July 18, 2025

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

Re: K250999
Trade/Device Name: V8 Diagnostic Ultrasound System; cV8 Diagnostic Ultrasound System; V7 Diagnostic Ultrasound System; cV7 Diagnostic Ultrasound System; V6 Diagnostic Ultrasound System; cV6 Diagnostic Ultrasound System; V5 Diagnostic Ultrasound System; cV5 Diagnostic Ultrasound System; V4 Diagnostic Ultrasound System; cV4 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: June 17, 2025
Received: June 17, 2025

Dear Yujin Kim:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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,

MARJAN NABILI -S for

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250999

Device Name
V8 Diagnostic Ultrasound System; cV8 Diagnostic Ultrasound System; V7 Diagnostic Ultrasound System; cV7 Diagnostic Ultrasound System; V6 Diagnostic Ultrasound System; cV6 Diagnostic Ultrasound System; V5 Diagnostic Ultrasound System; cV5 Diagnostic Ultrasound System; V4 Diagnostic Ultrasound System;cV4 Diagnostic Ultrasound Svstem

Indications for Use *(Describe)*
V8 Diagnostic Ultrasound System; cV8 Diagnostic Ultrasound System; V7 Diagnostic Ultrasound System; cV7 Diagnostic Ultrasound System; V6 Diagnostic Ultrasound System; cV6 Diagnostic Ultrasound System:
The 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) 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 mode(Dual, Quad), 3D/4D mode.

V5 Diagnostic Ultrasound System; cV5 Diagnostic Ultrasound System; V4 Diagnostic Ultrasound System; cV4 Diagnostic Ultrasound System:
The 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 Dermatology.
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 mode(Dual, Quad), 3D/4D mode, MV-Flow Mode.

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.

K250999

510(K) Summary:

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

1. Date Prepared – April 1st, 2025

2. Manufacturer
   SAMSUNG MEDISON CO., LTD.
   3366, Hanseo-ro, Nam-myeon, Hongcheon-gun, Gangwon-do 25108,
   Republic of Korea

3. Contact Person
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4. Secondary Contact Person
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   Vice President
   Phone: +1.978.564.8632
   Fax: +1.978.564.8677
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5. Proposed Device
   - Common/Usual Name : Diagnostic Ultrasound System and Accessories
   - Proprietary Name : V8 Diagnostic Ultrasound System
     cV8 Diagnostic Ultrasound System
     V7 Diagnostic Ultrasound System
     cV7 Diagnostic Ultrasound System
     V6 Diagnostic Ultrasound System
     cV6 Diagnostic Ultrasound System
     V5 Diagnostic Ultrasound System
     cV5 Diagnostic Ultrasound System
     V4 Diagnostic Ultrasound System
     cV4 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 / Reference Device
   - V8/cV8, V7/cV7, V6/cV6 Diagnostic Ultrasound System (K243702) – Predicate
   - V5/H5/XV5/XH5, V4/H4/XV4/XH4 (K242511) - Reference

7. Device Description

■ V8/cV8, V7/cV7, V6/cV6

The V8/cV8, V7/cV7, V6/cV6 Diagnostic Ultrasound Systems are general purpose, mobile, software controlled, diagnostic ultrasound systems. Its 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, Multi-Image mode(Dual, Quad), 3D/4D mode. The V8/cV8, V7/cV7, V6/cV6 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 V8/cV8, V7/cV7, V6/cV6 have real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

■ V5/cV5, V4/cV4

The V5/cV5, V4/cV4 Diagnostic Ultrasound Systems are general purpose, mobile, software controlled, diagnostic ultrasound systems. 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 V5/cV5, V4/cV4 diagnostic ultrasound systems 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. The V5/cV5, V4/cV4 diagnostic ultrasound systems have a real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

8. Intended Use

■ V8/cV8, V7/cV7, V6/cV6

The diagnostic ultrasound systems 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) and Peripheral vessel.

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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 mode(Dual, Quad), 3D/4D mode.

■ V5/cV5, V4/cV4

The diagnostic ultrasound systems 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 Dermatology.
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 mode(Dual, Quad), 3D/4D mode, MV-Flow Mode.

9. Technological Comparison to Predicate Device

The V8/cV8, V7/cV7, V6/cV6, V5/cV5, V4/cV4 employ the same fundamental scientific technology as its predicate device V8/cV8, V7/cV7, V6/cV6 (K243702).

