December 18, 2018

Samsung Medison Co., Ltd.
Ji Yea Lee
Regulatory Affairs Specialist
3366, Hanseo-ro, Nam-myeon,
Hongcheon-gun, Gangwon-do 25108
REPUBLIC OF KOREA

Re: K182595
Trade/Device Name: HERA W10 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: November 23, 2018
Received: November 26, 2018

Dear Ji Yea Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182595

Device Name
HERA W10 Diagnostic Ultrasound System

Indications for Use *(Describe)*
The ultrasound diagnostic system and probes are designed to obtain ultrasound images and analyze body fluids.
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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: HERA W10 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)*	N	N	N		N	Note 1	Notes 2, 3, 4, 7, 8, 9, 11, 14
	Abdominal *(See Note 10)*	N	N	N	N	N	Note 1	Notes 2, 4, 5, 6, 7, 8, 9, 11, 12, 14
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N	N	N	Note 1	Notes 2, 7, 8, 9, 11
	Small Organ *(See Note 5)*	N	N	N		N	Note 1	Note 2, 5, 6, 7, 8, 9, 11, 12, 14
	Neonatal Cephalic	N	N	N		N	Note 1	Notes 8, 9, 11
	Adult Cephalic	N	N	N	N	N	Note 1	Notes 7
	Trans-rectal	N	N	N		N	Note 1	Notes 2, 7, 8, 9, 11, 12
	Trans-vaginal	N	N	N		N	Note 1	Notes 2, 7, 8, 9, 11, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 8, 9, 11, 12, 14
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 8, 9, 11, 12, 14
	Intra-luminal							
	Other (*See Note 13*)	N	N	N		N	Note 1	Notes 2, 7, 8, 9, 12
Cardiac	Cardiac Adult	N	N	N	N	N	Note 1	Notes 4, 7
	Cardiac Pediatric	N	N	N	N	N	Note 1	Notes 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N	N	N	Note 1	Note 2, 5, 6, 7, 8, 9, 11, 14
	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: 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

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 HERA W10
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, 14
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Small Organ *(See Note 5)*	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 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, 12, 14
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11, 12, 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 K173204, K173513; 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

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 HERA W10
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	N	N	N		N	Note 1	Note 2, 5, 6, 7, 8, 9, 11
	Small Organ *(See Note 5)*	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 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, 11,12
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9, 11,12
	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 K173204, K173513; 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

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 HERA W10
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 2,5,6,7,8,9,11,12,14
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2,5,6,7,8,9,11,12,14
	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 K173204, K173513; 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

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 HERA W10
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
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2,6,7,8,9,11,14
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Notes 2,6,7,8,9,11,14
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (*See Note 13)*	P	P	P		P	Note 1	Notes 2,6,7,8,9,11,14
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Notes 2,6,7,8,9,11,14
	Other (spec.)							

N= new indication; P= previously cleared by FDA K173204, K173513; 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

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

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: CA2-9A for use with HERA W10
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
	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 K173513; E= added under Appendix 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

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: CA3-10A for use with HERA W10
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N= new indication; P= previously cleared by FDA K173204, K173513; E= added under Appendix 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

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 HERA W10
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 7, 8, 9, 11
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 7, 8, 9, 11
	Small Organ *(See Note 5)*							
	Neonatal Cephalic	P	P	P		P	Note 1	Notes 7, 8, 9, 11
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (*See Note 13)*							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Notes 8, 9, 11
	Other (spec.)							

N= new indication; P= previously cleared by FDA K173204, K173513; 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

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 HERA W10
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, 14
	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, 14
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K173204, K173513; 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

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

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: EA2-11B for use with HERA W10
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, 14
	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, 14
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K173204, K173513; 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

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: VR5-9 for use with HERA W10
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 K173513; 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

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

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: PA4-12B for use with HERA W10
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetrics *(See Note 3)*							
	Abdominal *(See Note 10)*	P	P	P	P	P	Note 1	Note 7
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	Note 1	Note 7
	Small Organ *(See Note 5)*							
	Neonatal Cephalic	P	P	P	P	P	Note 1	Note 7
	Adult Cephalic							
	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 K173204, K173513; 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

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

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: PA3-8B for use with HERA W10
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N= new indication; P= previously cleared by FDA K173204, K173513; 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

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: PM1-6A for use with HERA W10
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 K173204, K173513; 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

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 HERA W10
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 K173204, K173513; 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

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: EV3-10B for use with HERA W10
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, 11, 12
	Abdominal *(See Note 10)*	P	P	P		P	Note 1	Note 2, 7, 8, 9, 11, 12
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8, 9, 11, 12
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8, 9, 11, 12
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (*See Note 13)*	P	P	P		P	Note 1	Note 2, 7, 8, 9, 11, 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 K173513; 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

