



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

December 21, 2015

Re: K153408
Trade/Device Name: HM70A 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: November 23, 2015
Received: November 25, 2015

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Robert Ochs".

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)

K153408

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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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 (<i>See Note 3</i>)	N	N	N		N	Note 1	Notes 2, 4, 7, 8, 9, 11
	Abdominal (<i>See Note 12</i>)	N	N	N	N	N	Note 1	Notes 2, 4, 7, 8, 9, 10, 11
	Intra-operative (<i>See Note 6</i>)	N	N	N		N	Note 1	Note 7, 8, 9, 11
	Intra-operative (Neuro.)	N	N	N		N	Note 1	Note 7, 8, 9, 11
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Small Organ (<i>See Note 5</i>)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 8, 9, 10, 11
	Neonatal Cephalic	N	N	N		N	Note 1	Note 2, 7, 8, 9
	Adult Cephalic	N	N	N	N	N	Note 1	Note 4, 7
	Trans-rectal	N	N	N		N	Note 1	Note 2, 7, 8, 9, 10, 11
	Trans-vaginal	N	N	N		N	Note 1	Note 2, 7, 8, 9, 10, 11
	Trans-urethral							
	Trans-esoph. (non-Cardiac)	N	N	N	N	N	Note 1	Note 4, 7
	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 (spec.) (<i>See Note 13</i>)	N	N	N		N	Note 1	Note 2, 7, 8, 10, 11
Cardiac	Cardiac Adult	N	N	N	N	N	Note 1	Note 4, 7
	Cardiac Pediatric	N	N	N	N	N	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)	N	N	N	N	N	Note 1	Note 4, 7
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N	N	N	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

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: 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 (<i>See Note 3</i>)	P	P	P		P	Note 1	Notes 4, 7, 8, 9
	Abdominal (<i>See Note 12</i>)	P	P	P		P	Note 1	Notes 7, 8, 9
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 7, 8, 9
	Small Organ (<i>See Note 5</i>)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (<i>See Note 13</i>)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K130803; 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: 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 (<i>See Note 3</i>)	P	P	P		P	Note 1	Notes 2, 4, 7, 8, 9
	Abdominal (<i>See Note 12</i>)	P	P	P		P	Note 1	Notes 2, 7, 8, 9
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8, 9
	Small Organ (<i>See Note 5</i>)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (<i>See Note 13</i>)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K130803; 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: 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 (<i>See Note 3</i>)	P	P	P		P	Note 1	Notes 2, 7, 8, 9
	Abdominal (<i>See Note 12</i>)	P	P	P		P	Note 1	Notes 2, 7, 8, 9
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8, 9
	Small Organ (<i>See Note 5</i>)	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.) (<i>See Note 13</i>)							
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 K130803; 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: 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 (<i>See Note 3</i>)	N	N	N		N	Note 1	Note 2, 7, 11
	Abdominal (<i>See Note 12</i>)	N	N	N		N	Note 1	Note 2, 7, 10, 11
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		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.) (<i>See Note 13</i>)	N	N	N		N	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 K130803; 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 (<i>See Note 3</i>)							
	Abdominal (<i>See Note 12</i>)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Small Organ (<i>See Note 5</i>)	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.) (<i>See Note 13</i>)							
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 K130803; 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: 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 (<i>See Note 3</i>)							
	Abdominal (<i>See Note 12</i>)							
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Small Organ (<i>See Note 5</i>)	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.) (<i>See Note 13</i>)							
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 K130803; 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: 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 (<i>See Note 3</i>)							
	Abdominal (<i>See Note 12</i>)							
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Small Organ (<i>See Note 5</i>)	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.) (<i>See Note 13</i>)							
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 K130803; 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: 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 (<i>See Note 3</i>)							
	Abdominal (<i>See Note 12</i>)	P	P	P	P	P	Note 1	Note 4, 7
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)							
	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.) (<i>See Note 13</i>)							
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 K130803; 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 (<i>See Note 3</i>)							
	Abdominal (<i>See Note 12</i>)	P	P	P	P	P	Note 1	Note 4, 7
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)							
	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.) (<i>See Note 13</i>)							
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 K130803; 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 (<i>See Note 3</i>)	P	P	P		P	Note 1	Note 2, 7, 8
	Abdominal (<i>See Note 12</i>)	P	P	P		P	Note 1	Note 2, 7, 8
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 7, 8
	Small Organ (<i>See Note 5</i>)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (<i>See Note 13</i>)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K130803; 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 (<i>See Note 3</i>)							
	Abdominal (<i>See Note 12</i>)							
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)							
	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.) (<i>See Note 13</i>)							
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 K130803; 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: 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 (<i>See Note 3</i>)							
	Abdominal (<i>See Note 12</i>)							
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric				P			
	Small Organ (<i>See Note 5</i>)							
	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.) (<i>See Note 13</i>)							
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 K130803; 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: 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 (<i>See Note 3</i>)	N	N	N		N	Note 1	Notes 2, 4, 7, 8, 9, 11
	Abdominal (<i>See Note 12</i>)	N	N	N		N	Note 1	Notes 2, 4, 7, 8, 9, 11
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	N	N	N		N	Note 1	Notes 2, 7, 9, 11
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Notes 2, 7, 9, 11
	Intra-luminal							
	Other (spec.) (<i>See Note 13</i>)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	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: 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: 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 (<i>See Note 3</i>)							
	Abdominal (<i>See Note 12</i>)							
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)	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.) (<i>See Note 13</i>)							
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 K151663 (LA3-16A); 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 (<i>See Note 3</i>)							
	Abdominal (<i>See Note 12</i>)							
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (<i>See Note 13</i>)							
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-K151663; 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: 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)	N	N	N		N	Note 1	Note 7, 8, 9, 11
	Intra-operative (Neuro.)	N	N	N		N	Note 1	Note 7, 8, 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.)	N	N	N		N	Note 1	Note 7, 9, 11
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Note 7, 9, 11
	Intra-luminal							
	Other (spec.) (See Note 13)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note 1	Note 7, 9, 11
	Other (spec.)							

