



January 5, 2026

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

Re: K252018

Trade/Device Name: HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 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, LLZ, QIH

Dated: December 5, 2025

Received: December 5, 2025

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


YANNA S. KANG -S

Yanna Kang, Ph.D.
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Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252018

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Please provide the device trade name(s).

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HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System

Please provide your Indications for Use below.

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HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System and probes are designed to obtain ultrasound images and analyze body fluids.

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

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, M mode, Color Doppler mode, Pulsed Wave (PW) Doppler mode, Continuous Wave (CW) Doppler mode, Tissue Doppler Imaging (TDI) mode, Tissue Doppler Wave (TDW) mode, Power Doppler (PD) mode, ElastoScan Mode, MV-Flow Mode, Multi Image mode(Dual, Quad), Combined modes, 3D/4D mode.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

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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 30, 2025
2. Manufacturer
SAMSUNG MEDISON CO., LTD.
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Gangwon-do, Republic of Korea
3. Primary Contact Person
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5. Proposed Device
 - Common/Usual Name : Diagnostic Ultrasound System and Accessories
 - Proprietary Name : HERA Z20 Diagnostic Ultrasound System
HERA Z20e Diagnostic Ultrasound System;
HERA Z20s Diagnostic Ultrasound System;
R20 Diagnostic Ultrasound System;
HERA Z30 Diagnostic Ultrasound System;
R30 Diagnostic Ultrasound System
 - Regulation Name : Ultrasonic pulsed doppler imaging system
 - Regulatory Class : Class II
 - Product Code : IYN, IYO, ITX, LLZ, QIH
 - Regulation Number : 21 CFR 892.1550, 892.1560, 892.1570, 892.2050
6. Predicate Devices
 - HERA Z20, R20, HERA Z30, R30 Diagnostic Ultrasound System (K241971) – Primary predicate
 - V8 Diagnostic Ultrasound System; cV8 Diagnostic Ultrasound System; V7 Diagnostic Ultrasound System; cV7 Diagnostic Ultrasound System; V6 Diagnostic Ultrasound System; cV6 Diagnostic Ultrasound System (K243702) – Secondary predicate
7. Device Description
HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System;
HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30
Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System are a general purpose,

mobile, software controlled, diagnostic ultrasound system. Their function is to acquire ultrasound data and to display the data as 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, MV-Flow mode, Multi-Image mode(Dual, Quad), 3D/4D mode. HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System also give the operator the ability to measure anatomical structures and offer analysis packages that provide information that is used to make a diagnosis by competent health care professionals. HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System have a real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

8. Indication for Use

The diagnostic ultrasound system and transducers are designed to obtain ultrasound images and analyze body fluids.

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

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, MV-Flow mode, Combined modes, Multi-Image mode(Dual, Quad), 3D/4D mode.

9. Technological Comparison to Predicate Devices

HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System employ the same fundamental scientific technology as the primary predicate device HERA Z20, R20, HERA Z30, R30 Diagnostic Ultrasound System (K241971).

10. Determination of Substantial Equivalence

Comparison to Predicate: HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System are substantially equivalent to the primary predicate device with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.

- The proposed HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System and primary predicate device HERA Z20, R20, HERA Z30, R30 Diagnostic Ultrasound System (K241971) have the same clinical intended use.
- The proposed HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System have added a clinical application for ophthalmic use.
- The proposed HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System have migrated the biopsy guide BP-KIT-105 from the predicate device V8 (K243702).
- The proposed HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System and the primary predicate device HERA Z20, R20, HERA Z30, R30 Diagnostic Ultrasound System (K241971) have the same imaging modes and modes of operation.
- The proposed HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System have included new AI-ML based software features: **AbdomenAssist**, **BladderAssist**, **QualityCheck**, **PelvicAssist**. The detailed change descriptions of each feature are addressed below.
 - **AbdomenAssist**: a feature based on AI-ML technology, measures the size of the interested organ, thereby reducing user variability and simplifying workflow.
 - **BladderAssist**: a feature based on AI-ML technology, measures the size of the bladder, thereby reducing user variability and simplifying workflow
 - **QualityCheck**: a feature based on AI-ML technology to assess whether the views acquired during prenatal ultrasound examinations meet clinical standards.
 - **PelvicAssist**: a feature based on AI-ML technology, helps identify anatomical structures of the Pelvic floor through structural analysis and automatic measurement.
- The proposed HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System have migrated the detection sub-function of **NerveTrack**, the AI-ML based software feature from the predicate device V8 (K243702).

