December 10, 2024

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

Re: K242511
Trade/Device Name: V5 Diagnostic Ultrasound System, H5 Diagnostic Ultrasound System, XV5 Diagnostic Ultrasound System, XH5 Diagnostic Ultrasound System, V4 Diagnostic Ultrasound System, H4 Diagnostic Ultrasound System, XV4 Diagnostic Ultrasound System, XH4 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 23, 2024
Received: November 12, 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) 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
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Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
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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.

Submission Number *(if known)*

K242511

Device Name

V5 Diagnostic Ultrasound System
H5 Diagnostic Ultrasound System
XV5 Diagnostic Ultrasound System
XH5 Diagnostic Ultrasound System
V4 Diagnostic Ultrasound System
H4 Diagnostic Ultrasound System
XV4 Diagnostic Ultrasound System
XH4 Diagnostic Ultrasound System

Indications for Use *(Describe)*

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, 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.

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510(k) Summary: K242511

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

1. Date Prepared – August 23, 2024

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

3. Primary Contact Person
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   Regulatory Affairs Specialist
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4. Secondary Contact Person
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   Vice President
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   Fax: +1.978.564.8677
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5. Proposed Device
   - Common/Usual Name : Diagnostic Ultrasound System and Accessories
   - Proprietary Name : V5 Diagnostic Ultrasound System
     H5 Diagnostic Ultrasound System
     XV5 Diagnostic Ultrasound System
     XH5 Diagnostic Ultrasound System
     V4 Diagnostic Ultrasound System
     H4 Diagnostic Ultrasound System
     XV4 Diagnostic Ultrasound System
     XH4 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
   - V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 Diagnostic Ultrasound System (K240631) - Primary
   - HS40 Diagnostic Ultrasound System (K221599) - Reference
   - HM70 EVO Diagnostic Ultrasound System (K233112) - Reference

7. Device Description
   V5 Diagnostic Ultrasound System; H5 Diagnostic Ultrasound System; XV5 Diagnostic Ultrasound System; XH5 Diagnostic Ultrasound System; V4 Diagnostic Ultrasound System;

H4 Diagnostic Ultrasound System; XV4 Diagnostic Ultrasound System; XH4 Diagnostic Ultrasound System (*Hereinafter referred to as V5/H5/XV5/XH5, V4/H4/XV4/XH4 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. The V5/H5/XV5/XH5, V4/H4/XV4/XH4 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. The V5/H5/XV5/XH5, V4/H4/XV4/XH4 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, 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 Devices

The V5/H5/XV5/XH5, V4/H4/XV4/XH4 diagnostic ultrasound system employ the same fundamental scientific technology as its primary predicate device V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 Diagnostic Ultrasound System (K240631).

10. Determination of Substantial Equivalence

Comparison to Predicate: The V5/H5/XV5/XH5, V4/H4/XV4/XH4 diagnostic ultrasound systems are substantially equivalent to the predicate devices 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 V5/H5/XV5/XH5, V4/H4/XV4/XH4 diagnostic ultrasound system and the primary predicate V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6(K240631) diagnostic ultrasound system have the same clinical intended use.
- The proposed V5/H5/XV5/XH5, V4/H4/XV4/XH4 diagnostic ultrasound system

and the primary predicate V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6(K240631) diagnostic ultrasound system have the same imaging modes and modes of operation.

- The proposed V5/H5/XV5/XH5, V4/H4/XV4/XH4 have included one new transducer PA1-5AE.
- The proposed V5/H5/XV5/XH5, V4/H4/XV4/XH4 have included a clinical application for dermatology already cleared in the HM70 EVO(K233112).
- The proposed V5/H5/XV5/XH5, V4/H4/XV4/XH4 have included BiometryAssist, HeartAssist, ViewAssist, UterineAssist, NerveTrack already cleared in the V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 (K240631) without changes.
- The proposed V5/H5/XV5/XH5, V4/H4/XV4/XH4 have included a WiFi module.
- The proposed V5/H5/XV5/XH5, V4/H4/XV4/XH4 have included SonoSync, a cleared function in the primary predicate V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 (K240631), for diagnostic image viewing and review as similar indications for use of predicate.
- The proposed V5/H5/XV5/XH5, V4/H4/XV4/XH4 diagnostic ultrasound system and primary predicate V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6(K240631) diagnostic ultrasound system have the same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The proposed V5/H5/XV5/XH5, V4/H4/XV4/XH4 diagnostic ultrasound system and primary predicate V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6(K240631) diagnostic ultrasound system 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. The V5/H5/XV5/XH5, V4/H4/XV4/XH4 diagnostic ultrasound system and its 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)
IEC 60601-1-2	IEC60601-1-2:2014 [Including AMD 1:2021] , Medical electrical equipment - Part 1-2: General requirements for basic safety and essential

	performance - EMC
IEC 60601-2-37	IEC 60601-2-37 Edition 2.1 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	AAMI / ANSI / ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO14971	ISO 14971:2019, Medical devices - Application of risk management to medical devices
NEMA UD 2-2004	NEMA UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3

[The Summary of Testing for HeartAssist]

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

We tested adult and fetal hearts individually in three areas: view recognition, segmentation and size measurement.

