August 27, 2026

Samsung Electronics Co., Ltd
℅ Jaesang Noh
Regulatory Affairs, Principal Professional
129 Samsung-Ro, Yeongtong-gu,
SUWON-SI GYEONGGI-DO 16677
REPUBLIC OF KOREA

Re: K260481
Trade/Device Name: GC85A
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR
Dated: February 2, 2026
Received: July 30, 2026

Dear Jaesang Noh:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

for 

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260481

Device Name
GC85A

Indications for Use *(Describe)*
The GC85A Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted accordance with requirements of 21 CFR 807.92

1. **Date:** February 11, 2026

2. **Submitter**
   A. Company Name: SAMSUNG ELECTRONICS Co., Ltd.
   B. Address: 129, Samsung-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16677, Republic of Korea

3. **Primary Contact Person**
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4. **Secondary Contact Person**
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   D. FAX Number: 978-560-0602
   E. E-Mail: ngujar@neurologica.com

5. **Proposed Device**
   A. Trade Name: GC85A
   B. Device Name: GC85A
   C. Common Name: Digital Diagnostic X-ray System
   D. Classification Name: Stationary X-ray System
   E. Product Code: KPR
   F. Regulation: 21 CFR 892.1680

6. **Predicate Devices**

	Predicate Device
Device Name	GC85A
Classification Name	Stationary X-ray System
Product Code	KPR
Regulation	21 CFR 892.1680
510(K)#	K181629
510(K) Decision Date	July 20, 2018

7. Reference Devices

	Reference Device #1	Reference Device #2	Reference Device #3
Device Name	GF85 (Models GF85-3P, GF85-SP)	GM85	Discovery XR656
Classification Name	Stationary X-ray System	Mobile X-ray System	Stationary X-ray System
Product Code	KPR	IZL	KPR, MQB and IZF
Regulation	21 CFR 892.1680	21 CFR 892.1720	21 CFR 892.1680, 892.1680 and 892.1740
510(K)#	K242478	K242651	K132261
510(K) Decision Date	September 19, 2024	October 1, 2024	November 18, 2013

8. Device Description

The GC85A digital X-ray imaging system is used to capture images by transmitting X-ray to a patient's body. The X-ray passing through a patient's body is sent to the detector and then converted into electrical signals. These signals go through the process of amplification and digital data conversion in the signal process on the S-station, which is the Operation Software (OS) of Samsung Digital Diagnostic X-ray System, and save in DICOM file, a standard for medical imaging. The captured images are tuned up by an Image Post-processing Engine (IPE) which is exclusively installed in S-station, and sent to the Picture Archiving & Communication System (PACS) sever for reading images.

9. Intended Use

The GC85A Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.

10. Summary of Technological characteristic of the proposed device compared with the predicate devices

The GC85A digital X-ray imaging system was previously cleared with K181629. This submission is for a modified version of the GC85A.

The modifications consist of the introduction of new optional hardware configurations and enhanced software functionalities. The fundamental scientific technology and intended use the modified device remain identical to the predicate device.

Substantial equivalence for these modifications is established through a multi-faceted strategy that includes: 1) leveraging technology and components identical to those cleared in other legally marketed Samsung X-ray systems (e.g., GF85 – K242478, GM85 – K242651), and 2) demonstrating through performance testing and risk analysis that any new components or features do not raise new questions of safety or effectiveness.

The proposed modified GC85A and predicate device (K181629) are substantially equivalent in terms of intended use, operational principles, and fundamental scientific

technology. A summary comparison of their key features is provided below.

