



Food and Drug Administration
10903 New Hampshire Avenue
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SAMSUNG MEDISON CO., LTD.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

August 12, 2015

Re: K151663
Trade/Device Name: RS80A Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO and ITX
Dated: July 29, 2015
Received: July 30, 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,



For

Robert Ochs, Ph.D.
Acting 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)

K151663

Device Name

RS80A Diagnostic Ultrasound System

Indications for Use (Describe)

The RS80A Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric and Peripheral vessel.

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

Prescription Use (Part 21 CFR 801 Subpart D)

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

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: RS80A 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, 14
	Abdominal (See Note 10)	P	P	P	P	P	Note 1	Notes 2, 4, 5, 6, 7, 8, 9, 11, 12, 14, 15
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	N	P	Note 1	Notes 8, 9, 11
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11, 12, 14
	Neonatal Cephalic	P	P	P		P	Note 1	Notes 8, 9, 11
	Adult Cephalic	P	P	P	P	P	Note 1	Notes 7
	Trans-rectal	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 11, 12
	Trans-vaginal	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 11, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11, 14
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11, 14
Intra-luminal								
Other (See Note 13)	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 12	
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	Notes 4, 7
	Cardiac Pediatric	P	P	P	P	P	Note 1	Notes 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	Note 1	Note 2, 5, 6, 7, 8, 9, 11, 14
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Spatial Compound Imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Note 14: S-Fusion

Note 15: S-Shearwave

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: CA1-7A for use with RS80A

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 2,4,7,8,9,11,14
	Abdominal (See Note 10)	P	P	P		P	Note 1	Notes 2,6,7,8,9,11,14,15
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (See Note 13)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

Additional Comments:

- Color Doppler includes Power (Amplitude) Doppler
- Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Spatial Compound Imaging
- Note 10: Includes Renal, Gynecology/Pelvis
- Note 11: Panoramic imaging
- Note 12: ElastoScan
- Note 13: Includes Urology/Prostate
- Note 14: S-Fusion
- Note 15: S-Shearwave

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 RS80A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Notes 2, 4, 7, 8, 9, 11
	Abdominal (See Note 10)	P	P	P		P	Note 1	Notes 2, 6, 7, 8, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (See Note 13)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

Additional Comments:

- Color Doppler includes Power (Amplitude) Doppler
- Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Spatial Compound Imaging
- Note 10: Includes Renal, Gynecology/Pelvis
- Note 11: Panoramic imaging
- Note 12: ElastoScan
- Note 13: Includes Urology/Prostate
- Note 14: S-Fusion
- Note 15: S-Shearwave

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 RS80A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 10)	P	P	P		P	Note 1	Notes 8, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 8, 9, 11
	Small Organ (See Note 5)							
	Neonatal Cephalic	P	P	P		P	Note 1	Notes 8, 9, 11
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (See Note 13)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Notes 8, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

Additional Comments:

- Color Doppler includes Power (Amplitude) Doppler
- Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Spatial Compound Imaging
- Note 10: Includes Renal, Gynecology/Pelvis
- Note 11: Panoramic imaging
- Note 12: ElastoScan
- Note 13: Includes Urology/Prostate
- Note 14: S-Fusion
- Note 15: S-Shearwave

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: E3-12A for use with RS80A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Notes 2, 7, 8, 9
	Abdominal (See Note 10)	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 12
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 12
	Trans-vaginal	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (See Note 13)	P	P	P		P	Note 1	Notes 2, 7, 8, 9, 12	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

Additional Comments:

- Color Doppler includes Power (Amplitude) Doppler
- Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Spatial Compound Imaging
- Note 10: Includes Renal, Gynecology/Pelvis
- Note 11: Panoramic imaging
- Note 12: ElastoScan
- Note 13: Includes Urology/Prostate
- Note 14: S-Fusion
- Note 15: S-Shearwave

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: L3-12A for use with RS80A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 10)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11, 12, 14
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11, 14
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11, 14
Intra-luminal								
Other (See Note 13)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11, 14
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

Additional Comments:

- Color Doppler includes Power (Amplitude) Doppler
- Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Spatial Compound Imaging
- Note 10: Includes Renal, Gynecology/Pelvis
- Note 11: Panoramic imaging
- Note 12: ElastoScan
- Note 13: Includes Urology/Prostate
- Note 14: S-Fusion
- Note 15: S-Shearwave