☐ View recognition test

○ A deep learning based view recognition algorithm was validated using 280 fetal heart and 540 adult heart images collected at five hospitals.

○ (Fetus) The average recognition accuracy is 93.21% (threshold 89%)

○ (Adult) The average recognition accuracy is 98.31% (threshold 84%)

☐ Segmentation test

○ We use same datasets of view recognition test.

○ (Fetus) The average dice-score is 0.88 (threshold 0.8)

○ (Adult) The average dice-score is 0.93 (threshold 0.9)

☐ Size measurement test

○ We use same datasets of segmentation test.

○ (Fetus) The error rate of area measured value is 8% or less

○ (Fetus) The error rate of angle measured value is 4% or less

○ (Fetus) The error rate of circumference measured value is 11% or less

○ (Fetus) The error rate of diameter measured value is 11% or less

- ○ (Adult, B-mode) Pass if the PCC value is 0.8 or more of spec
- ○ (Adult, M-mode) Pass if the PCC value is 0.8 or more of spec
- ○ (Adult, Doppler-mode) Pass if the PCC value is 0.8 or more of spec

* The Pearson's correlation coefficient (PCC) that is a representative way to measure similarity is a measure of linear correlation between two sets of data. The HeartAssist's PCC was calculated to evaluate the auto measurement using the ground truth, defined as the cardiologist's measurements.

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

- ☐ (Fetus) A total 80 individuals contributed to the validation dataset.
- ☐ (Adult) A total 30 individuals contributed to the validation dataset.

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

- ☐ (Fetus) Each individual contributed at least 1 static image per view location
- ☐ (Fetus) Validation dataset included 280 static images of 2D sequences.
- ☐ (Adult) Each individual contributed at least 1 static image per view location
- ☐ (Adult) Validation dataset included 540 static images of 2D sequences.

▣ Demographic distribution:

- ☐ Gender: Male and Female
- ☐ Age: Reproductive age, specific age not collected
- ☐ Ethnicity/Country: Americans and Koreans

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

- ☐ We divided the fetal ultrasound images, depending on the ASE and AIUM guidelines, into 7 fetal heart views and 18 adult heart views.
- ☐ (Fetus) BMI: Ranging from 17 – 45.4, distributed across underweight, standard range or overweight categories
- ☐ (Fetus) Gestational age: Weeks from 17 - 38, distributed across 2nd trimester or 3rd trimester categories
- ☐ (Adult) BMI: Ranging from 14.88 - 49.2, distributed across underweight, standard range or overweight categories.
- ☐ (Adult) Age : Start from adulthood at age 20, distributed across the following ranges: 20-40 years, 40-60 years, and 60 years and above.

▣ Information about equipment and protocols used to collect images

- ☐ We acquired the data set with SAMSUNG MEDISON's ultrasound systems 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):

☐ (Fetus) 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.

☐ (Adult) Two cardiologists with at least 10 years of experience and two sonographers with at least 10 years of experience. These experts manually traced the contours of the heart and the signal outline on the images.

▣ 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 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.
- ○ The average dice-score is 0.919 (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 77 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 320 static images of 2D sequences.

▣ Demographic distribution:

☐ Gender: Female

☐ Age: Reproductive age, specific age not collected

☐ Ethnicity/Country: Americans and Koreans

▣ 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 – 49.2, distributed across underweight, standard range or overweight categories.

☐ Gestational age: Weeks from 8 – 37, 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 in order to secure diversity of the data set: Mix of data from retrospective data collection and prospective data collection in clinical practice.

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

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

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

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

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

[The Summary of Testing for ViewAssist]

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

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

☐ View recognition test

○ A deep learning based view recognition algorithm was validated using 680 fetal ultrasound images and fetal biometry images collected at two hospitals.

○ The average recognition accuracy is 94.26% (threshold 89%)

☐ Anatomy annotation(segmentation) test

○ We use same datasets of view recognition test.

○ The average dice-score is 0.885 (threshold 0.8)

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

☐ A total 77 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 680 static images of 2D sequences.

▣ Demographic distribution:

☐ Gender: Female

☐ Age: Reproductive age, specific age not collected

☐ Ethnicity/Country: Americans and Koreans

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

☐ We divided the fetal ultrasound images, depending on the ISUOG and AIUM guidelines, into 13 views.

☐ BMI: Ranging from 14 – 49.2, distributed across underweight, standard range or overweight categories.

☐ Gestational age: Weeks from 8 – 37, 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 in order to secure diversity of the data set: Mix of data from retrospective data collection and prospective data collection in clinical practice.

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

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

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

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

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

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

[The Summary of Testing for 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 450 sagittal uterus images and 150 transverse uterus images collected at three hospitals.
- ○ The average dice-score of uterus is 96%
- ○ The average dice-score of endometrium is 92%

☐ Feature points extraction test

- ○ We acquired, in addition, 48 sagittal and 44 transverse plane images of uterus collected at three hospitals.
- ○ The errors of uterus feature points are 5.8 mm or less
- ○ The errors of endometrium feature points are 4.3 mm or less

☐ Size measurement test

- ○ We use same data set of Feature points extraction test
- ○ The errors of Measurements performance are 2.0 mm or less

▣ 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 at least 1 static image per view location.

