February 13, 2023

Samsung Medison Co., Ltd.
% Ju Jee Young
Regulatory Affairs Specialist
Samsung Medison Co. Ltd.
3366, Hanseo-ro, Nam-myeon
Hongcheon-gun, Gangwon-do 25108
REPUBLIC OF KOREA

Re: K223387
Trade/Device Name: V8 Diagnostic Ultrasound System, V7 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: January 16, 2023
Received: January 18, 2023

Dear Ju Jee Young:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223387

Device Name
V8 Diagnostic Ultrasound System
V7 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, 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

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:

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

1. Date Prepared – November 04, 2022

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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   Vice President
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5. Proposed Device
   - Common/Usual Name : Diagnostic Ultrasound System and Accessories
   - Proprietary Name : V8 Diagnostic Ultrasound System
     V7 Diagnostic Ultrasound System
   - Regulation Name : Ultrasonic pulsed doppler imaging system
   - Regulatory Class : Class II
   - Product Code : IYN, IYO, ITX
   - Regulation Number : 21 CFR 892.1550, 892.1560, 892.1570

6. Predicate Devices
   - V8 / V7 Diagnostic Ultrasound System (K220975) – Primary
   - RS85 / RS80 EVO Diagnostic Ultrasound System (K221117) – Reference
   - HS50 / HS60 Diagnostic Ultrasound System (K210068) – Reference
   - HERA W9 / HERA W10 Diagnostic Ultrasound System (K220043) – Reference

7. Device Description
   The V8 / V7 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, Multi-Image mode(Dual, Quad), 3D/4D mode. The V8 / V7 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 V8 / V7 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

The V8 / V7 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.

9. Technological Comparison to Predicate Devices

The V8 / V7 employ the same fundamental scientific technology as its predicate devices V8 / V7 (K220975), RS85/ RS80 EVO(K221117), HS50 / 60 (K210068) and HERA W9 / W10(K220043) System.

10. Determination of Substantial Equivalence

Comparison to Predicate: The V8 / V7 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 V8 / V7 and the primary predicate V8 / V7 (K220975) have the same clinical intended use.
- The proposed V8 / V7 and the primary predicate V8 / V7 (K220975) have the same imaging modes and modes of operation.
- The proposed V8 / V7 have expanded the detection nerve type (Head: Greater Occipital / Leg : Sciatic, Common Peroneal, Tibial) of NerveTrack based on AI in the previously cleared V8/V7 (K220975)
- The proposed V8 / V7 have included the BiometryAssist and ViewAssist which are based on AI version from the previously cleared HERA W9/ HERA W10 (K220043).

- The proposed V8 / V7 have included the HeartAssist which is based on the AI version from the previously cleared HERA W9/ HERA W10 (K220043) and expanded the clinical application to adult.
- The proposed V8 / V7 have included the QUS(TSI/TAI) and EzHRI from the previously cleared RS85/ RS80 EVO (K221117).
- The proposed V8 / V7 have included the additional matching methods of S-Fusion in the previously cleared V8/V7 (K220975)
- The proposed V8 / V7 have included the EzPrep for work-flow improvement.
- The proposed V8/V7 have included one new transducer miniER7. PA4-12B and LA2-9S have been migrated from the predicate RS85/ RS80 EVO (K221117). Only V7 has included four new transducers LA4-18AD, EV2-11ARE, EV2-11AVE and CV1-8AE, and LA3-14AD has been migrated from the predicate HS50 / 60 (K210068). Biocompatibility test has been conducted for the new transducers, and image performance tests have been conducted for the new and migrated transducers.
- The proposed V8 / V7 and primary predicate V8 / V7 (K220975) have the same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The proposed V8 / V7 and primary predicate V8 / V7 (K220975) 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 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 V8 / V7 and its applications comply with the following FDA-recognized standards.

Reference No.	Title
IEC 60601-1	AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
IEC 60601-1-2	IEC60601-1-2: 2020-09(4.1 Edition) , Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - EMC
IEC 60601-2-37	IEC 60601-2-37 Edition 2.0 2007, Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance

	of ultrasonic medical diagnostic and monitoring equipment
ISO10993-1	AAMI / ANSI / ISO 10993-1:2009/(R)2013, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO14971	ISO 14971:2019, Medical devices - Application of risk management to medical devices
NEMA UD 2-2004	NEMA UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3

[The validation for expansion of the detection nerve of NerveTrack based on AI]

These are the details on validation of the AI algorithm used for all the new and improved AI-based features that includes expansion of the use of NerveTrack feature and the information about the dataset the device was tested on.

