



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

September 9, 2021

Re: K211824

Trade/Device Name: HERA W9, 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: June 11, 2021
Received: June 14, 2021

Dear Scully Kim:

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

Indications for Use

510(k) Number (if known)

K211824

Device Name

HERA W9, HERA W10 Diagnostic Ultrasound System

Indications for Use (Describe)

The diagnostic ultrasound system and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

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

It is intended for use by, or by the order of, and under the supervision of, an appropriately trained healthcare professional who is qualified for direct use of medical devices. It can be used in hospitals, private practices, clinics and similar care environment for clinical diagnosis of patients.

Modes of Operation: 2D mode, Color Doppler mode, Power Doppler (PD) mode, M mode, Pulsed Wave (PW) Doppler mode, Continuous Wave (CW) Doppler mode, Tissue Doppler Imaging (TDI) mode, Tissue Doppler Wave (TDW) mode, ElastoScan+™ Mode, Combined modes, Multi-Image modes (Dual, Quad), 3D/4D modes.

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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510(k) Summary

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

1. Date Prepared – June 11, 2021
2. Manufacturer
SAMSUNG MEDISON CO., LTD.
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Hongcheon-gun, Gangwon-do 25108,
REPUBLIC OF KOREA
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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, 892.1560, 892.1570
5. Predicate Device
 - HERA W9, HERA W10 Diagnostic Ultrasound System (K192319) – Primary Predicate
 - RS85 Diagnostic Ultrasound System (K192903) – Secondary Predicate
 - Voluson SWIFT, Voluson SWIFT+ (K201828) – Reference

6. Device Description

The HERA W9/ HERA W10 are 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 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.

7. Indications for Use

The diagnostic ultrasound system and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

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

It is intended for use by, or by the order of, and under the supervision of, an appropriately trained healthcare professional who is qualified for direct use of medical devices. It can be used in hospitals, private practices, clinics and similar care environment for clinical diagnosis of patients.

Modes of Operation: 2D mode, Color Doppler mode, Power Doppler (PD) mode, M mode, Pulsed Wave (PW) Doppler mode, Continuous Wave (CW) Doppler mode, Tissue Doppler Imaging (TDI) mode, Tissue Doppler Wave (TDW) mode, ElastoScan+™ Mode, Combined modes, Multi-Image modes (Dual, Quad), 3D/4D modes.

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 the primary predicate device (HERA W9 / HERA W10, K192319), the subject device has changes: addition of new software functions (HeartAssist, ViewAssist, Slice A), addition of migrated transducers (LA2-14A, PA1-5A), and improvement of cleared software functions (Changed an algorithm of BiometryAssist to AI version).

Feature	HERA W9 /HERA W10 (Under Review)	HERA W9/HERA W10 (K192319) Primary Predicate	RS85 (K192903) Secondary Predicate	Voluson SWIFT (K201828) Reference
Manufacturer	SAMSUNG MEDISON CO.,LTD	SAMSUNG MEDISON CO.,LTD	SAMSUNG MEDISON CO.,LTD	GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC
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 W9/ HERA W10 Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.	The RS85 Ultrasound Diagnostic System and probes are designed to obtain ultrasound images and analyze body fluids.	The Voluson SWIFT, Voluson SWIFT+ is a general-purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid.
Functionality	- Q Scan - ClearVision - MultiVision - Panoramic - NeedleMate+ - AutoIMT+ - Elastoscans+	- Q Scan - ClearVision - MultiVision - Panoramic - NeedleMate+ - AutoIMT+ - Elastoscans+	- Q Scan - ClearVision - MultiVision - Panoramic - NeedleMate+ - AutoIMT+ - Elastoscans+	

Feature	HERA W9 /HERA W10 (Under Review)	HERA W9/HERA W10 (K192319) Primary Predicate	RS85 (K192903) Secondary Predicate	Voluson SWIFT (K201828) Reference
	<ul style="list-style-type: none"> - 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) - 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 - BiometryAssist - E-Cervix - LumiFlow - ShadowHDR - MPI+* - Slice A - HeartAssist * - ViewAssist 	<ul style="list-style-type: none"> - 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 - 3DRendering MPR - 3D XI - MSV/Oblique View - Volume CT - 3D MagiCut - Volume Calculation (VOCAL, XI) - 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 - BiometryAssist - E-Cervix - LumiFlow - ShadowHDR - MPI+* 	<ul style="list-style-type: none"> - 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) - XI STIC - HDVI - RealisticVue - CEUS+ - HQ-Vision - MV-Flow - CrystalVue - CrystalVue Flow - - - 2D NT - IOTA-ADNEX - BiometryAssist - - LumiFlow - ShadowHDR 	<ul style="list-style-type: none"> - VCIA - SonoLystIR - SonoLystIR
Transducers	<ul style="list-style-type: none"> - L3-12A - LA2-9A - LA4-18B - CA1-7A - CA2-9A - CA3-10A - CF4-9 - E3-12A 	<ul style="list-style-type: none"> - L3-12A - LA2-9A - LA4-18B - CA1-7A - CA2-9A - CA3-10A - CF4-9 - E3-12A 	<ul style="list-style-type: none"> - L3-12A - LA2-9A - LA4-18B - - - CA3-10A - CF4-9 - E3-12A 	Unknown