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 RS80A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 10)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 8, 7, 9, 11, 12
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
Intra-luminal								
Other (See Note 13)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Spatial Compound Imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Note 14: S-Fusion

Note 15: S-Shearwave

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 RS80A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 10)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
Intra-luminal								
Other (See Note 13)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

Additional Comments:

- Color Doppler includes Power (Amplitude) Doppler
- Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Spatial Compound Imaging
- Note 10: Includes Renal, Gynecology/Pelvis
- Note 11: Panoramic imaging
- Note 12: ElastoScan
- Note 13: Includes Urology/Prostate
- Note 14: S-Fusion
- Note 15: S-Shearwave

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: LA2-9A for use with RS80A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 10)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
Intra-luminal								
Other (See Note 13)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Spatial Compound Imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Note 14: S-Fusion

Note 15: S-Shearwave

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 RS80A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 10)	P	P	P	P	P	Note 1	Note 7
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	Note 1	Note 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
Other (See Note 13)								
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	Note 4, 7
	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Spatial Compound Imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Note 14: S-Fusion

Note 15: S-Shearwave

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: PM1-6A for use with RS80A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 10)	P	P	P	P	P	Note 1	Note 7
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	Note 1	Note 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (See Note 13)								
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	Note 4, 7
	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

Additional Comments:

- Color Doppler includes Power (Amplitude) Doppler
- Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: Spatial Compound Imaging
- Note 10: Includes Renal, Gynecology/Pelvis
- Note 11: Panoramic imaging
- Note 12: ElastoScan
- Note 13: Includes Urology/Prostate
- Note 14: S-Fusion
- Note 15: S-Shearwave

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: V5-9 for use with RS80A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Note 2, 7, 8, 9
	Abdominal (See Note 10)	P	P	P		P	Note 1	Note 2, 7, 8, 9
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8, 9
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8, 9
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (See Note 13)	P	P	P		P	Note 1	Note 2, 7, 8, 9	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Spatial Compound Imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Note 14: S-Fusion

Note 15: S-Shearwave

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LV3-14A for use with RS80A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 10)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
Intra-luminal								
Other (See Note 13)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Spatial Compound Imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Note 14: S-Fusion

Note 15: S-Shearwave

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CW6.0 for use with RS80A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 10)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (See Note 13)								
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel				P			
	Other (spec.)							

N= new indication; P= previously cleared by FDA K141620; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Spatial Compound Imaging

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Note 14: S-Fusion

Note 15: S-Shearwave

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CA2-8A for use with RS80A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)	P	P	P		P	Note 1	Notes 2, 4, 7, 8, 9, 11
	Abdominal (See Note 10)	P	P	P		P	Note 1	Notes 2, 4, 7, 8, 9, 11
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (See Note 13)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K143089 ; E= added under Appendix E

Additional Comments:

- Color Doppler includes Power (Amplitude) Doppler
- Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: MultiVision (Spatial Compound Imaging)
- Note 10: Includes Renal, Gynecology/Pelvis
- Note 11: Panoramic imaging
- Note 12: ElastoScan
- Note 13: Includes Urology/Prostate
- Note 14: S-Fusion
- Note 15: S-Shearwave

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LA3-16A for use with RS80A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 10)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11, 12
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
Intra-luminal								
Other (See Note 13)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K150478; E= added under Appendix E

Additional Comments:

- Color Doppler includes Power (Amplitude) Doppler
- Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: MultiVision (Spatial Compound Imaging)
- Note 10: Includes Renal, Gynecology/Pelvis
- Note 11: Panoramic imaging
- Note 12: ElastoScan
- Note 13: Includes Urology/Prostate
- Note 14: S-Fusion
- Note 15: S-Shearwave

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: LA3-16AI for use with RS80A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)							
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)	
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)								
	Abdominal (See Note 10)								
	Intra-operative (See Note 6)								
	Intra-operative (Neuro.)								
	Laparoscopic								
	Pediatric								
	Small Organ (See Note 5)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Cardiac)								
	Musculo-skel. (Convent.)		P	P	P		P	Note 1	Note 7, 9, 11
	Musculo-skel. (Superfic.)		P	P	P		P	Note 1	Note 7, 9, 11
Intra-luminal									
Other (See Note 13)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Trans-esophageal (Cardiac)								
	Other (spec.)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 7, 9, 11	
	Other (spec.)								