- The proposed HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System have updated its cleared AI-ML based software features **EzVolume, UterineAssist**. The detailed change descriptions of each feature are addressed below.
 - **EzVolume** has been updated to provide measurement results based on its segmentation results, already cleared in the previously predicate device HERA Z20, R20, HERA Z30, R30 (K241971).
 - **UterineAssist** has updated its segmentation algorithm.
- The proposed HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System have included new software features as following: **IDEA, IETA, EzPictogram, 3D printing, Voice Command**.
 - **IDEA**: This feature is to provide the latest IDEA protocol guideline standardized for the workflow improvement to the ultrasound system for the assessment of endometriosis.
 - **IETA**: This feature is to provide the latest IETA protocol guideline standardized for the workflow improvement to the ultrasound system for the assessment of the endometrium and uterine cavity.
 - **EzPictogram**: EzPictogram displays the location of the fibroid in a pictogram.
 - **3D Printing**: Provide files compatible with 3D printers for users to 3D print 3D images of the fetus. This is not for diagnostic purpose.
 - **Voice Command**: Voice Command is a feature that allows the user to control the ultrasound system with voice.
- The proposed HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System have migrated the following software features from the predicate device V8 (K243702): **QUS, EzHRI, RFA viewer, S-Fusion, TMAD**.
 - **QUS**: This feature is the analysis tool for tissue characteristics consisted on the TAI™ (Tissue attenuation Imaging) and TSI™ (Tissue Scatter-distribution Imaging).
 - **EzHRI**: This feature is to provide a workflow for convenient measurement of the Hepato-Renal Index (HRI).
 - **RFA viewer**: This feature displays information in real-time, such as total ablation time and total energy, generated by the RFA Generator.
 - **S-Fusion**: This feature enables simultaneous localization of a lesion using real-time ultrasound in conjunction with other volumetric imaging modalities.
 - **TMAD**: This feature analyzes annular displacement to assess the function of the heart.

- The proposed HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System have updated its cleared software feature **CEUS+** to include two sub-functions; microvascular contrast enhanced ultrasound (**MV-CEUS**) and time of arrival (**ToA**).
 - **MV-CEUS**: It utilized advanced image processing technology in CEUS+ to enhance the visualization of microvessels within tissues.
 - **ToA**: It is a feature in ultrasound imaging with contrast agents to visually display the time information it takes to reach a specific brightness level in an image.
- The proposed HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System have expanded the application of the cleared software feature, **EzStructure** within the clinical application of the previously cleared predicate device HERA Z20, R20, HERA Z30, R30 (K241971). This software update has now extended its availability to include GYN, Abdomen, MSK, and Small Parts (Breast, Thyroid).
- The proposed HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System have expanded its cleared software feature, **AutoEF** to include an additional measurement item. This update has been already cleared in the predicate V8 (K243702).
- The proposed HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System have included 11 new transducers, **CA2-13M, CA1-7Sn, EA2-11ARn, EA2-11AVn, CA3-10An, LA2-9Sn, CM1-8, CM2-11, LM3-27, EV3-15, PA2-9S**.
- The proposed HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System have migrated a transducer **miniER7** from the predicate V8 (K243702).
- The proposed HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System have included an **EPP** (Extended Power Pack).
- The proposed HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System and

the primary predicate device HERA Z20, R20, HERA Z30, R30 Diagnostic Ultrasound System (K241971) have the same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.