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

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+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 K151663; 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 (<i>See Note 3</i>)	N	N	N		N	Note 1	Note 2, 4, 7, 8, 9, 11
	Abdominal (<i>See Note 10</i>)	N	N	N		N	Note 1	Note 2, 4, 7, 8, 9, 11
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (<i>See Note 5</i>)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.) (<i>See Note 13</i>)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	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: 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)	N	N	N	N	N	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)	N	N	N	N	N	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)

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1. Submitter's Information: 21 CFR 807.92(a)(1)

SAMSUNG MEDISON CO., LTD.
42, Teheran-ro 108-gil, Gangnam-gu,
Seoul, Korea

Contact Person:

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Data Prepared: September 15, 2015

2. Name of the device:

Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

HM70A Diagnostic Ultrasound System

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

3. Identification of the predicate or legally marketed device:

- UGEO H70c Diagnostic Ultrasound System (K130803)
- RS80A Diagnostic Ultrasound System (K151663)
- EKO7 Diagnostic Ultrasound System (K101455)
- ACCUVIX XG Diagnostic Ultrasound System (K103397)

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

5. Intended Uses:

The HM70A Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

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.

6. Technological Characteristics:

The HM70A is substantially equivalent with respect to safety, effectiveness, and functionality to the UGEO H70c Diagnostic Ultrasound System (K130803), RS80A Diagnostic Ultrasound System (K151663), EKO7 Diagnostic Ultrasound System (K101455) and ACCUVIX XG Diagnostic Ultrasound System (K103397).

All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All system allow for specialized measurements of structures and flow, and calculations.

These are described in detail in the technological characteristics comparison table as below.

