; 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

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: PA4-12B for use with HS70A

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

N= new indication; P= previously cleared by FDA K162094, K163691; 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

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: PA1-5A for use with HS70A

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

N= new indication; P= previously cleared by FDA K163691; 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

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: DP8B for use with HS70A

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 K163691; 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

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 HS70A

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

N= new indication; P= previously cleared by FDA K162094, K163691; 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



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LM4-15B for use with HS70A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 10)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7 8, 9, 11, 12
	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 K171048; 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+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C

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

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



5. 510(K) Summary

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

1. Date Prepared – February 26, 2018
2. Manufacturer
SAMSUNG MEDISON CO., LTD.
42, Teheran-ro 108-gil, Gangnam-gu, Seoul, Korea
3. Primary Contact Person
Ji Yea Lee
Regulatory Affairs Specialist
Phone: +82.2.2194.1594
Fax: +82.2.556.3974
Email: jiyea722.lee@samsungmedison.com
4. Secondary Contact Person
Ninad Gujar
Director of Regulatory & Quality
Phone: +1.978.564.8503
Email: ngujar@neurologica.com
5. Proposed Device
 - Common/Usual Name: Diagnostic Ultrasound System and Accessories
 - Proprietary Name: HS70A Diagnostic Ultrasound System
 - Common Name: Diagnostic Ultrasound System
 - Classification Names: system, imaging, pulsed doppler, ultrasonic
 - Product Code: IYN, IYO, ITX
 - Regulation: 892.1550
6. Predicate Device
 - RS80A Diagnostic Ultrasound System (K171048)
7. Device Description
The HS70A 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, 3D imaging mode (real-time 4D imaging mode), Elastoscan Mode or as a combination of these modes. The HS70A 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 HS70A has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.
8. Intended Use
The HS70A 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, Intra-operative, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Trans-esoph. (non-Cardiac), Muscular-Skeletal (Conventional, Superficial), Urology,



Cardiac Adult, Cardiac Pediatric, Trans-esophageal (Cardiac) and Peripheral vessel.

9. Technology

The HS70A employs the same fundamental scientific technology as its predicate device.

10. Determination of Substantial Equivalence

Comparison to Predicate: The HS70A is substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The HS70A and predicate RS80A systems have the same clinical intended use.
- The HS70A and predicate RS80A systems have the same imaging modes and modes of operation.
- The HS70A and RS80A have same transducer LM4-15B.
- The HS70A has E-Strain, S-Detect for Breast, and S-Detect for Thyroid which are same functionalities in the predicate RS80A.
- The system is manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The system has acoustic power levels which are below the applicable FDA limits.
- The HS70A and predicate RS80A systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The HS70A and predicate have been designed in compliance with approved electrical and physical safety standards.

11. Summary of Non-Clinical Test

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety, and has been found to conform with applicable medical device safety standards. The HS70A and its applications comply with voluntary standards.

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



12. Summary of Clinical Tests

The subject of this premarket submission, HS70A, is not required clinical studies to support substantial equivalence.

13. Conclusion

Intended uses and other key features are consistent with traditional clinical practices and FDA guidelines. The design, development and quality process of the manufacturer confirms with 21 CFR 820 and ISO 13485. The device is designed to conform to applicable medical device safety standards and compliance. Therefore, SAMSUNG MEDISON CO., LTD. considers the HS70A to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

-END of 510(K) Summary