10. Determination of Substantial Equivalence

Comparison to Predicate: The V8/cV8, V7/cV7, V6/cV6, V5/cV5, V4/cV4 are substantially equivalent to the predicate device with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

■ V8/cV8, V7/cV7, V6/cV6

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The proposed V8/cV8, V7/cV7, V6/cV6 and the predicate V8/cV8, V7/cV7, V6/cV6 (K243702) have the same intended use, and modes of operation.
- The proposed V8/cV8, V7/cV7, V6/cV6 have updated 'BiometryAssist', 'ViewAssist', and 'HeartAssist', the cleared features in the predicate V8/cV8, V7/cV7, V6/cV6 (K243702). The AI models for these features have been updated.
- The proposed V8/cV8, V7/cV7, V6/cV6 have included 'EzAssist'. This feature provides on-screen reference information on human anatomy about ultrasound scanning. It is designed for educational purposes, and it is not a real-time guidance function and is not intended for diagnostic purpose.
- The proposed V8/cV8, V7/cV7, V6/cV6 have included 'EzTrainer'. This feature provides users with a quick manual containing general information about the system and not intended for diagnostic purpose.
- The proposed V8/cV8, V7/cV7, V6/cV6 have included a new transducer, LM2-18D.
- The proposed V8/cV8, V7/cV7, V6/cV6 have included two caster brake options.

- The proposed V8/cV8, V7/cV7, V6/cV6 and the predicate V8/cV8, V7/cV7, V6/cV6 (K243702) have the same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The proposed V8/cV8, V7/cV7, V6/cV6 and the predicate V8/cV8, V7/cV7, V6/cV6 (K243702) have been designed in compliance with approved electrical and physical safety standards.
- The system is manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The system has acoustic power levels which are below the applicable FDA level.

■ V5/cV5, V4/cV4

- The proposed V5/cV5, V4/cV4 and the predicate V8/cV8, V7/cV7, V6/cV6 (K243702) have the same intended use, and modes of operation.
- The proposed V5/cV5, V4/cV4 have included a clinical application for Trans-esophageal (Cardiac) already cleared in V8/cV8, V7/cV7, V6/cV6 (K243702) by adding the TEE transducer.
- The proposed V5/cV5, V4/cV4 have updated ‘BiometryAssist’, ‘ViewAssist’, and ‘HeartAssist’, the cleared features in the reference device V5/H5/XV5/XH5, V4/H4/XV4/XH4 (K242511). The AI models for these features have been updated.
- The proposed V5/cV5, V4/cV4 have included ‘EzAssist’. This feature provides on-screen reference information on human anatomy about ultrasound scanning. It is designed for educational purposes, and it is not a real-time guidance function and is not intended for diagnostic purpose.
- The proposed V5/cV5, V4/cV4 have included ‘EzTrainer’. This feature provides users with a quick manual containing general information about the system and not intended for diagnostic purpose.
- The proposed V5/cV5, V4/cV4 have included ‘EzNerveMeasure’ previously cleared in the predicate V8/cV8, V7/cV7, V6/cV6 (K243702), as a sub-function of NerveTrack based on AI technology.
- The proposed V5/cV5, V4/cV4 have included ‘RFA Viewer’, the cleared function in the predicate V8/cV8, V7/cV7, V6/cV6 (K243702). This function displays information in real-time, such as total ablation time and total energy, generated by the RFA Generator.
- The proposed V5/cV5, V4/cV4 systems have updated the 'Strain+' function, which

was previously cleared in the predicate, by expanding its measurement items to include the left atrium (LA) and right ventricle (RV). This change has already been cleared in the predicate device V8/cV8, V7/cV7, V6/cV6 (K243702) and it has been migrated to V5/cV5, V4/cV4.

- The proposed V5/cV5, V4/cV4 have updated 'AutoEF' function, which was previously cleared in the predicate, by expanding its measurement item to include 'Global Longitudinal Strain(GLS)'. This change has already been cleared in the predicate device V8/cV8, V7/cV7, V6/cV6 (K243702), and it has been migrated to V5/cV5, V4/cV4.
- The proposed V5/cV5, V4/cV4 have included the five transducers: PA3-9B, miniER7, MMPT3-7, TA2-9, LA3-16AD.
- For marketing purpose, we've included the cV series product names(cV5 and cV4), which have the same specifications with V series.
- The proposed V5/cV5, V4/cV4 and the reference device V5/H5/XV5/XH5, V4/H4/XV4/XH4 (K242511) have the same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The proposed V5/cV5, V4/cV4 and the reference device V5/H5/XV5/XH5, V4/H4/XV4/XH4 (K242511) have been designed in compliance with approved electrical and physical safety standards.
- The system is manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The system has acoustic power levels which are below the applicable FDA level.