- The proposed HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System and the primary predicate device HERA Z20, R20, HERA Z30, R30 Diagnostic Ultrasound System (K241971) 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.

11. Summary of Non-Clinical Testing

The device has been evaluated for acoustic output, biocompatibility, software function, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety, and has been found to conform with applicable FDA guidances and medical device safety standards. HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System and their applications comply with the following FDA-recognized standards.

Reference No.	Title
IEC 60601-1	AAMI ANSI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021], Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD) [Including Amendment 2 (2021)]
IEC 60601-1-2	ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021], Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]
IEC 60601-2-37	IEC 60601-2-37 Edition 2.1 2015, 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	ANSI AAMI 10993-1 Fifth edition 2018-08, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO14971	ANSI AAMI 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 AbdomenAssist]

- Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance.
 - Kidney Length Measurement
 - The study confirmed that this feature achieved a Success Rate of 100% [94.17%, 100.00%]. This rate is defined by the measurement falling within a pre-specified clinical error margin compared to the reference standard.
 - The Bland-Altman analysis demonstrated a mean difference (Bias) of 1.5% with 95% Limits of Agreement (LoA) of [-4.53%, 7.64%].
 - Spleen Length Measurement
 - The study confirmed that this feature achieved a Success Rate of 96.77% [88.98%, 99.11%]. This rate is defined by the measurement falling within a pre-specified clinical error margin compared to the reference standard.
 - The Bland-Altman analysis demonstrated a mean difference (Bias) of 2.8% with 95% Limits of Agreement (LoA) of [-7.02%, 12.61%].
- The number of individual patients, images were collected from:
 - A total 62 individuals contributed to the validation dataset.
- The number of samples, if different from above, and the relationship between the two:
 - At least one ultrasound image of each spleen and kidney was used per patient.
 - The validation dataset consisted of 124 ultrasound images in total, including 62 kidney and 62 spleen.
- Demographic distribution:
 - Gender: Male/Female
 - Age: 20~40, 41~60, 60 over
 - BMI: Normal or Underweight(BMI<=24.9), Overweight(25<=BMI<=29.9), Obese(30>=BMI)
 - Ethnicity/Race : Asian, Black or African American, Hispanic or Latino, White
 - Country: United States and Germany
- Information about clinical subgroups and confounders present in the dataset:
 - We divided the abdominal ultrasound images, depending on guidelines, into 2 views (kidney sagittal, spleen sagittal). The acquired data were further stratified by patient gender, age, BMI, clinical site, and race/ethnicity for subgroup analysis.

- Information about equipment and protocols used to collect images
 - We acquired the data set with SAMSUNG MEDISON’s ultrasound system (R20) and probe (CA1-7S) 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):
 - The reference standard was established by two clinical experts (a sonographer with more than 20 years of experience and a sonographer with more than 10 years of experience), who independently performed manual measurements of kidney length or spleen length without sharing their results. A third senior expert (another radiologist with more than 20 years of experience) then reviewed and adjudicated the two measurements to determine the final value.

- Description of how the independence of test data from training data was ensured:
 - Data used for test and training/tuning purpose are completely separated from the ones during training process and there is no overlap between the two.

[The Summary of Testing for BladderAssist]

- Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance.
 - Bladder Width Measurement
 - The study confirmed that this feature achieved a Success Rate of 95.24% [86.91%, 98.37%]. This rate is defined by the measurement falling within a pre-specified clinical error margin compared to the reference standard.
 - The Bland Altman analysis demonstrated a mean difference (Bias) -4.81% with 95% Limits of Agreement (LoA) of [-12.94%, 3.31%].

 - Bladder Width Measurement
 - The study confirmed that this feature achieved a Success Rate of 96.83% [89.14%, 99.13%]. This rate is defined by the measurement falling within a pre-specified clinical error margin compared to the reference standard.
 - The Bland Altman analysis demonstrated a mean difference (Bias) -3.2%, with 95% Limits of Agreement (LoA) of [-11.86%, 5.47%].

