



June 12, 2024

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

Re: K240516

Trade/Device Name: RS85 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: February 23, 2024
Received: May 13, 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.

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

DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices

OHT8: Office of Radiological Health

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K240516

Device Name

RS85 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, Intraoperative, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans rectal, Trans vaginal, Muscular Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric, 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, M mode, Color Doppler mode, Pulsed Wave (PW) Doppler mode, Continuous Wave (CW) Doppler mode, Tissue Doppler Imaging (TDI) mode, Tissue Doppler Wave (TDW) mode, Power Doppler (PD) mode, ElastoScan™ Mode, Multi Image mode(Dual, Quad), Combined modes, 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 – Feb 23, 2024
2. Manufacturer
SAMSUNG MEDISON CO., LTD.
3366, Hanseo-ro, Nam-myeon,
Hongcheon-gun, Gangwon-do 25108,
REPUBLIC OF KOREA
3. Primary Contact Person
So-Yeon Jang
Regulatory Affairs Specialist
Phone: +82.2.2194.0875
Fax: +82. 2.2194.0273
Email: sy24.jang@samsungmedison.com
4. Secondary Contact Person
Ninad Gujar
Vice President of Regulatory & Quality
Phone: +1.978.564.8632
Fax: +1.978.564.8677
Email: ngujar@neurologica.com

5. Proposed Device

Common Name:	Diagnostic Ultrasound System and Accessories
Trade/Device Name:	RS85 Diagnostic Ultrasound System
Additional Marketing Name :	RS85 Prestige Diagnostic Ultrasound System
Regulation Name:	Ultrasound pulsed Doppler imaging system
Panel/ Regulatory Class:	Radiology / II
Product Code:	IYN, IYO, ITX
Regulation No.	892.1550, 892.1560, 892.1570

6. Predicate Device
 - RS85 Diagnostic Ultrasound System (K221117) – Primary
 - V8 Diagnostic Ultrasound System (K231772) – Reference
 - Collaboration Live (K212777) – Reference
 - ScanNav Anatomy Peripheral Nerve Block (DEN220024) - Reference

7. Device Description

The RS85 is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as 2D mode, M mode, Color Doppler imaging, Power Doppler imaging (including Directional Power Doppler mode; S-Flow), PW Spectral Doppler mode, CW Spectral Doppler mode, Harmonic imaging, Tissue Doppler imaging, Tissue Doppler Wave, 3D imaging mode (real-time 4D imaging mode), Elastoscans⁺ Mode, MV-Flow Mode or as a combination of these modes. The RS85 also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information that may aid in making a diagnosis by competent health care professionals. the RS85 has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

8. Indications for Use

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

The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Intraoperative, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric, 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, M mode, Color Doppler mode, Pulsed Wave (PW) Doppler mode, Continuous Wave (CW) Doppler mode, Tissue Doppler Imaging (TDI) mode, Tissue Doppler Wave (TDW) mode, Power Doppler (PD) mode, ElastoScan™ Mode, Multi-Image mode(Dual, Quad), Combined modes, 3D/4D mode.

9. Technological Comparison to Predicate Devices

The RS85 employs the same fundamental scientific technology as its predicate devices.

10. Determination of Substantial Equivalence

Comparison to Predicate: The RS85 is substantially equivalent to the predicate device with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The system is all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The proposed RS85 and the primary predicate RS85 (K221117) have the same clinical intended use.
- The proposed RS85 and the primary predicate RS85 (K221117) have the same imaging modes and modes of operation.
- The proposed RS85 has included two transducers (miniER7, L3-22) migrated from the predicate V8 (K231772).
- The proposed RS85 has included the EPP (Extended Power Pack) as an additional power supply.
- The proposed RS85 has included the 27 inch OLED monitor.
- The proposed RS85 has included NerveTrack previously cleared in the predicate V8 (K231772) based on AI technology, expanding the application of Segmentation and adding a sub-function, EzNerveMeasure.
- The proposed RS85 has indicated SonoSync, a cleared function in the primary predicate RS85 (K221117), for diagnostic image viewing and review as similar indications for use as Collaboration Live (K212777).
- The proposed RS85 has included Mobile Export as an optional feature, which has been previously cleared in the predicate V8 (K231772).
- The proposed RS85 has included three new biopsy kits with already cleared components.
- The proposed RS85 and the primary predicate RS85(K221117) 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 Test

The proposed device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety, and has been found to conform with applicable medical device safety standards. The RS85 and its applications comply with the following FDA-recognized standards.

