Samsung Medison Co., Ltd.
Yoojung Choi
Regulatory Affairs Specialist
3366, Hanseo-Ro, Nam-Myeon
Hongcheon-Gun, Gangwon-do 25108
Republic Of Korea

March 27, 2026

Re: K254099
Trade/Device Name: EVO Q30 Diagnostic Ultrasound System; EVO Q20 Diagnostic Ultrasound System; EVO Q10 Diagnostic Ultrasound System; EVO XQ30 Diagnostic Ultrasound System; EVO XQ20 Diagnostic Ultrasound System; EVO XQ10 Diagnostic Ultrasound System; EVO QH30 Diagnostic Ultrasound System; EVO QH20 Diagnostic Ultrasound System; EVO QH10 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, LLZ
Dated: December 17, 2025
Received: December 19, 2025

Dear Yoojung Choi:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Digitally signed by Michael D. O'hara -S
Date: 2026.03.27 08:58:29 -04'00' For

Yanna Kang
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254099

Please provide the device trade name(s).

EVO Q30 Diagnostic Ultrasound System; EVO Q20 Diagnostic Ultrasound System; EVO Q10 Diagnostic Ultrasound System; EVO XQ30 Diagnostic Ultrasound System; EVO XQ20 Diagnostic Ultrasound System; EVO XQ10 Diagnostic Ultrasound System; EVO QH30 Diagnostic Ultrasound System; EVO QH20 Diagnostic Ultrasound System; EVO QH10 Diagnostic Ultrasound System

Please provide your Indications for Use below.

EVO Q30 Diagnostic Ultrasound System; EVO Q20 Diagnostic Ultrasound System; EVO Q10 Diagnostic Ultrasound System; EVO XQ30 Diagnostic Ultrasound System; EVO XQ20 Diagnostic Ultrasound System; EVO XQ10 Diagnostic Ultrasound System; EVO QH30 Diagnostic Ultrasound System; EVO QH20 Diagnostic Ultrasound System; EVO QH10 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, Dermatology, 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 (including emergency rooms), 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, MV-Flow mode, Multi-Image mode(Dual, Quad), 3D/4D mode.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary: K254099

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

1. Date Prepared – Dec 17, 2025

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
   Phone: +1.978.564.8632
   Fax: +1.978.564.8677
   Email: ngujar@samsunghme.com

5. Proposed Device
   - Common/Usual Name : Diagnostic Ultrasound System and Accessories
   - Proprietary Name : EVO Q30 Diagnostic Ultrasound System
     EVO Q20 Diagnostic Ultrasound System
     EVO Q10 Diagnostic Ultrasound System
     EVO XQ30 Diagnostic Ultrasound System
     EVO XQ20 Diagnostic Ultrasound System
     EVO XQ10 Diagnostic Ultrasound System
     EVO QH30 Diagnostic Ultrasound System
     EVO QH20 Diagnostic Ultrasound System
     EVO QH10 Diagnostic Ultrasound System
     Regulation Name : Ultrasonic pulsed doppler imaging system
   - Regulatory Class : Class II
   - Product Code : IYN, IYO, ITX, LLZ
   - Regulation Number : 21 CFR 892.1550, 892.1560, 892.1570, 892.2050

6. Predicate Device
   - HM70 EVO Diagnostic Ultrasound System (K233112)

7. Reference Devices
   - HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System (K252018)
   - V8 Diagnostic Ultrasound System; cV8 Diagnostic Ultrasound System; V7 Diagnostic

Ultrasound System; cV7 Diagnostic Ultrasound System; V6 Diagnostic Ultrasound System; cV6 Diagnostic Ultrasound System; V5 Diagnostic Ultrasound System; cV5 Diagnostic Ultrasound System; V4 Diagnostic Ultrasound System; cV4 Diagnostic Ultrasound System (K250999)

8. Device Description

EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 Diagnostic Ultrasound System are general purpose, portable (without cart)/mobile (with cart), software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as 2D mode, Color Doppler mode, Power Doppler (PD) mode, M mode, Pulsed Wave (PW) Doppler mode, Continuous Wave (CW) Doppler mode, Tissue Doppler Imaging (TDI) mode, Tissue Doppler Wave (TDW) mode, ElastoScan Mode, Combined modes, MV-Flow mode, Multi-Image mode(Dual, Quad), 3D/4D mode.

EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 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.

EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 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.

9. Indication 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, Intra-operative, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric, Thoracic, Dermatology, 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 (including emergency rooms), 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(2D/C/PW, 2D/PD/PW, 2D/C/CW, 2D/PD/CW, 2D/C/M, 2D/TDI/TDW, Dual live), MV-Flow mode, Multi-Image mode(Dual, Quad), 3D/4D mode.

10. Technological Comparison to Predicate Device

EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 Diagnostic Ultrasound System employ the same fundamental scientific technology as the predicate device.

11. Determination of Substantial Equivalence

- Comparison to Predicate: EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 Diagnostic Ultrasound System 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 EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 Diagnostic Ultrasound System have included the clinical applications of intra-operative and thoracic applications.
- The proposed EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 Diagnostic Ultrasound System and predicate device have included MV-Flow mode.
- The proposed EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 Diagnostic Ultrasound System have included multiple transmit channels.
- The proposed EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 Diagnostic Ultrasound System have included accessories: Video Output Device, Pencil Gender and WLAN Adapter.
- The proposed EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 Diagnostic Ultrasound System have included the following new software features: IDEA, IETA, EzPictogram, Voice Command, EzGuide, EzDiagram, MirrorTouch and TouchSign.

  - IDEA: IDEA is to provide the latest IDEA protocol guideline standardized for the workflow improvement to the ultrasound system for the assessment of endometriosis. (cleared in the reference device, HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System under K252018)
  - IETA: IETA is to provide the latest IETA protocol guideline standardized for the workflow improvement to the ultrasound system for the assessment of the endometrium and uterine cavity. (cleared in the reference device, HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System under K252018)
  - EzPictogram: EzPictogram displays the location of the fibroid in a pictogram. (cleared in the reference device, HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System under K252018)

- Voice Command: Voice Command is a feature that allows the user to control the ultrasound system with voice. (cleared in the reference device, HERA Z20 Diagnostic Ultrasound System; HERA Z20e Diagnostic Ultrasound System; HERA Z20s Diagnostic Ultrasound System; R20 Diagnostic Ultrasound System; HERA Z30 Diagnostic Ultrasound System; R30 Diagnostic Ultrasound System under K252018)
- EzGuide: EzGuide provides on-screen anatomical guidance and reference images to support users in probe placement and scanning direction.
- EzDiagram: EzDiagram enables structured documentation and reporting during protocols like lung scan or eFAST.
- MirrorTouch: MirrorTouch is a feature that mirrors the monitor display onto a touchscreen.
- TouchSign: TouchSign is a digital signature feature that allows users to sign documents directly within the system.

- The proposed EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 Diagnostic Ultrasound System have included the following new probes compared to predicate device: LA2-9SD, LA3-16ADc, LA2-16Sc, L3-16D, PA1-5AED, PA2-9S and PA3-15S.

- The proposed EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 Diagnostic Ultrasound System have included WLAN, supporting Wi-Fi and Bluetooth modules.

- The proposed EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 Diagnostic Ultrasound System and the predicate device have the same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.

- The proposed EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 Diagnostic Ultrasound System and the predicate device 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.

12. 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. EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 Diagnostic Ultrasound System and their 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) [Including Amendment 2 (2021)]
IEC 60601-1-2	ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021], Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]
IEC 60601-2-18	IEC 60601-2-18:2009, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
IEC 60601-2-37	IEC 60601-2-37:2024, 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
ISO 10993-1	ANSI AAMI 10993-1 Fifth edition 2018-08, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 14971	ANSI AAMI 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

13. Summary of Clinical Tests

The proposed device EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 Diagnostic Ultrasound System does not require clinical studies to demonstrate substantial equivalence.

14. Conclusion

Since the predicate device 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 EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 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