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

June 24, 3021

Re: K210959
Trade/Device Name: RS85 Diagnostic Ultrasound System, RS80 EVO 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: May 25, 2021
Received: May 27, 2021

Dear Scully 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 (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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K210959

Device Name
RS85 Diagnostic Ultrasound System
RS80 EVO 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary:

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

1. Date Prepared – March 29, 2021

2. Manufacturer
   SAMSUNG MEDISON CO., LTD.
   3366, Hanseo-ro, Nam-myeon,
   Hongcheon-gun, Gangwon-do 25108,
   REPUBLIC OF KOREA

3. Primary Contact Person
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   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 RS80 EVO 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 (K192903)

7. Device Description
   The RS85 / RS80 EVO are 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), Elastoscan^{+} Mode, MV-Flow Mode or as a combination of these modes.
   The RS85 / RS80 EVO also give 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 / RS80 EVO have 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. Technology

The RS85 / RS80 EVO employ the same fundamental scientific technology as its predicate device.

10. Determination of Substantial Equivalence

Comparison to Predicate: The RS85 / RS80 EVO are substantially equivalent to the predicate device with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The proposed RS85 / RS80 EVO and predicate RS85(K192903) have the same clinical intended use.
- The proposed RS85 / RS80 EVO and predicate RS85(K192903) have the same imaging modes and modes of operation.
- The proposed RS85 / RS80 EVO added two new transducers (LA4-18A, LA3-22AI).
- The proposed RS85 / RS80 EVO and predicate RS85(K192903) have same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The proposed RS85 / RS80 EVO and predicate RS85(K192903) 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.

RS85 and RS80 EVO are the same systems that provide only different option configurations. There is an addition of new transducers (LA4-18A, LA3-22AI) compare to previously cleared RS85 (K192903) system.

The material and design changes of MMPT3-7 transducer will be applied to all SAMSUNG

MEDISON products after 510(k) clearance.

The material change of Endocavity transducers (EV2-10A, EA2-11AR/EA2-11AV) will be applied to all SAMSUNG MEDISON products after 510(k) clearance.

11. Summary of Non-Clinical Test

The proposed devices have 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 / RS80 EVO and its applications comply with voluntary standards.

Test	Standards and FDA Guidance
Risk Management	ISO 14971 Second edition 2007 Medical devices - Application of risk management to medical devices
Electrical Safety	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010 /(R)2012 Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance.
Electromagnetic Compatibility	IEC60601-1-2: 2014(4th Edition) Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
Biocompatibility	AAMI / ANSI / ISO 10993-1:2009/(R)2013, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
Reprocessing Medical Devices	FDA Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling issued on March 17, 2015, revised June 9, 2017.
Software/Firmware-driven Functionality	All migrated software functionality was evaluated using the same test criteria as the predicate for all applicable imaging modes to ensure that migration into a new system design did not compromise image quality with respect to the intended use of each feature. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued on May 11, 2005
Ultrasound Safety	Marketing Clearance of Diagnostic Ultrasound Systems and Transducers issued June 27, 2019
	IEC60601-2-37:2007 + A1:2015, Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
	NEMA UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3

12. Summary of Clinical Tests

The subject of this premarket submission, RS85 / RS80 EVO, did not require clinical studies to support substantial equivalence.

13. Conclusion

SAMSUNG MEDISON considers the RS85 and RS80 EVO to be as safe, as effective, and performance is substantially equivalent to the predicate device.

- END of 510(K) Summary