April 21, 2023

SAMSUNG MEDISON CO., LTD.
% So-Yeon Jang
Regulatory Affairs Specialist
3366, Hanseo-ro, Nam-myeon
Hongcheon-gun, Gangwon-do 25108
SOUTH KOREA

Re: K230084
Trade/Device Name: HERA W10 Diagnostic Ultrasound System; HERA W9 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: March 8, 2023
Received: March 14, 2023

Dear So-Yeon Jang:

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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230084

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 – January 05, 2023

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

3. Primary Contact Person
   So-Yeon Jang
   Regulatory Affairs Specialist
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4. Secondary Contact Person Ninad Gujar
   Vice President
   Phone: +1.978.564.8632
   Fax: +1.978.564.8677
   Email: ngujar@neurologica.com

5. 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

6. Predicate Device
   - HERA W9, HERA W10 Diagnostic Ultrasound System (K220043) – Primary Predicate

7. 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.

8. 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.

9. Technology

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

10. 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.

Feature	HERA W9 /HERA W10 (Under Review)	HERA W9/HERA W10 (K220043) Primary Predicate
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 W9/ HERA W10 Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.
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	- 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 - 3DRendering MPR - 3D XI MSV/Oblique View - Volume CT

Feature	HERA W9 /HERA W10 (Under Review)	HERA W9/HERA W10 (K220043) Primary Predicate
	- 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 - BiometryAssist - E-Cervix - LumiFlow - ShadowHDR - MPI+* - Slice A - HeartAssist * - ViewAssist	- 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 - BiometryAssist - E-Cervix - LumiFlow - ShadowHDR - MPI+* - Slice A - HeartAssist * - ViewAssist
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 - LA2-14A - PA1-5A - EV2-12 (NEW)	- 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 - LA2-14A - PA1-5A

* Note : This 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 (K220043) have the same clinical intended use, imaging modes and modes of operation.
- The proposed HERA W9/ HERA W10 have expanded the measurement parts of

BiometryAssist (AI version) in the previously cleared HERA W9/ HERA W10 (K220043).

- The proposed HERA W9/ HERA W10 have expanded the view recognition and the annotation of ViewAssist (AI version) in the previously cleared HERA W9/ HERA W10 (K220043)
- The proposed HERA W9/ HERA W10 have included a new transducer EV2-12. Biocompatibility has been evaluated and image performance tests have been conducted.
- The proposed HERA W9/ HERA W10 have added a 27 inch OLED monitor to the main monitors.
- The proposed HERA W9/ HERA W10 and predicate HERA W9/ HERA W10(K220043) 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(K220043) have been designed in compliance with approved electrical and physical safety standards.
- The systems are manufactured with materials that 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 limit defined by FDA.

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" / 27"	21.5"/ 23" / 23.8" / 27"

11. 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 the following FDA-recognized 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: 2020(4.1 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 10993-1:2018, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.
ISO14971	ISO 14971:2019, 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

[The Summary of Testing for BiometryAssist]

▣ Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance.

We tested on two areas: Segmentation and Size measurement.

☐ Segmentation test

- ○ A deep learning based segmentation algorithm was validated using 320 fetal biometry images collected at two hospitals (South Korea and United States).
- ○ The average dice-score is 0.91 (threshold 0.8)

☐ Size measurement test

- ○ We use same datasets of segmentation test.
- ○ The error rate of circumference measured value is 8% or less.
- ○ The error rate of distance measured value is 4% or less.
- ○ The error rate of NT measured value is 1mm or less.

▣ Demographic distribution:

- ☐ Gender: Female
- ☐ Age: Reproductive age, specific age not collected
- ☐ Ethnicity/Country: Not Available / United States and South Korea

▣ Information about clinical subgroups and confounders present in the dataset:

- ☐ We divided the fetal ultrasound images, depending on the ISUOG and AIUM guidelines, into 8 views.

▣ Information about equipment and protocols used to collect images

- ☐ We acquired the data set with SAMSUNG MEDISON's ultrasound systems (W10, W9) in order to secure diversity of the data set: Mix of data from retrospective data collection and prospective data collection in clinical practice

▣ Information about how the reference standard was derived from the dataset (i.e. the "Truthing" process):

- ☐ All acquired images for training, tuning and validation were first classified into the correct views by three participating experts. Afterwards, corresponding anatomy areas

were manually drawn for each of the image.

☐ The participating experts were composed of an obstetrician with more than 20 years of experience and two sonographers with more than 10 years of experience, all in fetal cardiology. The entire process was supervised by another obstetrician with more than 25 years of experience.

▣ Description of how the independence of test data from training data was ensured:

☐ Data used for training, tuning and validation purpose are completely separated from the ones during training process and there is no overlap between the three.

[The Summary of Testing for ViewAssist]

▣ Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance.

We tested on two areas: view recognition and anatomy annotation(segmentation).

☐ View recognition test

- A deep learning based view recognition algorithm was validated using 1,320 fetal heart and fetal biometry images collected at two hospitals (South Korea and United States).
- The average recognition accuracy is 94.70% (threshold 89%)

☐ Anatomy annotation(segmentation) test

- A deep learning based segmentation algorithm was validated using 1,320 fetal heart and fetal biometry images collected at two hospitals.
- The average dice-score is 0.875 (threshold 0.8)

▣ Demographic distribution:

☐ Gender: Female

☐ Age: Reproductive age, specific age not collected

☐ Ethnicity/Country: Not Available / United States and South Korea

▣ Information about clinical subgroups and confounders present in the dataset:

☐ We divided the fetal ultrasound images, depending on the ISUOG and AIUM guidelines, into 33 views.

▣ Information about equipment and protocols used to collect images

☐ We acquired the data set with SAMSUNG MEDISON's ultrasound systems (W10, W9) in order to secure diversity of the data set: Mix of data from retrospective data collection and prospective data collection in clinical practice

▣ Information about how the reference standard was derived from the dataset (i.e. the "Truthing" process):

☐ All acquired images for training, tuning and validation were first classified into the

correct views by three participating experts. Afterwards, corresponding anatomy areas were manually drawn for each of the image.

☐ The participating experts were composed of an obstetrician with more than 20 years of experience and two sonographers with more than 10 years of experience, all in fetal cardiology. The entire process was supervised by another obstetrician with more than 25 years of experience.

▣ Description of how the independence of test data from training data was ensured:

☐ Data used for training, tuning and validation purpose are completely separated from the ones during training process and there is no overlap between the three.

In addition to conformance to the harmonized standards above, 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

12. Summary of Clinical Tests

The subject of this premarket submission, HERA W9/ HERA W10, did not require clinical studies to demonstrate the substantial equivalence.

13. 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 subject device to be as safe, as effective, and performance is substantially equivalent to the primary predicate device(K220043) that is currently marketed for the same intended use.

END of 510(k) Summary