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. The V8/cV8, V7/cV7, V6/cV6, V5/cV5, V4/cV4 and its applications comply with the following FDA-recognized standards.

Reference No.	Title
IEC 60601-1	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
IEC 60601-1-2	IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020
IEC 60601-2-37	IEC 60601-2-37 (ed.2), am1 for use in conjunction with IEC60601-1 (ed.3), am1 with Corr1 and Corr2
IEC 60601-4-2	IEC TS 60601-4-2:2024
ISO10993-1	ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Reference No.	Title
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

All software tests met the acceptance criteria for verification and validation testing.

The AI summaries for 'BiometryAssist', 'ViewAssist' and 'HeartAssist' are applicable to V8/cV8, V7/cV7, V6/cV6 and V5/cV5, V4/cV4 diagnostic ultrasound systems.

[The AI 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 view recognition algorithm was validated using 320 fetal biometry images collected at hospitals (South Korea and United States).
- The average dice-score is 0.869 (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.

▣ The number of individual patients, images were collected from:
- A total of 52 individual patients contributed to the validation dataset (17 from South Korea, 35 from the US).
- From each of these 52 patients, multiple static images were randomly selected and used for the validation, resulting in a total of 320 images.

▣ The number of samples, if different from above, and the relationship between the two:
- Each individual contributed at least one static image across all views.
- Validation dataset includes a total of 320 static images.

▣ Demographic distribution:
- Gender: Female
- Age: Reproductive age, specific age not collected
- BMI: Normal (~24.9), Overweight (25~29), Obese (30~) categories.
- Ethnicity/Country: 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: Distributed across standard range, overweight or obesity 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 ultrasound systems (HERA W10, HERA W9, WS80A, V series (V8/V7/V6/V5/V4)) 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 images used for training and tuning were first classified into the correct ultrasound views by three participating experts. Following view classification, the corresponding anatomical structures were manually annotated for each image.
- For validation, the ground truth was established using the target ultrasound device. Expert reviewers manually performed view classification and measurements following the same protocol as used during actual device operation. This ensured that the reference standard closely reflects the clinical use environment and output behavior of the device.
- The participating experts included one obstetrician with over 20 years of experience in fetal cardiology and two sonographers, each with more than 10 years of experience. The entire process was supervised by a senior obstetrician with over 25 years of clinical experience, who reviewed and corrected all annotations to ensure consistency and accuracy.

▣ 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 AI 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 Segmentation.

■ View recognition test
- A deep learning based view recognition algorithm was validated using 680 fetal biometry images collected at hospitals (South Korea and United States).
- The achieved sensitivity is 93.97% and specificity is 99.62% (thresholds: 75.9%, 88.2%, respectively)

■ Segmentation test
- We use same datasets of view recognition test.
- The average dice-score is 0.863 (threshold 0.8)

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

- A total of 102 individual patients contributed to the validation dataset (42 from South Korea, 60 from the US).
- From each of these 102 patients, multiple static images were randomly selected and used for the validation, resulting in a total of 680 images.

▣ The number of samples, if different from above, and the relationship between the two:
- Each individual contributed at least one static image across all views.
- Validation dataset includes a total of 680 static images.

▣ Demographic distribution:
- Gender: Female
- Age: Reproductive age, specific age not collected
- BMI: Normal (~24.9), Overweight (25~29), Obese (30~) categories.
- Ethnicity/Country: 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 17 views.
- BMI: Distributed across standard range, overweight or obesity 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 ultrasound systems (HERA W10, HERA W9, WS80A, V series (V8/V7/V6/V5/V4)) 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 images used for training and tuning were first classified into the correct ultrasound views by three participating experts. Following view classification, the corresponding anatomical structures were manually annotated for each image.
- For validation, the ground truth was established using the target ultrasound device. Expert reviewers manually performed view classification and measurements following the same protocol as used during actual device operation. This ensured that the reference standard closely reflects the clinical use environment and output behavior of the device.
- The participating experts included one obstetrician with over 20 years of experience in fetal cardiology and two sonographers, each with more than 10 years of experience. The entire process was supervised by a senior obstetrician with over 25 years of clinical experience, who reviewed and corrected all annotations to ensure consistency and accuracy.
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▣ 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 AI Summary of Testing for HeartAssist(fetus)]

▣ 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: View recognition, Segmentation and Size measurement.

