



November 27, 2024

Samsung Medison Co., Ltd.  
So-Yeon Jang  
Regulatory Affairs Specialist  
3366, Hanseo-ro, Nam-myeon  
Hongcheon-gun, Gangwon 25108  
SOUTH KOREA

Re: K242444

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, QIH  
Dated: August 16, 2024  
Received: October 31, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto: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

Mammography and Ultrasound Team

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

## Indications for Use

Submission Number (if known)

K242444

Device Name

HERA W10 Diagnostic Ultrasound System; HERA W9 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.**

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**K242444****510(k) Summary**

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

1. Date Prepared – Aug. 16<sup>th</sup>, 2024.
2. Manufacturer  
SAMSUNG MEDISON CO., LTD.  
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Gangwon-do, 25108, REPUBLIC OF KOREA
3. Primary Contact Person  
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Vice President  
Phone: +1.978.564.8632  
Fax: +1.978.564.8677  
Email: [ngujar@neurologica.com](mailto: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, QIH, LLZ
  - Regulation: 892.1550, 892.1560, 892.1570
6. Predicate Device
  - HERA W9, HERA W10 Diagnostic Ultrasound System (K230084) – Primary Predicate
  - RS85 Diagnostic Ultrasound System(K240516) – Reference
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 devices with regards to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The proposed HERA W9/ HERA W10 and predicate HERA W9/ HERA W10(K230084) have the same clinical intended use, imaging modes and modes of operation.
- The proposed HERA W9/ HERA W10 have expanded the measurement items of NB(Nasal Bone), IT(Intracranial Translucency) in the MSP(Mid-Sagittal Plane) view of BiometryAssist based on the AI technology.
- The proposed HERA W9/ HERA W10 have improved the performance of ViewAssist through algorithm change based on the AI technology.
- The proposed HERA W9/ HERA W10 have improved the performance of HeartAssist through algorithm change based on the AI technology.
- The proposed HERA W9/ HERA W10 have indicated SonoSync, a cleared function in the primary predicate HERA W9/ HERA W10(K230084), for diagnostic image viewing and review as same indications for use as RS85(K240516).
- The proposed HERA W9/ HERA W10 have updated an alternative model for touch LCD module. The result of electrical safety test is attached in eSTAR section for EMC, Wireless, Electrical, Mechanical, and Thermal Safety.
- The proposed HERA W9/ HERA W10 have updated an alternative model for OLED module for monitor part. The result of electrical safety test is attached in eSTAR section for EMC, Wireless, Electrical, Mechanical, and Thermal Safety.
- The proposed HERA W9/ HERA W10 and the primary predicate HERA W9/ HERA W10 (K230084) system have same in indication for use, modes of operation, transducer

configuration as Linear array, Convex array, Endocavity, Phased array and Static probes

- The proposed HERA W9/ HERA W10 and predicate HERA W9/ HERA W10(K230084) 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(K230084) 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                |
| Hardware   | Caster size             | 5"                                  | 6"                       |
|            | Active array probe port | 3 port (default),<br>4 port(option) | 4 port                   |
|            | Control panel moving    | Rotate                              | Swivel                   |
|            | 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    | AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) |
| IEC 60601-1-2  | IEC60601-1-2: 2020-09(4.1 Edition) , Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - EMC                                                                                  |
| IEC 60601-2-37 | IEC 60601-2-37 Edition 2.0 2007, Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment                          |
| IEC 60601-4-2  | IEC TR 60601-4-2 Edition 1.0 2016-05, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems                    |
| ISO10993-1     | AAMI / ANSI / ISO 10993-1:2018/(R)2013, 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 HeartAssist]

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

We tested on the three areas: view recognition, segmentation and size measurement.

- ☐ View recognition test

- A deep learning based view recognition algorithm was validated using 280 fetal heart images collected at two hospitals.
- The average recognition accuracy is 96.07% (threshold 89%)

- ☐ Segmentation test

- We use the same datasets of view recognition test.
- The average dice-score is 0.88 (threshold 0.8).

- ☐ Size measurement test

- We use the same datasets of segmentation test.
- The error rate of area measured value is 8% or less.
- The error rate of angle measured value is 4% or less.
- The error rate of circumference measured value is 11% or less.
- The error rate of diameter measured value is 11% or less.

- The number of individual patients, images were collected from:

- ☐ A total 69 individuals contributed to the validation dataset.

- The number of samples, if different from above, and the relationship between the two:

- ☐ Each individual contributed at least 1 static image per view location
- ☐ Validation dataset included 315 static images of 2D sequences.

- 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, according to the ISUOG and AIUM guidelines, into 7 fetal heart views.
  - ☐ BMI: Ranging from 14.88 - 49.2, distributed across underweight, standard range or overweight categories
  - ☐ Gestational age: Weeks from 11 - 38, distributed across 1st trimester, 2nd trimester or 3rd trimester categories
- ☒ Information about equipment and protocols used to collect images
  - ☐ We acquired the data set with the three of SAMSUNG MEDISON's ultrasound systems (HERA W9/ HERA W10) 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 images.
  - ☐ The participating experts were composed of obstetricians 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 among the three.

[ 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, NB and IT measured value is 1mm or less.
- The number of individual patients, images were collected from:
  - ☐ A total 33 individuals contributed to the validation dataset.
- The number of samples, if different from above, and the relationship between the two:
  - ☐ Each individual contributed at least 1 static image per view location
  - ☐ Validation dataset included 360 static images of 2D sequences.
- 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.
  - ☐ BMI: Ranging from 14.88 - 49.2, distributed across underweight, standard range or overweight categories
  - ☐ Gestational age: Weeks from 11 - 38, distributed across 1st trimester, 2nd trimester or 3rd trimester categories
- Information about equipment and protocols used to collect images
  - ☐ We acquired the data set with SAMSUNG MEDISON's ultrasound systems (HERA W9/ HERA W10) 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.

- 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 94.92% (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 0.89 (threshold 0.8)

- The number of individual patients, images were collected from:

- ☐ A total 98 individuals contributed to the validation dataset.

- The number of samples, if different from above, and the relationship between the two:

- ☐ Each individual contributed at least 1 static image per view location
- ☐ Validation dataset included 1,485 static images of 2D sequences.

- 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.
- ☐ BMI: Ranging from 14.88 - 49.2, distributed across underweight, standard range or overweight categories
- ☐ Gestational age: Weeks from 11 - 38, distributed across 1st trimester, 2nd trimester or 3rd trimester categories

- Information about equipment and protocols used to collect images

- ☐ We acquired the data set with SAMSUNG MEDISON's ultrasound systems (HERA W9/ HERA W10) 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 validation for SonoSync ]

Pre-determined criteria were utilized in validation tests to assess whether remote viewing and reviewing with SonoSync matched the performance of local ultrasound systems. Labeling materials is provided to inform users about the necessary specifications for safely and effectively conducting remote diagnostic reviews and viewing.

#### 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(K230084) that is currently marketed for the same intended use.

**END of 510(k) Summary**