- The number of individual patients, images were collected from:
 - A total 63 individuals contributed to the validation dataset.

- The number of samples, if different from above, and the relationship between the two:
 - At least one ultrasound image of each bladder was used per patient.
 - The validation dataset consisted of 63 ultrasound bladder transverse images in total.

- Demographic distribution:

- Gender: Male/Female
- Age: 20~40, 41~60, 60 over
- BMI: Normal or Underweight(BMI<=24.9), Overweight(25<=BMI<=29.9), Obese(30<=BMI)
- Ethnicity/Race : Asian, Black or African American, Hispanic or Latino, White
- Country: United States and Germany

- ▣ Information about clinical subgroups and confounders present in the dataset:
 - We divided the Bladder ultrasound images, depending on guidelines, into bladder transverse view. The acquired data were further stratified by patient gender, age, BMI, clinical site, probe, and race/ethnicity for subgroup analysis.

- ▣ Information about equipment and protocols used to collect images
 - We acquired the data set with SAMSUNG MEDISON’s ultrasound system(R20) and probe (CA1-7S, CA3-10A) 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):
 - The reference standard was established by two clinical experts (a sonographer with more than 20 years of experience and a sonographer with more than 10 years of experience), who independently performed manual measurements of kidney length or spleen length without sharing their results. A third senior expert (another radiologist with more than 20 years of experience) then reviewed and adjudicated the two measurements to determine the final value.

- ▣ Description of how the independence of test data from training data was ensured:
 - Data used for test and training/tuning purpose are completely separated from the ones during training process and there is no overlap between the two.

[The Summary of Testing for QualityCheck]

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

The test evaluated the device's performance on two distinct workflows: (1) Manually acquired images (2) Images acquired via Live ViewAssist (LVA).

- View quality classification and structure detection test: A deep learning-based view classification and structure detection algorithm was validated using 43,737 fetal ultrasound images collected at hospitals. The evaluation covered standard obstetric views and their corresponding required anatomical structures.
- The performance of the view quality classification and structure detection:
 - Performance on Manually Acquired Images (N=25,786)
[View Classification]

- The Sensitivity ranged from 0.85 to 1.00, and the Specificity ranged from 0.85 to 1.00.
- The Positive Predictive Value (PPV) ranged from 0.80 to 1.00, and the Negative Predictive Value (NPV) ranged from 0.90 to 1.00.
- [Structure Detection]
- The Sensitivity ranged from 0.81 to 1.00, and the Specificity ranged from 0.99 to 1.00.
- The PPV ranged from 0.89 to 1.00, and the NPV ranged from 0.99 to 1.00.

- Performance on Live ViewAssist (LVA) Acquired Images (N=17,951)
- [View Classification]
- The Sensitivity ranged from 0.86 to 1.00, and the Specificity ranged from 0.85 to 1.00.
- The PPV ranged from 0.80 to 1.00, and the NPV ranged from 0.91 to 1.00.
- [Structure Detection]
- The Sensitivity ranged from 0.82 to 1.00, and the Specificity ranged from 1.00 to 1.00.
- The PPV ranged from 0.89 to 1.00, and the NPV ranged from 0.99 to 1.00.

- ▣ The number of individual patients, images were collected from:
 - Total Patients: A total of 283 individuals contributed to the validation dataset.
 - Total Images: From these 283 patients, multiple static images were collected for the performance evaluation, resulting in a total of 43,737 images (25,786 acquired via manual scanning and 17,951 acquired via Live ViewAssist).

- ▣ The number of samples, if different from above, and the relationship between the two:
 - The validation dataset consists of 43,737 static 2D B-mode images collected from the 283 patients.
 - Each patient contributed multiple images representing various standard obstetric views across different gestational ages.