Reference No.	Title
IEC 60601-1	AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
IEC 60601-1-2	IEC60601-1-2: 2020-09(4.1 Edition) , Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - EMC
IEC 60601-2-37	IEC 60601-2-37 Edition 2.0 2007, Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-4-2	IEC TR 60601-4-2 Edition 1.0 2016-05, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
ISO10993-1	AAMI / ANSI / ISO 10993-1:2018/(R)2013, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO14971	ISO 14971:2019, Medical devices - Application of risk management to medical devices
NEMA UD 2-2004	NEMA UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3

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

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

☐ Detection test

- A deep learning based detection algorithm was validated using 3,999 nerve images collected at eight hospitals.
- The average accuracy from 10 image sequence was 89.6% (95% Confidence Interval: 86.41, 92.79), and the average speed (fps) was 14.49 (95% CI: 13.86, 15.11).
To calculate accuracy, total number of correct detection 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.

☒ 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, depending on clinical need, into ten target nerves.

 - ☒ Information about equipment and protocols used to collect images
 - ☐ We acquired the dataset with the four of SAMSUNG MEDISON's ultrasound systems (HS40, V8, RS80A, and RS85) 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 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 validation for the segmentation of NerveTrack based on AI]
- ☒ Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance.

We tested on NerveTrack Segmentation

- ☐ Segmentation test
 - A deep learning based segmentation algorithm was validated using 1,753 nerve images collected at ten hospitals.
 - The average accuracy from nine image sequence is 99.78% (95% Confidence Interval: 99.34, 100), and average speed (fps) was 10.44 (95% CI: 10.03, 10.85). The average Dice similarity coefficient is 90.44% (95% Confidence Interval: 86.19, 94.69) and 95% Hausdorff distance excluding bone is 18.69 pixels (95% Confidence Interval: 9.21, 28.17). (Hausdorff distance for bone is 93.51 pixels (95% Confidence Interval: 27.31, 159.72)).
 - To calculate accuracy, total number of correct segmentation 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.

■ 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, depending on clinical need, into nine target nerves.

■ Information about equipment and protocols used to collect images

- ☐ We acquired the dataset with the four of SAMSUNG MEDISON's ultrasound systems (HS40, V8, RS80A, and RS85) 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.

[The validation for EzNerveMeasure of NerveTrack based on AI]

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

We tested on Flattening Ratio (FR) and Cross-sectional Area (CSA) of NerveTrack EzNerveMeasure.

- ☐ A deep learning based detection algorithm was validated using 50 median nerve images collected at a hospital.
- ☐ FR and CSA measure test
 - The average error rate of FR was 6.11% (95% Confidence Interval: 5.10, 7.12), and the average error rate of CSA was 9.75 (95% CI: 8.54, 10.96).
Error Rate (%) is calculated as follows: (GT Value - Measured Value)/GT Value x 100.

■ Demographic distribution:

- ☐ Gender: Female
- ☐ Age: 38~68 (mean: 45.8)
- ☐ BMI: 16-27.1 (mean: 20.53)
- ☐ Ethnicity/Country: Koreans

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

- ☐ We divided the nerve ultrasound images, depending on clinical need, into two types of median nerves: wrist and elbow.

■ Information about equipment and protocols used to collect images

- ☐ We acquired the dataset with the two of SAMSUNG MEDISON's ultrasound systems (HS40 and RS80A) 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 validation for SonoSync]

Pre-determined criteria were utilized in validation tests to assess whether remote viewing and reviewing with SonoSync matched the performance of local ultrasound systems.

Labeling materials is provided to inform users about the necessary specifications for safely and effectively conducting remote diagnostic reviews and viewing.

12. Summary of Clinical Tests

The proposed device RS85 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 RS85 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