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

December 10, 2019

Re: K192319
Trade/Device Name: HERA W9 Diagnostic Ultrasound System, 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: October 31, 2019
Received: November 4, 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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)*

K192319

Device Name
HERA W9 Diagnostic Ultrasound System
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.

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

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6. 510(K) Summary

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

1. Date Prepared – August 23, 2019

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 W9, 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

5. Predicate Device
   - HERA W10 Diagnostic Ultrasound System (K182595)
     · 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 number : 892.1550
     · Class : Class II

6. Device Description
   The HERA W9/ HERA W10 are 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 W9/HERA W10 also give 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 W9/HERA W10 have real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

   As compared with predicate device(HERA W10, K182595), the subject device has added new three transducers(EV2-10A, EA2-11AV and EA2-11AR) and nine biopsy kits (BP-KIT-079, BP-KIT-080, BP-KIT-081, BP-KIT-082, BP-KIT-085, BP-KIT-086, BP-KIT-088, BP-KIT-089 and BP-KIT-090) and the product name of HERA W9. There are no change and new software features from the predicate device. The HERA ultrasound system is supported by software and the software is not modified for the subject system.

Also, the differences between HERA W10 and HERA W9 in the subject device are as below.

Difference		HERA W10	HERA W9
Software	QuickPrep.	Supported	Not Supported
Hardware	Internal DVD	Included	Not Included
	Caster size	6"	5"
	Active array probe port	4 port	3 port (default), 4 port(option)
	Main monitor	default: 21.5", option: 23", 23.8"	default: 21.5", option: 23.8"

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 W9/ HERA W10 employ the same fundamental scientific technology as its predicate device.

9. Determination of Substantial Equivalence

The proposed HERA W9/ HERA W10 are substantially equivalent to the predicate device with regards to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

As compared with predicate device(HERA W10, K182595), the subject device has added new three transducers(EV2-10A, EA2-11AV and EA2-11AR) and nine biopsy kits (BP-KIT-079, BP-KIT-080, BP-KIT-081, BP-KIT-082, BP-KIT-085, BP-KIT-086, BP-KIT-088, BP-KIT-089 and BP-KIT-090) and the product name of HERA W9.

Feature	HERA W9/ HERA W10 (Under Review)	HERA W10 (K182595)
Manufacturer	SAMSUNG MEDISON CO.,LTD	SAMSUNG MEDISON CO.,LTD
Intended Use	The HERA W9/ HERA W10 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,	- Fetal/Obstetrics - Abdominal - Gynecology - Pediatric - Small Organ - Neonatal Cephalic - Adult Cephalic - Trans-rectal - Trans-vaginal - Muscular-Skeletal (Conventional,

Feature	HERA W9/ HERA W10 (Under Review)	HERA W10 (K182595)
	Superficial) - Urology - Cardiac Adult - Cardiac Pediatric - Peripheral vessel	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) - 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	- 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^{+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	- IEC 60601-1 - IEC 60601-1-2-37

Feature	HERA W9/ HERA W10 (Under Review)	HERA W10 (K182595)
	- CSA C22.2 No.601.1	- 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 - NeedleMate+ - AutoIMT+ - Elastoscan+ - E-Thyroid - E-Breast - E-Strain - S-Detect for Breast - S-Detect for Thyroid - ADVR - 3D Imaging - (Volume Data Acquisition) - 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 - RealisticVue - CEUS+ - HQ-Vision - MV-Flow - CrystalVue - CrystalVue Flow - 5D CNS+ - 5D Follicle - 5D Heart Color - 5D Limb Vol - 5D LB - 5D NT - 2D NT - IOTA-ADNEX	- Q Scan - ClearVision - MultiVision - Panoramic - NeedleMate+ - AutoIMT+ - Elastoscan+ - E-Thyroid - E-Breast - E-Strain - S-Detect for Breast - S-Detect for Thyroid - ADVR - 3D Imaging - (Volume Data Acquisition) - 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 - RealisticVue - CEUS+ - HQ-Vision - MV-Flow - CrystalVue - CrystalVue Flow - 5D CNS+ - 5D Follicle - 5D Heart Color - 5D Limb Vol - 5D LB - 5D NT - 2D NT - IOTA-ADNEX

Feature	HERA W9/ HERA W10 (Under Review)	HERA W10 (K182595)
	- BiometryAssit - E-Cervix - LumiFlow - ShadowHDR - MPI+	- BiometryAssit - E-Cervix - LumiFlow - 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 - EV2-10A - EA2-11AV - EA2-11AR	- 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-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-079 - BP-KIT-080 - BP-KIT-081 - BP-KIT-082 - BP-KIT-085 - BP-KIT-086 - BP-KIT-088 - BP-KIT-089 - BP-KIT-090	- BP-KIT-029 - BP-KIT-041 - BP-KIT-043 - 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

Feature	HERA W9/ HERA W10 (Under Review)	HERA W10 (K182595)
Etc.	- Digital Storage/Transfer Station	- Digital Storage/Transfer Station
Accessories	- Foot Switch - ECG - Gel Warmer - WLAN Adapter	- 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 W9/ 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

11. Summary of Clinical Tests

The subject of this premarket submission, HERA W9/ 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 W9/ HERA W10 to be as safe, as effective, and performance is substantially equivalent to the predicate device.

END of 510(K) Summary