- ▣ Demographic distribution:
 - Gender: Female
 - Maternal Age: 17-47 (Mean 29.42)
 - Gestational Age: 11 to 38 weeks, covering 1st, 2nd, and 3rd trimesters.
 - BMI: 17-53.61(Mean 29.65)
 - Race/Ethnicity: White, Black, Asian, Hispanic, Non-Hispanic, Unknown
 - Country: United States

- ▣ Information about clinical subgroups and confounders present in the dataset:
 - We divided the obstetric ultrasound images, depending on guidelines, into 40 standard views with 65 required anatomical structures. The acquired data were further stratified by maternal age, gestational age, patient BMI, clinical site, and race/ethnicity for subgroup analysis.

- Information about equipment and protocols used to collect images.
 - We acquired the data set with SAMSUNG MEDISON's ultrasound system (HERA Z20) and probes (CA3-10A, CMV1-10, CA1-7S, EV2-12, CV1-8A) 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):
 - For the independent validation dataset, the ground truth was established by a completely separate and distinct group of expert reviewers to ensure an unbiased performance evaluation. These experts followed a strict, pre-defined protocol to classify each test image and determine the presence or absence of all required anatomical structures, thereby creating the definitive reference standard for the test.
 - The expert panel for the validation ground truth consisted of two sonographers, each with 20 or more years of experience, who performed the annotation, and an Obstetrician-Gynecologist with over 10 years of experience, who provided the review and final confirmation.

- 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 PelvicAssist]

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

We tested two features of PelvicAssist: i) pelvic floor volume alignment and ii) levator hiatus (LH) measurement.

- Volume alignment
 - We performed a test using a total of 120 volumes (40 rest, 40 contraction and 40 Valsalva)
 - The acceptance rates is 96.67%.

- LH measurement
 - We used same datasets above.
 - The resulting Intraclass Correlation Coefficient (ICC) for six measurements were LH Area (0.9802), LH Circ. (0.9837), LH AP (0.9910), LH Lat. (0.9536), Right LUG (0.9423), and Left LUG (0.9596).
 - The analysis by Bland-Altman plot showed that the mean difference is near zero (up to 1.1cm² and 0.53cm) and the majority 95.8% of data points fell within the 95% lower and upper LoAs.

- The number of individual patients, images were collected from:
 - A total of 40 individual patients contributed to the validation dataset.

- The number of samples, if different from above, and the relationship between the two:
 - From 40 individual patients, three volumes were obtained corresponding to rest, contraction, and Valsalva phases, respectively, resulting in a total of 120 validation datasets.

- Demographic distribution:
 - Gender: Female
 - Age: 23 - 64 (mean 44.3)
 - BMI: 18 - 31 (mean 23.7)
 - Race/Ethnicity: White, Black, Hispanic, Asian
 - Country: United States and Italy

- Information about clinical subgroups and confounders present in the dataset:
 - Pelvic ultrasound images were classified into three physiological phases (rest, contraction, and Valsalva) in accordance with established guidelines. The acquired data were further stratified by patient age, BMI, clinical site, and race/ethnicity for subgroup analysis.

- Information about equipment and protocols used to collect images
 - We acquired the data set with SAMSUNG MEDISON's ultrasound system (HERA Z20) and probe (CMV1-10) 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):
 - The reference standard for test of PelvicAssist was obtained by three participating clinical experts, which were not involved in building the training dataset at all. Three clinical experts have over 20 years of experience. The experts are unaware of each other's identities. The completed GT's were permuted and sent to the experts for peer review. Rejected data were re-labeled by the initial assigned expert, and the process is repeated.

- 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 EzVolume – addition of measurement]

- Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance.
 - EzVolume Measurement test.
 - The clinical experts used the "Show Measurement" button to measure the volume of each segmented label.

