



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 3, 2014

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

Re: K142466
Trade/Device Name: UGEO PT60A 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: August 28, 2014
Received: September 2, 2014

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.

This determination of substantial equivalence applies to the following transducers intended for use with the UGEO PT60A Diagnostic Ultrasound System, as described in your premarket notification:

<u>Transducer Model Number</u>		
<u>C2-5</u>	<u>C2-8</u>	<u>LN5-12</u>
<u>LS6-15</u>	<u>PN2-4</u>	<u>CF4-9</u>
<u>EVN4-9</u>	<u>P4-12</u>	

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

Janine M. Morris
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)

K142466

Device Name

UGEO PT60A Diagnostic Ultrasound System

Indications for Use (Describe)

The UGEO PT60A 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, 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)

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

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K142466

Device Name: UGEO PT60A 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>)	P	P	P		P	Note 1	Notes 2, 7
	Abdominal (<i>See Note 8</i>)	P	P	P		P	Note 1	Notes 2, 7
	Intra-operative (<i>See Note 6</i>)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7
	Small Organ (<i>See Note 5</i>)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Neonatal Cephalic							
	Adult Cephalic	P	P	P		P	Note 1	Note 7
	Trans-rectal	P	P	P		P	Note 1	Notes 2
	Trans-vaginal	P	P	P		P	Note 1	Notes 2
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 9
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 9
Intra-luminal								
Other (<i>See Note 10</i>)	P	P	P		P	Note 1	Notes 2	
Cardiac	Cardiac Adult	P	P	P		P	Note 1	Note 2, 7
	Cardiac Pediatric	P	P	P		P	Note 1	Note 2, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132228; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+C+PW, B+PD+PW, Dual(B, B/C, B/PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Obstetrics and 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, lung

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: Includes Gynecology

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: 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.: K142466

Device Name: C2-5 for use with UGEO PT60A

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
	Abdominal (See Note 8)	P	P	P		P	Note 1	Notes 2, 7
	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 10)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132228; E= added under Appendix E

Additional Comments:

- Color Doppler includes Power (Amplitude) Doppler
- Note 1: B+M, B+PW, B+C, B+PD, B+C+PW, B+PD+PW, Dual(B, B/C, B/PD)
- Note 2: Includes imaging for guidance of biopsy
- Note 3: Obstetrics and 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, lung
- Note 6: Abdominal organs and peripheral vessel
- Note 7: Tissue Harmonic Imaging (THI)
- Note 8: Includes Gynecology
- Note 9: MultiVision (Spatial Compound Imaging)
- Note 10: 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.: K142466

Device Name: C2-8 for use with UGEO PT60A

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
	Abdominal (See Note 8)	P	P	P		P	Note 1	Notes 2, 7
	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 10)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K132228; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+C+PW, B+PD+PW, Dual(B, B/C, B/PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Obstetrics and 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, lung

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: Includes Gynecology

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: 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.: K142466

Device Name: LN5-12 for use with UGEO PT60A

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

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

N= new indication; P= previously cleared by FDA K132228; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+C+PW, B+PD+PW, Dual(B, B/C, B/PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Obstetrics and 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, lung

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: Includes Gynecology

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: 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.: K142466

Device Name: LS6-15 for use with UGEO PT60A

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

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

N= new indication; P= previously cleared by FDA K132228; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+C+PW, B+PD+PW, Dual(B, B/C, B/PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Obstetrics and 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, lung

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: Includes Gynecology

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: 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.: K142466

Device Name: PN2-4 for use with UGEO PT60A

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

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

N= new indication; P= previously cleared by FDA K132228; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+C+PW, B+PD+PW, Dual(B, B/C, B/PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Obstetrics and 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, lung

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: Includes Gynecology

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: 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.: K142466

Device Name: CF4-9 for use with PT60A

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

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

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+C+PW, B+PD+PW, Dual(B, B/C, B/PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Obstetrics and 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, lung

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: Includes Gynecology

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: 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.: K142466

Device Name: EVN4-9 for use with PT60A

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

N= new indication; P= previously cleared by FDA K132861; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+C+PW, B+PD+PW, Dual(B, B/C, B/PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Obstetrics and 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, lung

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: Includes Gynecology

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: 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.: K142466

Device Name: P4-12 for use with PT60A

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics (See Note 3)							
	Abdominal (See Note 8)	P	P	P		P	Note 1	Note 2, 7
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	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 10)								
Cardiac	Cardiac Adult	P	P	P		P	Note 1	Note 2, 7
	Cardiac Pediatric	P	P	P		P	Note 1	Note 2, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 7
	Other (spec.)							

N= new indication; P= previously cleared by FDA K103397; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+C+PW, B+PD+PW, Dual(B, B/C, B/PD)

Note 2: Includes imaging for guidance of biopsy

Note 3: Obstetrics and 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, lung

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: Includes Gynecology

Note 9: MultiVision (Spatial Compound Imaging)

Note 10: 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:

Kyeong-Mi, Park
Regulatory Affairs Manager

Telephone: 82.2.2194.1373

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Data Prepared: July 2, 2014

2. Name of the device:

Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

UGEO PT60A 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 PT60A Diagnostic Ultrasound System (K132228)
- UGEO H60 Diagnostic Ultrasound System (K132861)
- ACCUVIX XG Diagnostic Ultrasound System (K103397)
- GE Venue 40 Diagnostic Ultrasound System (K112122)

4. Device Description:

The UGEO PT60A is a general purpose, hand-held, 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, PW Spectral Doppler mode, Harmonic imaging or as a combination of these modes. The UGEO PT60A 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 UGEO PT60A has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

The UGEO PT60A has been designed to meet the following product safety standards:

- 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

5. Intended Uses:

The UGEO PT60A 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, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric and Peripheral vessel.

6. Technological Characteristics:

The UGEO PT60A is substantially equivalent with respect to safety, effectiveness, and functionality to the UGEO PT60A Diagnostic Ultrasound System (K132228), UGEO H60 Diagnostic Ultrasound System (K132861) 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.

<Technological Characteristics Comparison Table>

Feature / Characteristics	The subject device	The predicate devices		
	UGEO PT60A	UGEO PT60A (K132228)	UGEO H60 (K132861)	ACCUVIX XQ (K103397)
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	√	√	√	√
- 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				
- IEC60601-1	√	√	√	√
- UL 60601-1				

Feature / Characteristics	The subject device	The predicate devices		
	UGEO PT60A	UGEO PT60A (K132228)	UGEO H60 (K132861)	ACCUVIX XQ (K103397)
- 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				
- Quick Scan (Q Scan)	√	√	√	√
- Spatial Compound Imaging	√ ¹⁾	√	√	√
- SMDR	√ ²⁾	√	√	√
- Auto IMT	√	√	√	√

1) The name of the feature is changed to MultiVison.

2) The name of the feature is changed to ClearVision.

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 UGEO PT60A 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, UGEO PT60A, 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 UGEO PT60A to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

END of 510(K) Summary