Feature	HERA W9 /HERA W10 (Under Review)	HERA W9/HERA W10 (K192319) Primary Predicate	RS85 (K192903) Secondary Predicate	Voluson SWIFT (K201828) Reference
	<ul style="list-style-type: none"> - EA2-11B - VR5-9 - PA4-12B - PA3-8B - PM1-6A - CV1-8A - EV3-10B - EV2-10A - EA2-11AV - EA2-11AR - LA2-14A - PA1-5A 	<ul style="list-style-type: none"> - EA2-11B - VR5-9 - PA4-12B - PA3-8B - PM1-6A - CV1-8A - EV3-10B - EV2-10A - EA2-11AV - EA2-11AR 	<ul style="list-style-type: none"> - EA2-11B - PA4-12B - PA3-8B - PM1-6A - CV1-8A - EV3-10B - EV2-10A - EA2-11AV - EA2-11AR - LA2-14A - PA1-5A 	

* Note : SW feature is supported in HERA W10 only.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The proposed HERA W9/ HERA W10 and predicate HERA W9/ HERA W10 (K192319) have the same clinical intended use.
- The proposed HERA W9/ HERA W10 and predicate HERA W9/ HERA W10 (K192319) have the same imaging modes and modes of operation.
- The proposed HERA W9/ HERA W10 added two transducers (LA2-14A, PA1-5A) that previously cleared in predicate RS85 (K192903) system.
- The proposed HERA W9/ HERA W10 added new SW features AI based HeartAssist(HERA W10 only), and ViewAssist. It provides similar functionality to SonoLystIR in predicate Voluson SWIFT (K201828).
HeartAssist is a deep learning based function that provides classification of ultrasound image into measurement views required for fetal heart scanning and provides measurement results. The feature recognizes views and proposes caliper placements and corresponding measurements allowing users to save time and increase examination efficiency through reducing key-strokes and proposing measurements which can be edited by the user.
ViewAssist is a deep learning based function that provides classification of ultrasound image into key scanning views and provides annotations. The feature recognizes views and proposes corresponding anatomy annotations and initiates measurements allowing users to save time and increase examination efficiency through reducing key-strokes and proposing annotations which can be edited by the user.
- The proposed HERA W9/ HERA W10 added new SW feature Slice A. It provides similar functionality to VCIA in predicate Voluson SWIFT (K201828).
- The proposed HERA W9/ HERA W10 implemented an AI version of BiometryAssist which improved from previously cleared function BiometryAssist in predicate HERA W9/ HERA W10 (K192319).
BiometryAssist, a feature based on deep learning technology, is an automatic technology for biometric measurement which can be edited by the user. It enables users to measure the fetal growth parameters with one click while maintaining exam consistency.
- The proposed HERA W9/ HERA W10 and predicate HERA W9/ HERA W10 (K192319) have same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.

- The proposed HERA W9/ HERA W10 and predicate HERA W9/ HERA W10 (K192319) have been designed in compliance with approved electrical and physical safety standards.
- The systems are manufactured with materials which 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 differences between HERA W9 and HERA W10 in the subject device are as below.

Difference		HERA W9	HERA W10
Software	CrystalVue Flow	Not Supported	Supported
	MPI+	Not Supported	Supported
	HeartAssist	Not Supported	Supported
Hardware	Internal DVD	Not Included	Included
	Caster size	5"	6"
	Active array probe port	3 port (default), 4 port(option)	4 port
	Main monitor	21.5"/ 23.8"	21.5"/ 23" / 23.8"

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

In addition to conformance to the above harmonized standards, HERA W9 / HERA W10 quality assurance activities include the following:

- Risk analysis and mitigation
- Software verification and validation testing
- System verification and validation testing
- Image quality tests

Below a summary has been provided from testing results that demonstrated that the HERA W9 / HERA W10 systems meet all the image quality criteria.

- Two transducers LA2-14A, PA1-5A are migrated from the predicate device RS85 (K192903) to this submission. The image performance tests were completed to confirm all requirements were

met.

- Performance testing was successfully completed for the new software functions (artificial intelligence based features HeartAssist, ViewAssist and Slice A) to show passing results for pre-defined testing criteria.
- The improved feature of BiometryAssist based on artificial intelligence was validated through performance testing to confirm the measurement accuracy requirements were met.

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 provide performance substantially equivalent to the primary predicate device(K192319).

END of 510(k) Summary