■ View recognition test
- A deep learning based view recognition algorithm was validated using 280 fetal biometry images collected at hospitals (South Korea and United States).
- The achieved sensitivity is 94.29% and specificity is 99.62% (thresholds: 75.9%, 88.2%, respectively)
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■ Segmentation test
- We use same datasets of view recognition test.
- The average dice-score is 0.865 (threshold 0.8)

■ Size measurement test
- We use 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 of 70 individual patients contributed to the validation dataset (26 from South Korea, 44 from the US).
- From each of these 70 patients, multiple static images were randomly selected and used for the validation, resulting in a total of 280 images.

▣ The number of samples, if different from above, and the relationship between the two:
- Each individual contributed at least one static image across all views.
- Validation dataset includes a total of 280 static images.

▣ Demographic distribution:
- Gender: Female
- Age: Reproductive age, specific age not collected
- BMI: Normal (~24.9), Overweight (25~29), Obese (30~) categories.
- Ethnicity/Country: 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 7 views.
- BMI: Distributed across standard range, overweight or obesity 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 ultrasound systems (HERA W10, HERA W9, V series (V8/V7/V6/V5/V4)) 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 images used for training and tuning were first classified into the correct ultrasound views by three participating experts. Following view classification, the corresponding anatomical structures were manually annotated for each image.
- For validation, the ground truth was established using the target ultrasound device. Expert reviewers manually performed view classification and measurements following the same protocol as used during actual device operation. This ensured that the reference standard closely reflects the clinical use environment and output behavior of the device.
- The participating experts included one obstetrician with over 20 years of experience in fetal cardiology and two sonographers, each with more than 10 years of experience. The entire process was supervised by a senior obstetrician with over 25 years of clinical experience, who reviewed and corrected all annotations to ensure consistency and accuracy.

▣ 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 AI summary of 'EzNerveMeasure of NerveTrack' is applicable to V5/cV5, V4/cV4 diagnostic ultrasound systems.

[The AI Summary of testing for EzNerveMeasure of NerveTrack]

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

We tested on the flattening ratio (FR) and cross-sectional area (CSA) of NerveTrack EzNerveMeasure.

☐ A deep learning-based segmentation algorithm was validated using 200 median nerve images collected at a hospital.

☐ FR and CSA measure test

○ The average error rate of FR was 8.05% (95% Confidence Interval: [7.64, 8.46]), and the average error rate of CSA was 13.11% (95% Confidence Interval: [11.83, 14.38]). The standard devitation error rate of FR was 0.87, and the standard devitation error

rate of CSA was 2.73. Error Rate (%) is calculated as follows: (GT Value - Measured Value) / GT Value x 100.

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

☐ A total of 20 individual patients contributed to the validation dataset (10 from South Korea, 10 from the US).

☐ From each of these 20 patients, 10 static images were randomly selected and used for the validation, resulting in a total of 200 images.

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

☐ Each individual contributed at 10 static images. In other words, the 10 static images from a 2D sequence data acquired from an individual were used for validation.

☐ Validation dataset includes a total of 200 static images.

▣ Demographic distribution:

☐ Gender: Female and male

☐ Age: 22–68 (mean: 36.2)

☐ BMI: 16.0–29.0 (mean: 22.75)

☐ Ethnicity/Country: Korean and American

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

☐ BMI: Distributed across underweight, standard range or overweight categories.

☐ Gender: Female and male.

▣ Information about equipment and protocols used to collect images

☐ We acquired the dataset using the Samsung ultrasound systems (RS80A and V8) in order to secure diversity of ultrasound images and prospective data in clinical practice was collected.

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

☐ The ground truth (GT) for median nerve locations was established by three anesthesiologists, each with over 10 years of experience. One doctor performed the initial ultrasound scans and drew the GT, which was then verified by the other two doctors.

☐ Disagreements during review were resolved by a senior anesthesiologist with over 10 years of extensive clinical experience in regional anesthesia and ultrasound-guided procedures, considering both the initial annotations and the two review annotations. The clinical evaluation has been conducted to get the clinical

significance of the developed EzNerveMeasure by doctors having experience in respective fields more than 10 years.

▣ 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

12. Summary of Clinical Tests

The proposed device V8/cV8, V7/cV7, V6/cV6, V5/cV5, V4/cV4 diagnostic ultrasound systems did not require clinical studies to demonstrate substantial equivalence.

13. Conclusion

Since the predicate device and the proposed device have a similar intended use and key technological features, the non-clinical data support the safety of the device and demonstrate that the V8/cV8, V7/cV7, V6/cV6, V5/cV5, V4/cV4 diagnostic ultrasound systems should perform as intended in the specified use conditions. Therefore, SAMSUNG MEDISON CO., LTD. considers the proposed device to be as safe, as effective, and substantially equivalent in performance to the predicate device that is currently marketed for the same intended use.

- END of 510(k) Summary -