A. Comparing with Predicate Device

Feature	Predicate Device (GC85A, K181629)	Proposed Device (GC85A)	Discussion
Intended Use	The GC85A digital X-ray imaging system is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.	The GC85A Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.	No change in intended use
Imaging Technology	Digital Flat-Panel Detector	Digital Flat-Panel Detector	No change in fundamental technology
Hardware Configuration	Established set of previously cleared hardware options	Expanded selection of optional configurations	Difference: The proposed device offers an expanded range of hardware choices by adding models for the Ceiling Suspension, Wall Stand, and Collimators. Justification: These are minor mechanical modifications that do not impact safety or imaging performance, as confirmed by risks analysis.
Detector Options	Previously cleared set of 5 detector models	Expanded with 6 additional models	Difference: Six new detector models are offered, expanding the available options. Justification: These additional detectors are identical to those previously cleared in the GM85 (K242451), establishing their safety and performance.
Software Features	Feature set with previously cleared optional functions.	Adds new optional software features and packages (“Vision Assist”, “Value-up Package”, and “Dual Energy Subtraction”)	Difference: The proposed device expands the available software capabilities by introducing new optional features Justification: The majority of these

			features are identical to those cleared in the GF85 (K242478) and GM85 (K242651). The new Dual Energy Subtraction feature operates on the same scientific principles as other legally marketed devices and has been verified through performance testing.

B. Safety, EMC and Performance Data

Electrical, mechanical, environmental safety and performance testing were successfully performed in accordance with internationally recognized standards, including ES 60601-1, IEC 60601-1-3, IEC 60601-2-28, and IEC 60601-2-54. EMC testing was verified according to IEC 60601-1-2. All modifications were assessed under ISO14971 compliant risk management process, which confirmed no new unacceptable risks are introduced.

C. Software Verification and Validation

The integrity and performance of the device's software were validated through a multi-tiered testing strategy:

. Comprehensive Integration Testing: As the foundation of our validation, full integration testing was conducted on the entire software system. This testing, documented in the Test Case, verifies that all software modules – including new features and critical update (such as those addressing software component end-of-life) – function correctly as a single, integrated system without performance degradation.

. In-Depth Feature Verification: In addition to the integration testing, key new features underwent further, in-depth verification. This included dedicated Software Verification Reports (SVRs) for the Camera Solution (Vision Assist) to validate its specific performance and reliability.

D. Non-clinical and Clinical Performance Evaluation

Performance of the new feature, Dual Energy Subtraction, was validated through a multi-faceted approach to demonstrate its diagnostic equivalence:
Non-Clinical Phantom Evaluation: A comparative phantom imaging study was conducted against the Dual Energy Subtraction function of the reference device (K132261). The results, assessed by three radiologists, showed no significant difference in image quality.

Supplemental Clinical Evaluation: While not required for this submission, a formal clinical image evaluation was conducted to further substantiate the non-clinical findings. This evaluation, using patient images acquired from the device, confirmed the conclusions of the phantom study, demonstrating that the resulting images are equivalent image quality.

E. Summary of the Standards and Guidance Compliance

1. ANSI AAMI 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
2. IEC 60601-1-2 Edition 4.1 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic compatibility – Requirements and Tests
3. IEC 60601-1-3 Edition 2.2 Medical Electrical Equipment – Part 1-3: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Radiation protection in Diagnostic X-ray Equipment
4. IEC 60601-2-28 Edition 3 Medical Electrical Equipment – Part 2-28: Particular Requirements for the Basic Safety and Essential Performance of X-ray Tube Assemblies for Medical Diagnosis
5. IEC 60601-2-54 Edition 2.0 Medical Electrical Equipment – Part 2-54: particular Requirements for the Basic Safety and Essential Performance of X-ray Equipment for Radiography and Radioscopy
6. IEC 62220-1-1 Edition 1.0 Medical electrical Equipment - Characteristics of digital X-ray imaging devices Part 1-1: Determination of the detective quantum efficiency Detectors used in radiographic imaging
7. Cybersecurity in Medical Device: Quality System Considerations and Content of Premarket Submissions issued on September 27, 2023
8. Content of Premarket Submissions for Device software Functions issued on June 14, 2023
9. Guidance for the Submission for 510(k) for Solid State X-ray Imaging Devices Guidance for Industry and Food and Drug Administration Staff issued on September 1, 2016
10. Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff issued on November 28, 2017

F. Conclusions

A comprehensive suite of performance tests was conducted to demonstrate that the modified GC85A is as safe and effective as the predicate device and that its new technological characteristics do not raise new questions of safety or effectiveness. The collective results of these tests support the determination of substantial equivalence.