N= new indication; P= previously cleared by FDA K150478 (LS6-15); E= added under Appendix E

Additional Comments:

- Color Doppler includes Power (Amplitude) Doppler
- Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: MultiVision (Spatial Compound Imaging)
- Note 10: Includes Renal, Gynecology/Pelvis
- Note 11: Panoramic imaging
- Note 12: ElastoScan
- Note 13: Includes Urology/Prostate
- Note 14: S-Fusion
- Note 15: S-Shearwave

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

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LA4-18B for use with RS80A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 10)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 8, 9, 11
Intra-luminal								
Other (See Note 13)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	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+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: MultiVision (Spatial Compound Imaging)
- Note 10: Includes Renal, Gynecology/Pelvis
- Note 11: Panoramic imaging
- Note 12: ElastoScan
- Note 13: Includes Urology/Prostate
- Note 14: S-Fusion
- Note 15: S-Shearwave

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: PA3-8B for use with RS80A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 10)	P	P	P	P	P	Note 1	
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	N	P	Note 1	
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	Note 1	
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
Other (See Note 13)								
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	Note 4, 7
	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K130803 (P3-8); E= added under Appendix E

Additional Comments:

- Color Doppler includes Power (Amplitude) Doppler
- Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: MultiVision (Spatial Compound Imaging)
- Note 10: Includes Renal, Gynecology/Pelvis
- Note 11: Panoramic imaging
- Note 12: ElastoScan
- Note 13: Includes Urology/Prostate
- Note 14: S-Fusion
- Note 15: S-Shearwave

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: PA4-12B for use with RS80A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 10)	P	P	P	P	P	Note 1	Note 2
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	N	P	Note 1	Note 2
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (See Note 13)								
Cardiac	Cardiac Adult	P	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 K142466 (P4-12); E= added under Appendix E

Additional Comments:

- Color Doppler includes Power (Amplitude) Doppler
- Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: MultiVision (Spatial Compound Imaging)
- Note 10: Includes Renal, Gynecology/Pelvis
- Note 11: Panoramic imaging
- Note 12: ElastoScan
- Note 13: Includes Urology/Prostate
- Note 14: S-Fusion
- Note 15: S-Shearwave

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

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CV1-8A for use with RS80A

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
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (See Note 13)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K150478; E= added under Appendix E

Additional Comments:

- Color Doppler includes Power (Amplitude) Doppler
- Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: MultiVision (Spatial Compound Imaging)
- Note 10: Includes Renal, Gynecology/Pelvis
- Note 11: Panoramic imaging
- Note 12: ElastoScan
- Note 13: Includes Urology/Prostate
- Note 14: S-Fusion
- Note 15: S-Shearwave

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: V4-8 for use with RS80A

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
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (See Note 13)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K150478; E= added under Appendix E

Additional Comments:

- Color Doppler includes Power (Amplitude) Doppler
- Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Includes infertility monitoring of follicle development
- Note 4: Color M-mode
- Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: 3D imaging
- Note 9: MultiVision (Spatial Compound Imaging)
- Note 10: Includes Renal, Gynecology/Pelvis
- Note 11: Panoramic imaging
- Note 12: ElastoScan
- Note 13: Includes Urology/Prostate
- Note 14: S-Fusion
- Note 15: S-Shearwave

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: DP2B for use with RS80A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 10)							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Intra-luminal								
Other (See Note 13)								
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K150478; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+DPD, B+PPI, B+TD, B+CW, B+C+PW, B+PD+PW, B+DPD+PW, B+PPI+PW, B+TD+PW, B+C+M, Dual/Quad, B+C+CW, B+PD+CW, B+E, B+B/C

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: Includes Renal, Gynecology/Pelvis

Note 11: Panoramic imaging

Note 12: ElastoScan

Note 13: Includes Urology/Prostate

Note 14: S-Fusion

Note 15: S-Shearwave

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: March 24, 2013

2. Name of the device:

Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

RS80A 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:

- RS80A Diagnostic Ultrasound System (K141620)
- A35 Diagnostic Ultrasound System (K150478)
- WS80A Diagnostic Ultrasound System (K143089)
- HM70A Diagnostic Ultrasound System (K130803)
- PT60A Diagnostic Ultrasound System (K142466)
- LOGIQ E9 Diagnostic Ultrasound System (K142160)
- Aixplorer Diagnostic Ultrasound System (K132274)
- S2000/S3000 Diagnostic Ultrasound System (K131164/K130881)
- QLAB (K021966)

4. Device Description:

The RS80A is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as B mode, M mode, Color Doppler imaging, Power Doppler imaging (including Directional Power Doppler mode; S-Flow), PW Spectral Doppler mode, CW Spectral Doppler mode, Harmonic imaging, Tissue Doppler imaging, Tissue Doppler Wave, 3D imaging mode (real time 4D imaging mode), Elastocan Mode or as a combination of these modes. The RS80A 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 RS80A 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 RS80A Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric and Peripheral vessel.