Acceptance Criteria:

Validation Type	Definition	Acceptance Criteria
Accuracy (%)	$\frac{\text{Number of correctly detected frames}}{\text{Total number of frames with nerve}} \times 100$	≥ 80%
Speed (FPS)	$\frac{1000}{\text{Average latency time of each frame (msec)}}$	≥ 2 FPS

Summary Performance data, Standard Deviations & Confidence Intervals:

Validation Type	Average	Standard Deviation	95% CI
Accuracy (%)	90.3	4.8	88.6 to 92.0
Speed (FPS)	3.54	0.13	3.47 to 3.61

Testing Data Information:

	Females	Males	Total
Number of Subjects	13	5	18
Number of Images	1,168	978	2,146
Age range	32~68	22~50	22~68
Average age	45.7	35.0	42.7
BMI range	16~27.1	31.5	16~31.5
Average BMI	20.5	31.5	21.5
Ethnicity	All Koreans		

The standalone performance of NerveTrack was evaluated for BMI (Body Mass Index) subgroups, which are potential subject and image confounder. For subgroup analysis, we divided BMI values into four groups according to the CDC (Centers for Disease Control and Prevention) definition for adult overweight & obesity. They are underweight (BMI < 18.5), healthy weight (18.5 ≤ BMI < 25), overweight (25 ≤ BMI < 30), and obesity (BMI ≥ 30).

We evaluated the performance for the four groups and observed very good generalizability for BMI, because the average accuracy of all subgroups is included within the confidence interval of the accuracy for the full dataset. The depth range was set 2.5cm to 4.5cm, and the maximum depth of the detected nerve was 3.31 cm from skin. When we calculate the relationship between BMI and the maximum depth of nerves, it illustrates a low correlation and no significant difference of NerveTrack performance according to the patient's BMI information. Therefore, we believe that our model is robust even if the cases with various BMI information exist.

When collecting scan data, the speed of the probe varies approximately from 1cm to 5cm per second. The orientation of the probe was short-axis imaging and perpendicular to the skin, obtained by sliding the probe in both the proximal and distal directions. All the nerve data were acquired on Samsung ultrasound devices including V8.

Ten anesthesiologists and five sonographers with more than 10 years of experience participated to establish the ground truth (GT) for the location of 12 different kinds of nerves. One anesthesiologist who scanned the ultrasound directly drew the GT of nerve location, and two or more other anesthesiologists and sonographers reviewed and confirmed that it was correct. If there was any mistake during the review, it was revised again.

The training data used for the training of the NerveTrack algorithm are independent of the data used to test the NerveTrack algorithm.

[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 0.928 (threshold 0.8)

☐ Size measurement test

- ○ We use the 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(Nuchal Translucency) measured value is 1mm or less.

▣ 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.

▣ Information about equipment and protocols used to collect images

- ☐ We acquired the data set with the three of SAMSUNG MEDISON's ultrasound systems (W10, W9 and V8) in order to secure diversity of the data set: Mix of data from retrospective data collection and prospective data collection in clinical practice (Only V8 images have been used for the Performance Test).

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

- ☐ All acquired images for training, tuning and validation were first classified into the correct views by three participating experts. Afterwards, corresponding anatomy areas were manually drawn for each of the images.
- ☐ The participating experts were composed of obstetricians with more than 20 years of experience and two sonographers with more than 10 years of experience; all in fetal cardiology. The entire process was supervised by another obstetrician with more than 25 years of experience.

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

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

[The Summary of Testing for 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 heart and fetal biometry images collected at two hospitals.
- ○ The average recognition accuracy is 94.56% (threshold 89%)

☐ Anatomy annotation(segmentation) test

- We use the same datasets of view recognition test.
- The average dice-score is 0.898 (threshold 0.8)

▣ 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, according to the ISUOG and AIUM guidelines, into 17 views.

▣ Information about equipment and protocols used to collect images

☐ We acquired the data set with the three of SAMSUNG MEDISON's ultrasound systems (W10, W9 and V8) in order to secure diversity of the data set: Mix of data from retrospective data collection and prospective data collection in clinical practice (Only V8 images have been used for the Performance Test).

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

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

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

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

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

[The Summary of Testing for 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 the three areas: view recognition, segmentation and size measurement.

☐ View recognition test

- ○ A deep learning based view recognition algorithm was validated using 888 fetal heart and 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 the 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 the 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 greater than the specification.
- ○ (Adult, M-mode) Pass if the *PCC value is 0.8 or greater than the specification.
- ○ (Adult, Doppler-mode) Pass if the *PCC value is 0.8 or greater than the specification.

* The Pearson 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.

▣ 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, according to the ASE and AIUM guidelines, into 7 fetal heart views and 16 adult heart views.

▣ Information about equipment and protocols used to collect images

☐ We acquired the data set with the three of SAMSUNG MEDISON's ultrasound systems (W10, W9 and V8) in order to secure diversity of the data set: Mix of data from retrospective data collection and prospective data collection in clinical practice (Only V8 images have been used for the Performance Test).

▣ 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) We employed the help of four professionals: 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 among the three.

12. Summary of Clinical Tests

The proposed device V8 / V7 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 V8 / V7 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**