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

6. 510(K) Summary

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

1. Date Prepared - November 23, 2018

K182595

2. Manufacturer
   SAMSUNG MEDISON CO., LTD.
   3366, Hanseo-ro, Nam-myeon,
   Hongcheon-gun, Gangwon-do 25108,
   REPUBLIC OF KOREA

3. Primary Contact Person
   Ji Yea Lee
   Regulatory Affairs Specialist
   Phone: +82.2.2194.1594
   Fax: +82. 31.8017.9573
   Email: jiyea722.lee@samsungmedison.com

4. Proposed Device
   - Common/Usual Name: Diagnostic Ultrasound System and Accessories
   - Proprietary Name: HERA W10 Diagnostic Ultrasound System
   - Common Name: Diagnostic Ultrasound System
   - Classification Names: system, imaging, pulsed doppler, ultrasonic
   - Product Code: IYN, IYO, ITX
   - Regulation: 892.1550, 892.1560, 892.1570

5. Primary Predicate Device
   - RS85 Diagnostic Ultrasound System (K173204)

   Reference Device
   - WS80A Diagnostic Ultrasound System (K173513)
   - Voluson E10 (K172342)

6. Device Description
   The HERA W10 is general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound dasta and to display the data as B-mode, M-mode, Pulsed wave (PW) Doppler, Continuous wave (CW) Doppler, Color Doppler, Tissue Doppler Imaging (TDI), Tissue Doppler Wave (TDW), Power Amplitude Doppler, Pulse Inversion Harmonic Imaging (S-Harmonic), Directional Power Doppler (S-Flow), Color M-Mode, 3D Imaging Mode, 4D Imaging Mode, Elastoscan+ Mode, Tissue Harmonic Imaging, MV-Flow Mode or as a combination of these modes.
   The HERA W10 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 HERA W10 has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

7. Intended Uses
   The ultrasound diagnostic system and probes are designed to obtain ultrasound images and analyze body fluids.
   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.

8. Technology
   The HERA W10 employs the same fundamental scientific technology as its predicate device(s).
9. Determination of Substantial Equivalence

The proposed HERA W10 is substantially equivalent to the predicate devices with regards to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The proposed HERA W10 and predicate RS85 system have the same clinical intended use.
- The proposed HERA W10 and predicate RS85 system have the same imaging modes, and mode of operation.
- The proposed HERA W10 system transducers are cleared in the predicate RS85 and WS80A.
- The system indications for use are equivalent to the predicate devices.
- The system are manufactured with materials with have been evaluated and found to be safe for the intended use of the device.
- The systems have acoustic power levels which are below the applicable FDA limits.
- The proposed HERA W10 and predicates RS85 and WS80A Systems have similar capacity in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The HERA W10 and predicate systems have been designed in compliance with approved electrical and physical safety standards.
- The proposed HERA W10 system adds an improved version of cleared software feature MPI and change name to MPI+.
- The proposed HERA W10 system adds a transducer recognition tool called QuickPrep.
- The proposed HERA W10 system adds a simple image transferring software feature called SonoSync which is not intended for diagnosis.
- The proposed HERA W10 system adds three transducers CV1-8A, EV3-10B, LA4-18B supporting the cleared software feature HQ Vision and adds a supporting preset OB/GYN.
- The proposed HERA W10 system adds two transducers CV1-8A, CA1-7A supporting the cleared software feature MV-Flow and adds a supporting preset OB.
- The proposed HERA W10 system adds two new features LumiFlow, and ShadowHDR.
- The proposed HERA W10 system adds pediatric application to cleared L3-12A and LA2-9A due to Pediatric ABD and Pediatric Hip presets. The presets have already included in the L3-12A and LA2-9A of the predicate RS85 and WS80A.
- The proposed HERA W10 system adds Neonatal Cephalic application to cleared CA3-10A due to Neonatal preset. The preset has already included in the CA3-10A of the predicate RS85.

10. Summary of Non-Clinical Test

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety, and has been found to conform with applicable medical device safety standards. The HERA W10 and its applications comply with voluntary standards.

Reference No.	Title
IEC 60601-1	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010 /(R)2012 Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance.
IEC 60601-1-2	IEC60601-1-2: 2014(4th Edition), Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - EMC
IEC 60601-2-37	IEC60601-2-37:2007 + A1:2015, Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
ISO10993-1	ISO 10993-1, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.
ISO14971	ISO 14971:2007, Medical devices - Application of risk management to medical devices
NEMA UD 2-2004	NEMA UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3
NEMA UD 3-2004	NEMA UD 3-2004 (R2009) Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 2

11. Summary of Clinical Tests
    The subject of this premarket submission, HERA W10, did not require clinical studies to support substantial equivalence.

12. 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 HERA W10 to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

END of 510(K) Summary