6. Technological Characteristics:

The RS80A is substantially equivalent with respect to safety, effectiveness, and functionality to the RS80A Diagnostic Ultrasound System (K141620), A35 Diagnostic Ultrasound System (K150478), WS80A Diagnostic Ultrasound System (K143089), HM70A Diagnostic Ultrasound System (K130803) and PT60A Diagnostic Ultrasound System (K142466).

- It is substantially equivalent with respect to safety, effectiveness, and functionality to the **Realistic Vue of RS80A (K141620)** in regards to the device with **Natural Vue**.
- It is substantially equivalent with respect to safety, effectiveness, and functionality to the **Clear Track of RS80A (K141620)** in regards to the device with **Virtual Track**.
- It is substantially equivalent with respect to safety, effectiveness, and functionality to the **Breast Productivity package³⁾** of GE's LOGIQ E9 (K142160) in regards to the device with **S-Detect**.
- It is substantially equivalent with respect to safety, effectiveness, and functionality to the **Volume Navigation⁴⁾** of GE's LOGIQ E9 (K142160) in regards to the device with **S-Fusion**.
- It is substantially equivalent with respect to safety, effectiveness, and functionality to the **VTQ⁷⁾** of Siemens's S2000/S3000 (K131164) and **Shearwave elastography⁶⁾** of SSI's AIXPLORER (K132274) in regards to the device with **S-Shearwave**.
- It is substantially equivalent with respect to safety, effectiveness, and functionality to the **Elastocan of RS80A (K141620)** and **Phillips's QLAB ROI⁵⁾** (K021966) in regards to the device with **E-Thyroid**.

- It is substantially equivalent with respect to safety, effectiveness, and functionality to the **Elastoscan of RS80A (K141620)** and **Shearwave elastography⁶⁾ of SSI's AIXPLORER (K132274)** in regards to the device with E-Breast.

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>

RS80A	V2.00	Remarks																				
Clinical application	<ul style="list-style-type: none"> No addition 																					
Operation of modes	<ul style="list-style-type: none"> No addition 																					
Applied transducers	<ul style="list-style-type: none"> Addition of 9 transducers : CA2-8A, LA3-16A, LA3-16AI, LA4-18B, PA3-8B, PA4-12B, CV1-8A, V4-8 and DP2B. 	<table border="1"> <thead> <tr> <th>Transducers</th> <th>The previously cleared transducers</th> </tr> </thead> <tbody> <tr> <td>CA2-8A</td> <td>K143089</td> </tr> <tr> <td>LA3-16A</td> <td>K150478</td> </tr> <tr> <td>LA3-16AI</td> <td>K150478 (LS6-15)</td> </tr> <tr> <td>LA4-18B</td> <td>None</td> </tr> <tr> <td>PA3-8B</td> <td>K130803</td> </tr> <tr> <td>PA4-12B</td> <td>K142466 (P4-12)</td> </tr> <tr> <td>CV1-8A</td> <td>K150478</td> </tr> <tr> <td>V4-8</td> <td>K150478</td> </tr> <tr> <td>DP2B</td> <td>K150478</td> </tr> </tbody> </table>	Transducers	The previously cleared transducers	CA2-8A	K143089	LA3-16A	K150478	LA3-16AI	K150478 (LS6-15)	LA4-18B	None	PA3-8B	K130803	PA4-12B	K142466 (P4-12)	CV1-8A	K150478	V4-8	K150478	DP2B	K150478
Transducers	The previously cleared transducers																					
CA2-8A	K143089																					
LA3-16A	K150478																					
LA3-16AI	K150478 (LS6-15)																					
LA4-18B	None																					
PA3-8B	K130803																					
PA4-12B	K142466 (P4-12)																					
CV1-8A	K150478																					
V4-8	K150478																					
DP2B	K150478																					
SW Features	<ul style="list-style-type: none"> Adding the new S/W features : Natural Vue, S-Shearwave, S-Fusion, Virtual Track, S-Detect, E-Thyroid, E-Breast Adding the predicate S/W feature : Needle Mate, Strain+, StressEcho Improving the S/W feature that was previously cleared in RS80A(K141620) : DICOM, EZ Exam+ Changing the S/W feature's name <ul style="list-style-type: none"> SCI (Spatial Compound Imaging) → MultiVision Low MI → CUES+ EZexam → EZexam+ <p>Software improvements migrated from predicate device as below.</p> <table border="1"> <thead> <tr> <th>SW Features</th> <th>The previously cleared SW Features</th> </tr> </thead> <tbody> <tr> <td>Needle Mate</td> <td>K142466</td> </tr> <tr> <td>Strain+</td> <td>K150478</td> </tr> </tbody> </table>	SW Features	The previously cleared SW Features	Needle Mate	K142466	Strain+	K150478	<p>Description of S/W Features</p> <ul style="list-style-type: none"> Natural Vue: This function allows realistic visualization of 3D Volume Data by specular shading technique. It is a rendering method that uses global illumination and used to create a realistic volume rendering image. S-Shearwave: It provides the user with tissue stiffness information. This is mainly used to help diagnose hepatic tissues. S-Fusion: Based on the 3 dimensional CT, MR, ultrasound (US) images acquired previously, the sensors installed in the probe will be used to adjust with the real-time ultrasound wave. The position of the probe will be tracked to display the real-time ultrasound image of the same plane and the registered 3-dimensional image Virtual Track: This module tracks the direction of needle by using the sensing device. S-Detect: This module analyzes the selected lesion from the ultrasound image and shows 														
SW Features	The previously cleared SW Features																					
Needle Mate	K142466																					
Strain+	K150478																					