- The performance of the EzVolume Measurement was tested by error rate using a Bland-Altman analysis to evaluate the agreement between the EzVolume Measurement and the reference standard.
 - The bias (Mean Difference) for each analyzed label did not exceed $\pm 2\%$, and the 95% confidence interval for the mean error included zero, confirming the absence of a statistically significant systematic bias.
 - The 95% Limits of Agreement (LoA) for all labels fell within the pre-specified clinical acceptance range of $\pm 15\%$.
- ▣ The number of individual patients, images were collected from:
 - A total 200 individuals contributed to the validation dataset. (100 for the 1st trimester and 100 for the 2nd/3rd trimesters).
 - ▣ The number of samples, if different from above, and the relationship between the two:
 - Each individual contributed with one 3D volume so the number of individuals and samples are same
 - ▣ Demographic distribution:
 - Gender: Female
 - Age: 17 - 43 (mean: 28.94)
 - BMI: 17.0 - 45 (mean: 26.3)
 - Race and Ethnicity: Asian, Black or African American, Hispanic or Latino, White, Other Multiracial
 - Country: South Korea, and United States
 - ▣ Information about clinical subgroups and confounders present in the dataset:
 - The acquired data were further stratified by patient age, Gestational age, BMI, clinical site, and race/ethnicity for subgroup analysis.
 - ▣ Information about equipment and protocols used to collect images:
 - We acquired the data set with the three of SAMSUNG MEDISON's ultrasound systems (HERA Z20, HERA W10, V8) and the probes (CMV1-10, CV1-8A, EV2-12) in order to secure diversity of the data set: Mix of data from retrospective data collection and prospective data collection in clinical practice. We performed subgroup analysis according to the system and the probe used for image acquisition.
 - ▣ Information about how the reference standard was derived from the dataset (i.e. the "Truthing" process):
 - The final Ground Truth (GT) was established through a consensus process involving three clinical experts, each with over 10 years of experience. First, for each case, one of the three experts is randomly assigned to create the initial 3D segmentation annotation. This initial result is then reviewed independently and blindly by the other two experts, each of whom has the authority to accept it as is or propose modifications. If both reviewers accept the initial annotation, it is finalized as the GT. However, if any reviewer proposes modifications, all three experts

convene to review the case together, and the final GT is determined only upon unanimous agreement. This protocol ensures that the reference standard, while grounded in deep clinical expertise, is also the product of a reproducible and collaborative validation process.

- ▣ 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 UterineAssist]

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

We tested on three areas: image segmentation, feature points extraction and size measurement.

- Segmentation test
 - A deep learning based segmentation algorithm was validated using 60 sagittal uterus images and 60 transverse uterus images collected from variety hospitals.
 - The average dice-score of uterus of sagittal view is 96.7%.
 - The average dice-score of uterus of transverse view is 95.8%.
 - The average dice-score of endometrium is 86.8%.
- Feature points extraction test
 - We acquired, in addition, 60 sagittal and 60 transverse plane images of uterus collected from variety hospitals.
 - The average error range of uterus feature points: 1.5 – 2.6 mm.
 - The average error range of endometrium feature points: 0.9 - 1.7 mm.
- Size measurement test
 - We use same data set of Feature points extraction test.
 - The average error range of Measurements: 0.87 – 1.79 mm.
 - The Bland-Altman analysis of the uterus measurements showed that the widest 95% LoA range was [-2.96, 4.04] and the largest Mean difference was 1.23 mm.
 - The Bland-Altman analysis of the endometrium measurements showed that the 95% LoA range was [-1.59, 2.09] and the mean difference was 0.25 mm.
- ▣ Demographic distribution:
 - Gender: Female
 - Age: 18 - 55
 - BMI: 18 - 40
 - Race/Ethnicity: African American, Asian, Hispanic, White, Unknown
 - Country: South Korea and United States
- ▣ The number of individual patients, images were collected from:

