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

May 22, 2019

Re: K190444
Trade/Device Name: HERA I10 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: February 21, 2018
Received: February 25, 2019

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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*

K190444

Device Name
HERA I10 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 I10 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 I10
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 K182595; 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 I10
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 K182595; 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 I10
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 K182595; 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 I10
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 K182595; 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 I10
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 K182595; 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 I10
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 K182595; 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 I10
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 K182595; 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 I10
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 K182595; 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 I10
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 K182595; 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 I10
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 I10
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 K182595; 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 I10
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 K182595; 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 I10
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 K182595; 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 I10
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 K182595; 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 I10
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 K182595; 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

K190444

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

1. Date Prepared - February 21, 2019

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

3. Primary Contact Person
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4. Proposed Device (K190444)
- Common/Usual Name: Diagnostic Ultrasound System and Accessories
- Proprietary Name: HERA I10 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. Predicate Device
- HERA W10 D iagnostic Ultrasound System (K182595)

6. Device Description
The HERA I10 is 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, 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 I10 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 I10 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 I10 employs the same fundamental scientific technology as its predicate device.

9. Determination of Substantial Equivalence
The proposed HERA I10 is substantially equivalent to the predicate devices with regards to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

Feature	HERA I10 (Under Review)	HERA W10 (K182595)
Manufacturer	Samsung Medison, Co.,LTD	Samsung Medison, Co.,LTD
Intended Use	The HERA I10 Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.	The HERA W10 Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.
Clinical Application	- Fetal/Obstetrics - Abdominal - Gynecology - Pediatric - Small Organ - Neonatal Cephalic - Adult Cephalic - Trans-rectal - Trans-vaginal - Muscular-Skeletal (Conventional, Superficial) - Urology - Cardiac Adult - Cardiac Pediatric - Peripheral vessel	- Fetal/Obstetrics - Abdominal - Gynecology - Pediatric - Small Organ - Neonatal Cephalic - Adult Cephalic - Trans-rectal - Trans-vaginal - Muscular-Skeletal (Conventional, Superficial) - Urology - Cardiac Adult - Cardiac Pediatric - Peripheral vessel
Scanhead Types	- Linear Array - Curved Linear Array - Endocavity - Phased Array	- Linear Array - Curved Linear Array - Endocavity - Phased Array
Scanhead Frequency	1.0 ~ 20.0 MHz	1.0 ~ 20.0 MHz
Acoustic Output Display & FDA Limits	- Display Feature for Higher Output– Track3 - MI Output Display TI Output Display	- Display Feature for Higher Output– Track3 - MI Output Display TI Output Display
Modes of Operation	- B-mode - M-mode - Pulsed wave (PW) Doppler - Continuous wave (CW) Doppler - Color Doppler - Tissue Doppler Imaging (TDI)	- B-mode - M-mode - Pulsed wave (PW) Doppler - Continuous wave (CW) Doppler - Color Doppler - Tissue Doppler Imaging (TDI)

Feature	HERA I10 (Under Review)	HERA W10 (K182595)
	- 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^{+TM} Mode - MV-Flow Mode - Tissue Harmonic Imaging - Combination Modes	- 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^{+TM} Mode - MV-Flow Mode - Tissue Harmonic Imaging - Combination Modes
#Transmit Channels	192	192
#Receive Channels	192	192
System Characteristics:	- Beamformer 192 - Mobile cart - LCD Monitor (LED Backlight unit) - 256 gray shades on monitor - 100-240VAC, 1100VA, 50/60Hz	- Beamformer 192 - Mobile cart - LCD Monitor (LED Backlight unit) - 256 gray shades on monitor - 100-240VAC, 1100VA, 50/60Hz
Product Safety Certification	- IEC 60601-1 - IEC 60601-1-2-37 - CSA C22.2 No.601.1	- IEC 60601-1 - IEC 60601-1-2-37 - CSA C22.2 No.601.1
EMC Compliance	IEC 60601-1-2	IEC 60601-1-2
Acoustic Output Display Standard	Track 3	Track 3
Biocompatibility Compliance	ISO10993-1	ISO10993-1
Functionality	- Q Scan - ClearVision - MultiVision - Panoramic - Needle Mate - Auto IMT+ - Strain+ - Elastoscan - E-Thyroid - E-Breast - E-Strain - S-Detect for Breast - S-Detect for Thyroid - ADVR - 3D Imaging - (Volume Data Acquisition)	- Q Scan - ClearVision - MultiVision - Panoramic - Needle Mate - Auto IMT+ - Strain+ - Elastoscan - E-Thyroid - E-Breast - E-Strain - S-Detect for Breast - S-Detect for Thyroid - ADVR - 3D Imaging - (Volume Data Acquisition)