RS80A	V2.00		Remarks				
	StressEcho	K150478	the analyzed data. <ul style="list-style-type: none"> E-Thyroid: This function assists with the diagnosis of thyroid lesions. ROI is used to show the contrast of an elastogram. E-Breast: This is the function for breast lesion exam. Calculates the strain between the area of the suspected lesion (ROI) and normal breast fat and displays the results. 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. 				
HW Features	<ul style="list-style-type: none"> Applying the previously cleared Wireless LAN Card with system. <table border="1"> <tr> <td>HW Features</td> <td>The previously cleared HW Features</td> </tr> <tr> <td>Wireless LAN Card</td> <td>K142466</td> </tr> </table>		HW Features	The previously cleared HW Features	Wireless LAN Card	K142466	<ul style="list-style-type: none"> Wireless LAN Card: It is intended use a USB adapter to connect the system to a wireless network.
HW Features	The previously cleared HW Features						
Wireless LAN Card	K142466						

<Technological Characteristics Comparison Table 1>

Feature / Characteristics	The subject device	The predicate devices					
	RS80A V2.00	RS80A (K141620)	A35 (K150478)	WS80A (K143089)	HM70A (K130803)	PT60A (K142466)	LOGIQ E9 (K123564)
Indication for Use							
- Fetal/Obstetrics	√	√	√	√	√	√	√
- Abdominal	√	√	√	√	√	√	√
- Gynecology	√	√	√	√	√	√	√
- Pediatric	√	√	√	√	√	√	√
- Small Organ	√	√	√	√	√	√	√
- Neonatal Cephalic	√	√	√	√	√		√
- Adult Cephalic	√	√	√	√	√	√	√
- Trans-rectal	√	√	√	√	√	√	√
- Trans-vaginal	√	√	√	√	√	√	√
- Musculo-skeletal (Conventional)	√	√	√	√	√	√	√
- Musculo-skeletal (Superficial)	√	√	√	√	√	√	√
- Urology	√	√	√	√	√	√	√
- Cardiac Adult	√	√	√	√	√	√	√
- Cardiac Pediatric	√	√	√	√	√	√	√
- Peripheral vessel	√	√	√	√	√	√	√
Scanhead Types							
- Linear Array	√	√	√	√	√	√	√
- Curved Linear Array	√	√	√	√	√	√	√

