



Samsung Medison Co., Ltd.  
Scully Kim  
Regulatory Affairs Specialist  
3366, Hanseo-ro, Nam-myeon  
Hongcheon-gun, 25108  
REPUBLIC OF KOREA

January 22, 2019

Re: K182894  
Trade/Device Name: HM70A Diagnostic Ultrasound System  
LS3-14B Transducer

Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic Pulsed Doppler Imaging System  
Regulatory Class: Class II  
Product Code: IYN, IYO, ITX  
Dated: October 12, 2018  
Received: December 28, 2018

Dear Scully Kim:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



For

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

Enclosure

## Indications for Use

510(k) Number (if known)

K182894

Device Name

HM70A Diagnostic Ultrasound System

Indications for Use (Describe)

The HM70A 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-esophageal (non-Cardiac), Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric, Trans-esophageal (Cardiac), Peripheral vessel.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRAStaff@fda.hhs.gov

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



**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT**

510(k) No.:

Device Name: HM70A 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, 4, 7, 8, 9, 11
	Abdominal (See Note 12)	P	P	P	P	P	Note 1	Notes 2, 4, 7, 8, 9, 10, 11
	Intra-operative (See Note 6)	P	P	P		P	Note 1	Note 7, 8, 9, 11
	Intra-operative (Neuro.)	P	P	P		P	Note 1	Note 7, 8, 9, 11
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 10, 11
	Neonatal Cephalic	P	P	P		P	Note 1	Note 2, 7, 8, 9
	Adult Cephalic	P	P	P	P	P	Note 1	Note 4, 7
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8, 9, 10, 11
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8, 9, 10, 11
	Trans-urethral							
	Trans-esoph. (non-Cardiac)	P	P	P	P	P	Note 1	Note 4, 7
	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 (spec.) (See Note 13)	P	P	P		P	Note 1	Note 2, 7, 8, 10, 11	
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)	P	P	P	P	P	Note 1	Note 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+TD, B+CW, B+C+PW, B+PD+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: Panoramic imaging

Note 10: ElastoScan

Note 11: MultiVision (old name: Spatial Compound Imaging)

Note 12: Includes Renal, Gynecology/Pelvis

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: SC1-6 for use with HM70A

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 4, 7, 8, 9
	Abdominal (See Note 12)	P	P	P		P	Note 1	Notes 7, 8, 9
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 7, 8, 9
	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 (spec.) (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 K153408; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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: Panoramic imaging

Note10: ElastoScan

Note11: MultiVision (old name: Spatial Compound Imaging)

Note12: Includes Renal, Gynecology/Pelvis

Note13: 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: C2-6 for use with HM70A

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
	Abdominal (See Note 12)	P	P	P		P	Note 1	Notes 2, 7, 8, 9
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8, 9
	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 (spec.) (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 K153408; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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: Panoramic imaging

Note 10: ElastoScan

Note 11: MultiVision (old name: Spatial Compound Imaging)

Note 12: Includes Renal, Gynecology/Pelvis

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: CF4-9 for use with HM70A

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

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

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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: Panoramic imaging

Note 10: ElastoScan

Note 11: MultiVision (old name: Spatial Compound Imaging)

Note 12: Includes Renal, Gynecology/Pelvis

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: EVN4-9 for use with HM70A

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, 11
	Abdominal (See Note 12)	P	P	P		P	Note 1	Note 2, 7, 10, 11
	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, 10, 11
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8, 9, 10, 11
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (spec.) (See Note 13)	P	P	P		P	Note 1	Note 2, 7, 10, 11	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

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

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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: Panoramic imaging

Note 10: ElastoScan

Note 11: MultiVision (old name: Spatial Compound Imaging)

Note 12: Includes Renal, Gynecology/Pelvis

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: L4-7 for use with HM70A

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 1	Note 2, 5, 6, 7, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 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 (spec.) (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 K153408; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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: Panoramic imaging

Note 10: ElastoScan

Note 11: MultiVision (old name: Spatial Compound Imaging)

Note 12: Includes Renal, Gynecology/Pelvis

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: L5-13 for use with HM70A

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	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 10, 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 (spec.) (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 K153408; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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: Panoramic imaging

Note 10: ElastoScan

Note 11: MultiVision (old name: Spatial Compound Imaging)

Note 12: Includes Renal, Gynecology/Pelvis

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: L7-16 for use with HM70A

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	P	P		P	Note 1	Note 2, 5, 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 (spec.) (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 K153408; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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: Panoramic imaging

Note 10: ElastoScan

Note 11: MultiVision (old name: Spatial Compound Imaging)

Note 12: Includes Renal, Gynecology/Pelvis

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: PE2-4 for use with HM70A

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 4, 7
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	Note 1	Note 4, 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (spec.) (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 K153408; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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: Panoramic imaging

Note10: ElastoScan

Note11: MultiVision (old name: Spatial Compound Imaging)