<Change list>

HM70A	V2.00	Remarks																
Model Name	Change of model name in the V2.00 - UGEO H70c → HM70A																	
Clinical application	Adding intra-operative and transesophageal (Non-cardiac, Cardiac) application.	The clinical application was described in Section 1.3 Indication For Use of this submission.																
Operation of modes	No addition																	
Applied transducers	Addition of 7 transducers : CA1-7AD, LA3-16AD, LS6-15, V5-9, CV1-8AD, DP2B, MMPT3-7	<table><tr><th>Transducers</th><th>The previously cleared transducers</th></tr><tr><td>CA1-7AD</td><td>K151663 *Same with CA1-7A</td></tr><tr><td>LA3-16AD</td><td>K151663 *Same with LA3-16A</td></tr><tr><td>LS6-15</td><td>K151663 * Same with LA3-16AI</td></tr><tr><td>V5-9</td><td>K151663</td></tr><tr><td>CV1-8AD</td><td>K151663 *Same with CV1-8A</td></tr><tr><td>DP2B</td><td>K151663</td></tr><tr><td>MMPT3-7</td><td>None</td></tr></table>	Transducers	The previously cleared transducers	CA1-7AD	K151663 *Same with CA1-7A	LA3-16AD	K151663 *Same with LA3-16A	LS6-15	K151663 * Same with LA3-16AI	V5-9	K151663	CV1-8AD	K151663 *Same with CV1-8A	DP2B	K151663	MMPT3-7	None
Transducers	The previously cleared transducers																	
CA1-7AD	K151663 *Same with CA1-7A																	
LA3-16AD	K151663 *Same with LA3-16A																	
LS6-15	K151663 * Same with LA3-16AI																	
V5-9	K151663																	
CV1-8AD	K151663 *Same with CV1-8A																	
DP2B	K151663																	
MMPT3-7	None																	
SW Features	- Adding the predicate SW Features : StressEcho, Strain, Needle Mate - Improving the SW feature that was previously cleared in UGEO H70c(K130803) : DICOM (Multiple Worklist, Net profile manger) - Changing the SW feature’s name - SCI(Spatial Compound Imaging) → Multi Vision. - SDMR → Clear Vision. Software improvements migrated from predicate device as below. <table><tr><th>SW Features</th><th>The previously cleared SW Features</th></tr><tr><td>Stress Echo, Strain</td><td>K151663</td></tr><tr><td>Needle Mate</td><td>K151663</td></tr></table>	SW Features	The previously cleared SW Features	Stress Echo, Strain	K151663	Needle Mate	K151663	Description of S/W Features - Stress Echo: It provides functions to support cardio-vascular application. It’s for diagnosis of heart moving, using by agents or exercises. - Strain: It provides functions to support cardio-vascular application. It’s for diagnosis of heart moving, using by motion vector. - Needle Mate: It provides the Needle Mate function to display the Needle position more clearly in B Image by emphasizing the Needle image. It will help user to see the biopsy needle in the ultrasound image better. The user can set Needle Enhance (L, M or H) and adjust depth using Needle ROI button. Needle Mate is only available when using a Linear Probe in 2D mode.										
SW Features	The previously cleared SW Features																	
Stress Echo, Strain	K151663																	
Needle Mate	K151663																	
HW Features	- Improving the battery packs. (Reduced the current rating from 6000mAh to 5000mAh.) - Adding the extended battery pack. - Applying the previously cleared Wireless LAN Card with system. <table><tr><th>HW Features</th><th>The previously cleared HW Features</th></tr><tr><td>Wireless LAN Card</td><td>K151663</td></tr></table>	HW Features	The previously cleared HW Features	Wireless LAN Card	K151663													
HW Features	The previously cleared HW Features																	
Wireless LAN Card	K151663																	