Feature / Characteristics	The subject device	The predicate devices					
	RS80A V2.00	RS80A (K141620)	A35 (K150478)	WS80A (K143089)	HM70A (K130803)	PT60A (K142466)	LOGIQ E9 (K123564)
- 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	√	√	√	√	√	√	√
- 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							
- Q Scan	√	√	√	√	√	√	-
- ClearVision	√	√	√	√	√	√	-
- Spatial Compound Imaging	√ ^D	√	√	√ ^D	√	√ ^D	-
- Panoramic	√	√	√	√	√		-
- Needle Mate	√					√	-
- Auto IMT+ (Auto IMT)	√	√	√	√	√	√	-
- Strain+	√		√				
- Stress Echo	√		√				
- Elastoscan	√	√	√	√	√	√	√
- E-Thyroid	√ (Table 2)						
- E-Breast	√ (Table 2)						
- S-Shearwave	√						√

Feature / Characteristics	The subject device	The predicate devices					
	RS80A V2.00 (Table 2)	RS80A (K141620)	A35 (K150478)	WS80A (K143089)	HM70A (K130803)	PT60A (K142466)	LOGIQ E9 (K123564)
- S-Detect	√	√					√ ³⁾
- S-Fusion	√						√ ⁴⁾
- Clear Track	√	√					√
- Virtual Track	√						√
- ADVR	√	√	√	√	√		-
- 3D Imaging (Volume Data Acquisition)	√	√	√	√	√		√
- 3D Imaging presentation 3D Cine/4D Cine	√	√	√	√	√		-
- 3D Rendering MPR	√	√	√	√	√		-
- 3D XI MSV/Oblique View	√	√	√	√	√		-
- 3D MXI Volume Slice/Mirror View	√	√	√	√			-
- Volume CT	√	√	√	√			-
- 3D MagiCut	√	√	√	√	√		-
- Volume Calculation (VOCAL, XI VOCAL)	√	√	√	√	√		-
- XI STIC	√	√	√	√	√		-
- HDVI	√	√	√	√	√		-
- Realistic Vue	√	√	√ ²⁾	√ ²⁾			-
- Natural Vue	√						

<Technological Characteristics Comparison Table 2>

Feature / Characteristics	The subject device	The predicate devices		
	RS80A V2.00	Aixplorer (K132274)	S2000/S3000 (K131164/ K130881)	QLAB (K021966)
Indication for Use				
- Fetal/Obstetrics	√		√	-
- Abdominal	√	√	√	-
- Gynecology	√	√	√	-
- Pediatric	√	√	√	-
- Small Organ	√	√	√	-
- Neonatal Cephalic	√	√	√	-
- Adult Cephalic	√		√	-
- Trans-rectal	√	√	√	-
- Trans-vaginal	√	√	√	-
- Musculo-skeletal (Conventional)	√	√	√	-
- Musculo-skeletal (Superficial)	√	√	√	-
- Urology	√	√		-
- Cardiac Adult	√		√	-

Feature / Characteristics	The subject device	The predicate devices		
	RS80A V2.00	Aixplorer (K132274)	S2000/S3000 (K131164/ K130881)	QLAB (K021966)
- Cardiac Pediatric	√		√	-
- Peripheral vessel	√	√	√	-
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	√	√	√	-
- 3D/4D imaging mode	√	√	√	-
- Combined modes	√	√	√	-
Safety & EMC Compliance				
- IEC 60601-1				
- UL 60601-1	√	√	√	-
- CSA C22.2No.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				
- Q Scan	√			-
- ClearVision	√			-
- Spatial Compound Imaging	√ ¹⁾	√	√	-
- Panoramic	√	√	√	-
- Needle Mate	√			-
- Auto IMT+ (Auto IMT)	√			-
- Strain+	√			-
- Stress Echo	√			-
- Elastoscan	√	√	√	-

Feature / Characteristics	The subject device	The predicate devices		
	RS80A V2.00	Aixplorer (K132274)	S2000/S3000 (K131164/ K130881)	QLAB (K021966)
- E-Thyroid	√			√ ⁵⁾
- E-Breast	√	√ ⁶⁾		-
- S-Shearwave	√	√ ⁶⁾	√ ⁷⁾	-
- S-Detect	√			-
- S-Fusion	√			-
- Clear Track	√			-
- Virtual Track	√			-
- 3D Imaging	√	√	√	-

1) The name of the feature is changed to MultiVision.	4) Volume Navigation
2) The old name of this feature is FRV.	5) QLAB ROI
3) Breast Productivity Package	6) Shearwave Elastography
	7) VTQ

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 RS80A 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, RS80A, 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 RS80A to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

END of 510(K) Summary