Note12: Includes Renal, Gynecology/Pelvis

Note13: 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: P3-8 for use with HM70A

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 4, 7
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	Note 1	Note 4, 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (spec.) (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 K153408; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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: Panoramic imaging

Note 10: ElastoScan

Note 11: MultiVision (old name: Spatial Compound Imaging)

Note 12: Includes Renal, Gynecology/Pelvis

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: VN4-8 for use with HM70A

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
	Abdominal (See Note 12)	P	P	P		P	Note 1	Note 2, 7, 8
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 7, 8
	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 (spec.) (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 K153408; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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: Panoramic imaging

Note10: ElastoScan

Note11: MultiVision (old name: Spatial Compound Imaging)

Note12: Includes Renal, Gynecology/Pelvis

Note13: 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: CW2.0 for use with HM70A

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 (spec.) (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 K153408; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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: Panoramic imaging

Note 10: ElastoScan

Note 11: MultiVision (old name: Spatial Compound Imaging)

Note 12: Includes Renal, Gynecology/Pelvis

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 HM70A

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 (spec.) (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 K153408; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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: Panoramic imaging

Note 10: ElastoScan

Note 11: MultiVision (old name: Spatial Compound Imaging)

Note 12: Includes Renal, Gynecology/Pelvis

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: CA1-7AD for use with HM70A

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.)	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 (spec.) (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 K153408 ; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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: Panoramic imaging

Note10: ElastoScan

Note11: MultiVision (old name: Spatial Compound Imaging)

Note12: Includes Renal, Gynecology/Pelvis

Note13: 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: LA3-16AD for use with HM70A

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, 9, 10, 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 (spec.) (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 K153408 ; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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: Panoramic imaging

Note 10: ElastoScan

Note 11: MultiVision (old name: Spatial Compound Imaging)

Note 12: Includes Renal, Gynecology/Pelvis

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: DP2B for use with HM70A

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 (spec.) (See Note 13)								
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

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

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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: Panoramic imaging

Note 10: ElastoScan

Note 11: MultiVision (old name: Spatial Compound Imaging)

Note 12: Includes Renal, Gynecology/Pelvis

Note 13: Includes Urology/Prostate



**DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT**

510(k) No.:

Device Name: LS6-15 for use with HM70A

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)	P	P	P		P	Note 1	Note 7, 8, 9, 11 <sup>b)</sup>	
	Intra-operative (Neuro.)	P	P	P		P	Note 1	Note 7, 8, 9, 11 <sup>b)</sup>	
	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 <sup>a)</sup>
	Musculo-skel. (Superfic.)		P	P	P		P	Note 1	Note 7, 9, 11 <sup>a)</sup>
Intra-luminal									
Other (spec.) (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 <sup>a)</sup>	
	Other (spec.)								

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

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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: Panoramic imaging

Note 10: ElastoScan

Note 11: MultiVision (old name: Spatial Compound Imaging)

Note 12: Includes Renal, Gynecology/Pelvis

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 HM70A

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, 11
	Abdominal (See Note 12)	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	P	P	P		P	Note 1	Note 2, 7, 8, 11
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8, 11
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (spec.) (See Note 13)	P	P	P		P	Note 1	Note 2, 7, 8, 11	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

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

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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: Panoramic imaging

Note10: ElastoScan

Note11: MultiVision (old name: Spatial Compound Imaging)

Note12: Includes Renal, Gynecology/Pelvis

Note13: 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: CV1-8AD for use with HM70A

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, 11
	Abdominal (See Note 10)	P	P	P		P	Note 1	Note 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 (spec.) (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 K153408 ; E= added under Appendix E

**Additional Comments:**

- Color Doppler includes Power (Amplitude) Doppler
- Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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 (MultiVision (old name: 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 HM70A

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 (spec.) (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								
	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+TD, B+CW, B+C+PW, B+PD+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 (MultiVision (old name: 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: CA2-9AD for use with HM70A

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
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		Note 15	Note 1	Notes 2, 6, 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.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (See Note 13)		P	P	P		Note 15	Note 1	Notes 2, 7, 9, 11
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+TD, B+CW, B+C+PW, B+PD+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 (MultiVision (old name: 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: P4-12 for use with HM70A

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 8)	P	P	P		P	Note 1	Note 2, 7
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2, 7
	Small Organ (See Note 5)							
	Neonatal Cephalic	N	N	N		N	Note 1	Note 2, 7
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (See Note 10)								
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	Note 2, 7
	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 2, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K142466 ; E= added under Appendix E

**Additional Comments:**

- Color Doppler includes Power (Amplitude) Doppler
- Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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 (MultiVision (old name: 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: LS3-14B for use with HM70A

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 8)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)	N	N	N		N	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.)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9, 11
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9, 11
Intra-luminal								
Other (See Note 10)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9, 11
	Other (spec.)							