▣ Demographic distribution:

☐ Gender : Female

☐ Age : Reproductive age, specific age not collected

☐ Ethnicity/Country : All Koreans

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

☐ BMI: Ranging from 17–50.6, distributed across underweight, standard range or overweight categories,

■ overweight (25 and Above), standard range (18.5 - 24.9), underweight (below 18.5)

☐ Age : Ranging from 18 – 58, divided into 10-year age categories.

▣ Information about equipment and protocols used to collect images

☐ We acquired the data set with SAMSUNG MEDISON's ultrasound systems and probes 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) :

☐ Segmentation of the ground truth was generated by three participating OB/GYN experts with more than 10 years' experience.

☐ The set of images (uterus and endometrium) were divided into 3 subsets and the three participating OB/GYN experts each drew the ground truths for one of the subsets.

☐ The ground truths drawn by an expert were cross-checked by the other two experts. Any images that do not meet the inclusion/exclusion criteria were excluded from the set of images.

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

☐ Data used for test/training validation purpose are completely separated from the ones during training process and there is no overlap between the two.

[The Summary of Testing the nerve detection 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 Detection function.

☐ Detection test

◌ A deep learning-based detection algorithm was validated using a total of 3,999 images collected at eight hospitals.

◌ The average accuracy from 10 image sequence was 89.91% (95% Confidence Interval: 86.51, 93.35), and the average speed (fps) was 3.98 (95% CI: 3.98, 3.99). To calculate accuracy, total number of correct detections is divided by test image number, in which a detection is considered correct if value of dice coefficient is 0.5 or more for each image.

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

☐ A total of 22 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 ten images for each 2D sequence.

☐ Validation dataset includes a total of 3,999 images extracted from 2D sequences.

▣ Demographic distribution:

☐ Gender: Male (28%) / Female (72%)

☐ Age: 22–68 (mean: 42.7)

☐ BMI: 16.0–31.5 (mean: 21.5)

☐ Ethnicity/Country: Koreans

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

☐ We divided the nerve ultrasound images into ten target nerves.

☐ BMI: ranging from 16.0 to 31.5, distributed across underweight, standard range or overweight categories.

☐ Gender: Both the male (28%) and female (72%) are used for validation.

▣ Information about equipment and protocols used to collect images

☐ We acquired the dataset with SAMSUNG MEDISON's ultrasound systems 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 GT data were built by three participating experts. Nerve areas in all acquired images for training, tuning and validation were manually drawn by an anesthesiologist with more than 10 years of experience in pain management. The doctors who scanned the ultrasound were directly involved for the construction of GT data. Drawn GT rectangles covered the nerve region perfectly.

☐ For verification of GT, other doctors with more than 10 years of experience checked every frame of each scanned sequences. If they did not agree on median nerve locations, necessary corrections were made to make the final GT.

▣ 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 the nerve segmentation 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 Segmentation function.

☐ Segmentation test

○ A deep learning based segmentation algorithm was validated using 1,675 nerve images collected at ten hospitals.

○ The average accuracy from nine image sequences is 98.30% (95% Confidence Interval: 95.43, 100), and average speed (fps) was 3.98 (95% CI: 3.98, 3.98). To calcuate accuracy, total number of correct segmentations is divided by test image number, in which a segmentation is considered correct if value of dice coefficient is 0.5 or more for each image.

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

☐ A total of 20 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 ten images for each 2D sequence.

☐ Validation dataset includes a total of 1,675 images extracted from 2D sequences.

▣ Demographic distribution:

☐ Gender: Male (50%) / Female (50%)

☐ Age: 27–85 (mean: 41.2)

☐ BMI: 17.8–30.8 (mean: 23.6)

☐ Ethnicity / Country: Koreans

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

☐ We divided the nerve ultrasound images into nine target nerves.

☐ BMI: ranging from 17.8 to 30.8, distributed across underweight, standard range or overweight categories.

☐ Gender: Male 50% and Female 50%

▣ Information about equipment and protocols used to collect images

☐ We acquired the dataset with SAMSUNG MEDISON's ultrasound systems 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 GT data were built by three participating experts. Nerve areas in all acquired images for training, tuning and validation were manually drawn by an anesthesiologist with more than 10 years of experience in pain management. The doctors who scanned the ultrasound were directly involved for the construction of GT data. Drawn GT contours covered the nerve region perfectly.

☐ For verification of GT, other doctors with more than 10 years of experience checked every frame of each scanned sequences. If they did not agree on nerve and other organs contours, necessary corrections were made to make the final GT.

▣ 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 V5/H5/XV5/XH5, V4/H4/XV4/XH4 diagnostic ultrasound system did 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 the V5/H5/XV5/XH5, V4/H4/XV4/XH4 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**