- A total 60 individuals contributed to the validation dataset.
- The number of samples, if different from above, and the relationship between the two:
 - Each individual contributed one pair of the image (Sagittal view, Transverse view)
 - Validation dataset included 120 static images of 2D sequences.
- Information about clinical subgroups and confounders present in the dataset:
 - We divided the sagittal and transverse uterus images. The acquired data were further stratified by patient age, BMI, clinical site, and race/ethnicity for subgroup analysis.
- Information about equipment and protocols used to collect images
 - We acquired the data set with SAMSUNG MEDISON's ultrasound systems (HERA Z20, V8) and probes (EA2-11AR, EV2-12, EV2-10A) in order to secure diversity of the data set: Mix of data from retrospective data collection and prospective data collection in clinical practice. We performed subgroup analysis according to the system and the probe used for image acquisition.
- Information about how the reference standard was derived from the dataset (i.e. the "truthing" process):
 - All ground truth (Measure, points, segmentation) were made by sonographer.
 - Images for validation were first classified into the correct views by participating sonographer. Afterwards, corresponding anatomy areas were manually drawn for each of the image by two sonographers.
 - The expert who classified views of the validation images has more than 10 years of experience. The sonographer who made the ground truth of the validation images have more than 10 years of experience.
- Description of how the independence of test data from training data was ensured:
 - Data used for test and training/tuning purpose are completely separated from the ones during training process and there is no overlap between the two.

[The Summary of Testing for NerveTrack]

- Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance.
 - Detection test
The feature demonstrated a localization accuracy success rate of 92.19% (95% CI: [90.03%, 94.34%]) and a processing speed of approximately 3.98 FPS. The success rate was defined as the percentage of frames within entire image sequences that achieve the pre-specified frame accuracy criteria, in accordance with a reference standard (truthing process).
- The number of individual patients, images were collected from:
 - A total of 46 individuals participated in the NerveTrack validation dataset.

- ▣ The number of samples, if different from above, and the relationship between the two:
 - ▣ At least two nerve views were used per patient, with 2D sequences consisting of at least 10 images.
 - ▣ The validation dataset consisted of at least 24 and up to 42 ultrasound images for each of the 10 nerves.

- ▣ Demographic distribution:
 - ▣ Gender: Male/ Female
 - ▣ Age: 20-40, 41-60, 61 and over
 - ▣ BMI: Normal/Underweight ($BMI < 25$), Overweight ($25 \leq BMI < 30$), Obese ($BMI \geq 30$)
 - ▣ Race/Ethnicity: Asian, African American, Hispanic, White, Unknown
 - ▣ Country: South Korea and United States

- ▣ Information about clinical subgroups and confounders present in the dataset:
 - ▣ We divided the nerve ultrasound images into ten nerve groups depending on the scanning region. The acquired data were further stratified by patient gender, age, BMI, clinical site, and race/ethnicity for subgroup analysis.

- ▣ Information about equipment and protocols used to collect images
 - ▣ We acquired the data set with SAMSUNG MEDISON's ultrasound system (R20, RS85, V8, V7, V5) and probe (LA2-14A, LA2-9S, L3-22) 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):
 - ▣ The reference standard for NerveTrack was established through a rigorous, multi-expert process to ensure accuracy and objectivity. The process was initiated by two clinical experts, each with extensive experience in musculoskeletal ultrasound, who independently performed manual segmentation by drawing a Region of Interest (ROI) around the target nerve in each frame of the test data clips. A third, senior clinical expert, also with extensive experience in the field, then acted as an adjudicator. This senior expert reviewed the two independent segmentations and resolved any discrepancies to establish the single, definitive ground truth ROI for each frame used in the performance evaluation.

- ▣ Description of how the independence of test data from training data was ensured:
 - ▣ Data used for test and training/tuning purpose are completely separated from the ones during training process and there is no overlap between the two.

12. Summary of Clinical Tests

The proposed device HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System

does not require clinical studies to demonstrate substantial equivalence.

13. Conclusion

Since the predicate devices and the subject device have a similar intended use and key technological features, the non-clinical data support the safety of the device and demonstrate that HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System should perform as intended in the specified use conditions. 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 that is currently marketed for the same intended use.

- **END of 510(k) Summary**