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

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+TD, B+CW, B+C+PW, B+PD+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 (MultiVision (old name: 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)

# SAMSUNG MEDISON Co., Ltd.

510(k) Premarket Notification – Traditional

## 5. 510(K) Summary

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

1. Date Prepared – Oct 12, 2018
2. Manufacturer  
SAMSUNG MEDISON CO., LTD.  
3366, Hanseo-ro, Nam-myeon,  
Hongcheon-gun, Gangwon-do 25108,  
REPUBLIC OF KOREA
3. Primary Contact Person  
Scully KIM  
Regulatory Affairs Specialist  
Phone: +82.2.2194.1312  
Fax: +82.31.8017.9573  
Email: [scully.kim@samsungmedison.com](mailto:scully.kim@samsungmedison.com)
4. Secondary Contact Person  
Roberto Cunha  
Director of Regulatory & Quality  
Phone: +1.978.564.8503  
Email: [rcunha@samsungneurologica.com](mailto:rcunha@samsungneurologica.com)
5. Proposed Device
  - Proprietary Name: HM70A Diagnostic Ultrasound System
  - Common Name: System, Imaging, Pulsed Doppler, Ultrasonic
  - System, Imaging, Pulsed Echo, Ultrasonic
  - Transducer, Ultrasonic, Diagnostic
  - Classification : 21 CFR 892.1550 Ultrasonic pulsed doppler imaging system  
21 CFR 892.1560 Ultrasonic pulsed echo imaging system  
21 CFR 892.1570 Diagnostic ultrasonic transducer
  - Product Code(s): IYN, IYO, ITX
6. Predicate Device
  - HM70A Diagnostic Ultrasound System (K153408)
  - UGEO PT60A Diagnostic Ultrasound System (K142466)
  - HS50/60 Diagnostic Ultrasound System (K170493)
  - eZono 4000 (K140254)

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

7. Device Description  
The HM70A is a general purpose, hand-held, 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/CW Spectral Doppler mode, Harmonic imaging, Tissue Doppler imaging, 3D imaging mode (real-time 4D imaging mode), Elastocan Mode or as a combination of these modes. The HM70A 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 HM70A has real time

# SAMSUNG MEDISON Co., Ltd.

510(k) Premarket Notification – Traditional

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

## 8. Indications for Use

The HM70A 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-esophageal (non-Cardiac), Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric, Trans-esophageal (Cardiac), Peripheral vessel.

The indications for use of **the proposed device** are the same as the primary predicate HM70A (K153408). Therefore, **the proposed device** does not raise new questions of safety and effectiveness

## 9. Technological Comparison to Predicate Devices

The **proposed HM70A Diagnostic Ultrasound System** and the currently marketed predicate device HM70A (K153408) employ the same fundamental scientific technology as all of the features are migrated from the predicate.

## 10. Determination of Substantial Equivalence

Comparison to Predicate: The HM70A 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 HM70A V3.00 and predicate HM70A V2.00 (K153408) have the same clinical intended use.
- The HM70A V3.00 and predicate HM70A V2.00 (K153408) have the same imaging modes and modes of operation.
- The transducers CA2-9AD, P4-12 and LS3-14B are added in this submission. The CA2-9AD previously cleared in the predicate HS50/60 (K1170493) and P4-12 previously cleared in the predicate UGEO PT60A (K142466). The new transducer LS3-14B is added in this submission. The substantial equivalence has been discussed and the Image Performance test report and Biocompatibility test report are attached in Appendix.
- The Needle Pilot and eZGuide of the predicate eZono 4000 (K140254) have same intended use for similar clinical applications; the similarity has been evaluated to be substantial Equivalence.
- 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 HM70A V3.00 and predicate HM70A V2.00 have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The HM70A V3.00 and predicate systems 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

# SAMSUNG MEDISON Co., Ltd.

510(k) Premarket Notification – Traditional

safety, and has been found to conform with applicable medical device safety standards.

All transducers proposed in the present submission were migrated from previously cleared systems. Therefore, 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	<p>The HM70A Ultrasound System with defibrillation-proof ECG electrode was evaluated per the following standards.</p> <p>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.</p>
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	<p>All Migrated probes and software functionality were evaluated using the same test criteria as the predicates for all applicable imaging modes to ensure that migration from a 128-channel system to 128-channel system did not compromise image quality with respect to the intended use of each feature.</p> <p>Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued on May 11, 2005</p>
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

## 12. Summary of Clinical Tests

The subject of this premarket submission, HM70A, is not required clinical studies to support substantial equivalence.



# **SAMSUNG MEDISON Co., Ltd.**

510(k) Premarket Notification – Traditional

## 13. Conclusion

Since the predicate device and subject device have a similar intended use and key technological features, the non-clinical data support the safety of the device and demonstrate that the HM70A Diagnostic Ultrasound System should perform as intended in the specified use conditions. Therefore, SAMSUNG MEDISON CO., LTD. concludes that the performance of the subject device is as safe and effective, and is therefore substantially equivalent, to the predicate device that are currently marketed for the same intended use.

- **END of 510(K) Summary**