Feature	HERA I10 (Under Review)	HERA W10 (K182595)
	- 3D Imaging presentation - 3D Cine/4D Cine - 3D Rendering MPR - 3D XI MSV/Oblique View - Volume CT - 3D MagiCut - Volume Calculation - (VOCAL, XI VOCAL) - XI STIC - HDVI - Realistic Vue - CEUS+ - HQ Vision - MV-Flow - Crystal Vue - CrystalVue Flow - 5D CNS+ - 5D Follicle - 5D Heart Color - 5D Limb Vol - 5D LB - 5D NT - 2D NT - IOTA-ADNEX - BiometryAssit - E-Cervix - Lumi-Flow - ShadowHDR - MPI+	- 3D Imaging presentation - 3D Cine/4D Cine - 3D Rendering MPR - 3D XI MSV/Oblique View - Volume CT - 3D MagiCut - Volume Calculation - (VOCAL, XI VOCAL) - XI STIC - HDVI - Realistic Vue - CEUS+ - HQ Vision - MV-Flow - Crystal Vue - CrystalVue Flow - 5D CNS+ - 5D Follicle - 5D Heart Color - 5D Limb Vol - 5D LB - 5D NT - 2D NT - IOTA-ADNEX - BiometryAssit - E-Cervix - Lumi-Flow - ShadowHDR - MPI+
Transducers	- L3-12A - LA2-9A - LA4-18B - CA1-7A - CA2-9A - CA3-10A - CF4-9 - E3-12A - EA2-11B - VR5-9 - PA4-12B - PA3-8B - PM1-6A - CV1-8A - EV3-10B	- L3-12A - LA2-9A - LA4-18B - CA1-7A - CA2-9A - CA3-10A - CF4-9 - E3-12A - EA2-11B - VR5-9 - PA4-12B - PA3-8B - PM1-6A - CV1-8A - EV3-10B
Biopsy Guides	- BP-KIT-029 - BP-KIT-041 - BP-KIT-043	- BP-KIT-029 - BP-KIT-041 - BP-KIT-043

Feature	HERA I10 (Under Review)	HERA W10 (K182595)
	- BP-KIT-054 - BP-KIT-057 - BP-KIT-058 - BP-KIT-059 - BP-KIT-060 - BP-KIT-065 - BP-KIT-066 - BP-KIT-067 - BP-KIT-069 - BP-KIT-071 - BP-KIT-076 - BP-KIT-077 - BP-KIT-078	- BP-KIT-054 - BP-KIT-057 - BP-KIT-058 - BP-KIT-059 - BP-KIT-060 - BP-KIT-065 - BP-KIT-066 - BP-KIT-067 - BP-KIT-069 - BP-KIT-071 - BP-KIT-076 - BP-KIT-077 - BP-KIT-078
Digital Storage/Transfer Station	- Digital Storage/Transfer Station - Foot Switch - ECG - Gel Warmer - WLAN Adapter	- Digital Storage/Transfer Station - Foot Switch - ECG - Gel Warmer - WLAN Adapter

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 I10 and its applications comply with voluntary standards.

Test	Standards and FDA Guidance
Risk Management	ISO 14971 Second edition 2007 Medical devices - Application of risk management to medical devices
Electrical Safety	The HERA I10 Ultrasound System with defibrillation-proof ECG electrode was evaluated per the following standards. IEC 60601-1:2005+AMD1:2012 Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance.
Electromagnetic Compatibility	IEC60601-1-2: 2014(4th Edition) Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
Biocompatibility	ISO 10993-1 Fourth edition 2009-10-15 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
Reprocessing Medical Devices	FDA Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling issued on March 17, 2015, revised June 9, 2017.
Software/Firmware-driven Functionality	All migrated software functionality was evaluated using the same test criteria as the predicate for all applicable imaging modes to ensure that migration into a new system design did not compromise image quality with respect to the intended use of each feature.

	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued on May 11, 2005
Ultrasound Safety	Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers issued September 9, 2008
	IEC60601-2-37:2007 + A1:2015, Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
	NEMA UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3
	NEMA UD 3-2004 (R2009) Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 2

11. Summary of Clinical Tests
    The subject of this premarket submission, HERA I10, did not require clinical studies to support substantial equivalence.

12. Conclusion
    SAMSUNG MEDISON CO., LTD. considers the HERA I10 to be as safe, as effective, and performance is substantially equivalent to the predicate device.

END of 510(K) Summary