<Technological Characteristics Comparison Table>

Feature / Characteristics	The subject device	The predicate device			
	HM70A	UGEO H70c (K130803)	RS80A (K151663)	EKO7 (K101455)	ACCUVIX XG (K103397)
Indication for Use					
- Fetal/Obstetrics	√	√	√	√	√
- Abdominal	√	√	√	√	√
- Gynecology	√	√	√	√	√
- Intra-operative	√				√
- Pediatric	√	√	√	√	√
- Small Organ	√	√	√	√	√
- Neonatal Cephalic	√	√	√		√
- Adult Cephalic	√	√	√	√	√
- Trans-rectal	√	√	√		√
- Trans-vaginal	√	√	√		√
- Transesophageal (Non-cardiac)	√			√	
- Musculo-skeletal (Conventional)	√	√	√	√	√
- Musculo-skeletal (Superficial)	√	√	√	√	√
- Urology	√	√	√	√	√
- Cardiac Adult	√	√	√	√	√
- Cardiac Pediatric	√	√	√	√	√
- Transesophageal (Cardiac)	√			√	
- Peripheral vessel	√	√	√	√	√
- Intra-operative	√				√
Scanhead Types					
- Linear Array	√	√	√	√	√
- Curved Linear Array	√	√	√	√	√
- Endocavity	√	√	√		√
- Phased Array	√	√	√	√	√
- Static Probes	√		√	√	√
Scanhead Frequency					
1.0 ~ 20.0 MHz	√	√	√	√	√
Modes of Operation					
- B-mode	√	√	√	√	√
- M-mode	√	√	√	√	√
- Pulsed wave (PW) Doppler	√	√	√	√	√
- Continuous wave (CW) Doppler	√	√	√	√	√
- Color Doppler	√	√	√	√	√
- Power Amplitude Doppler	√	√	√	√	√
- Tissue Harmonic Imaging	√	√	√	√	√

Feature / Characteristics	The subject device	The predicate device			
	HM70A	UGEO H70c (K130803)	RS80A (K151663)	EKO7 (K101455)	ACCUVIX XG (K103397)
- 3D/4D imaging mode	√	√	√	√	√
- Combined modes	√	√	√	√	√
Safety & EMC Compliance					
- IEC 60601-1 - UL 60601-1 - CSA C22.2 No.601.1	√	√	√	√	√
- IEC 60601-2-37	√	√	√	√	√
- IEC 60601-1-2	√	√	√	√	√
Acoustic Output Display Standard					
Track 3	√	√	√	√	√
Patient Contact Materials					
Tested to ISO 10993-1	√	√	√	√	√
Functionality					
- Volume NT	√	√	√		√
- Q Scan	√	√	√	√	√
- ClearVision (SDMR)	√	√	√	√ ¹⁾	√ ¹⁾
- MultiVision (Spatial Compound Imaging)	√	√	√	√ ²⁾	√ ²⁾
- Auto IMT+ (Auto IMT)	√	√	√	√	√
- Elastoscans	√	√	√		√
- Panoramic	√	√	√		
- Strain	√		√	√	
- Stress Echo	√		√	√	
- ADVR	√	√	√		
- Needle Mate	√		√		
- 3D Imaging (Volume Data Acquisition)	√	√	√		√
- 3D Imaging presentation 3D Cine/4D Cine	√	√	√		√
- 3D Rendering MPR	√	√	√		√
- 3D XI MSV/Oblique View	√	√	√		√
- 3D MagiCut	√	√	√		√
- Volume Calculation (VOCAL, XI VOCAL)	√	√	√		√

1) The old name of ClearVision is Dynamic MR or Dynamic MR Plus(+).

2) The old name of MultiVison is Spatial Compound Imaging.

7. A brief discussion of the bench and non-clinical tests conducted on the subject device

The device has been evaluated for acoustic output, biocompatibility effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and has been found to conform to applicable medical device safety standards.

The HM70A and its application comply with voluntary standards as below:

- UL 60601-1, Safety requirements for Medical Equipment
- CSA C22.2 No. 601.1, Safety requirements for Medical Equipment
- IEC60601-2-37, Diagnostic Ultrasound Safety Standards
- EN/IEC60601-1, Safety requirements for Medical Equipment
- EN/IEC60601-1-2, EMC requirements for Medical Equipment
- NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- ISO10993-1, Biocompatibility
- ISO14971, Application of risk management to medical devices

Summary of Clinical Tests:

Not applicable. The subject of this submission, HM70A, did not require clinical studies to support substantial equivalence.

8. Conclusion

Intended uses and other key features are consistent with traditional clinical practices and FDA guidelines. The design, development and quality process of the manufacturer confirms with 21 CFR 820 and ISO 13485. The device is designed to conform to applicable medical device safety standards and compliance. Therefore, SAMSUNG MEDISON CO., LTD. considers the HM70A to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

END of 510(K) Summary