September 19, 2024

Samsung Electronics Co., Ltd.
℅ Jaesang Noh
Regulatory Affairs, Principal Professional
129, Samsung-ro, Yeongtong-gu
Suwon-si, Gyeonggi 16677
SOUTH KOREA

Re: K242478
Trade/Device Name: Gf85 (models gf85-3p, gf85-sp)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR
Dated: August 19, 2024
Received: August 21, 2024

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 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.

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostoc X-Ray Systems Team
DHT8B: Division of Radiologic 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)*
K242478

Device Name
GF85 (models GF85-3P, GF85-SP)

Indications for Use *(Describe)*

"The GF85 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.

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K242478 510(k) Summary

This 510k Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. **Date:** August 19, 2024

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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   C. Phone Number: 978-564-8503
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   E. E-Mail: ngujar@neurologica.com

5. **Proposed Device**
   A. Trade Name: GF85 (models GF85-3P, GF85-SP)
   B. Device Model Names: GF85-3P, GF85-SP
   C. Common Name: Stationary X-ray System
   D. Classification Name: System, X-ray, Stationary
   E. Product Code: KPR
   F. Regulation: 21 CFR 892.1680

6. **Predicate Devices**

	Predicate Device #1	Predicate Device #2
Device Name	GC85A	GM85
Classification Name	Stationary X-ray System	Mobile X-ray System
Product Code	KPR	IZL
Regulation	21 CFR 892.1680	21 CFR 892.1720
510(K)#	K181629	K222353
510(K) Decision Date	July 20, 2018	September 29, 2022

7. **Device Description**
   The GF85 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.
The GF85 Digital X-ray Imaging System includes two models, namely the GF85-3P and GF85-SP. These two models differ primarily in terms of their respective configurations of High Voltage Generators (HVGs). Specifically, the GF85-3P features capacities of 80 kW, 65 kW and 50 kW with 3 phases, whereas the GF85-SP provides a capacity of 40 kW with a single phase. However, all other specifications remain consistent across both models.

8. Intended Use

The GF85 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.

9. Summary of Technological characteristic of the proposed device compared with the predicate device

Though the gantry of the proposed device, GF85, is newly designed, it has the same detectors and image processing as predicate devices. Therefore, it does not have significant changes in image characteristics compared to the predicate device #1 and #2, GC85A and GM85.

Comparisons of technological characteristics were executed and demonstrate the substantial equivalence to the predicate devices.

A. Comparing with Predicate Devices

Attribute	Predicate Device #1	Proposed Device	Predicate Device #2	Comparison Results
Name	GC85A	GF85 (GF85-3P/GF85-SP)	GM85	
Manufacturer	SAMSUNG ELECTRONICS Co., Ltd.	SAMSUNG ELECTRONICS Co., Ltd.	SAMSUNG ELECTRONICS Co., Ltd.	
510(k) Number	K181629	None	K222353	
Appearances				Similar as PD #1
Intended Use	The GC85A digital X-ray imaging system is intended for use in	The GF85 Digital X-ray Imaging System is intended for use in generating	The GM85 Digital Mobile X-ray imaging System is intended for use in	Same as PD #1

	generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.	radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.	generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.	

Attribute		Predicate Device #1 (GC85A, K181629)				GF85				Comparison Results
						GF85-3P			GF85 -SP	
(1)High Voltage Generator										
Name		GXR-82	GXR-52	ZR75 PN80	ZR75 PN50	Cetus 80R01	Cetus 65R01	Cetus 50R01	Cetus 40R03	Different (1)
Max. Power		82kW	52kW	80kW	50kW	80kW	65kW	50kW	40kW	Different (1)
Output RANGE	Tube Voltage	40-150kV				40-150kV				Same
	Tube Current	10-1000 mA	10-640mA	10-1000 mA	10-630mA	10 ~ 1000 mA	10 ~ 800 mA	10 ~ 630 mA	10 ~ 500 mA	Different (1)
	Exposure Time	1msec-10sec				1msec-10sec				Same
AEC (Automatic Exposure Control)		Yes				Yes				Same
APR (Anatomically Programmed Radiography)		Yes				Yes				Same

Attribute	Predicate Device #1 (GC85A, K181629)		GF85			Comparison Results
(2) X-ray tube						
Name	E7869X	E7252X	H2100X E7254FX	H1080X E7252X	H1086X E7843X	Different (2)
Focal spot	0.6/1.2mm		0.6/1.2mm			Same
Target Angle	12°		12°			Same
Target Material	Rhenium-tungsten faced molybdenum		Rhenium-tungsten faced molybdenum			Same

Attribute	Predicate Device #1 (GC85A, K181629)		GF85			Comparison Results
Max. Anode HU	600kHU	300kHU	400kHU	300kHU	150kHU	Different (2)

Attribute		Predicate Device #1 (GC85A, K181629)	GF85	Comparison Results
(3) Tube Stand				
Moving Range (mm)	Longitudinal	1,680~4,180 (Varies with room size)	2,100	Different (3)
	Lateral	1,030~3,030 (Varies with room size)	150	Different (3)
	Vertical	1,800	1,500	Different (3)
Vertical Tube Moving method		Motorized	Manual & Motorized	Different (3)
Tube Assembly Rotation		-157 ~ +183	±90°	Different (3)
Brake locking Method		Electromagnetic	Electromagnetic	Same
Automatic Centering		O	O	Same
Moving Rail Type		Al Extrusion	Steel	Different (3)
Image Preview		O	O	Same
Display Type		Color LCD	Color LCD	Same
Control Switch Type		Button + Touch Screen	Button + Touch Screen	Same
Vertical Sync.	With Table	O	O	Same
	With Stand	O	O	Same
Tube Support Mounting		Ceiling-mounted	Floor-mounted	Different (3)

Attribute		Predicate Device #1 (GC85A, K181629)	GF85	Comparison Results
(4) Wall Stand				
Vertical	Mechanism	Motorized	Manual & Motorized	Different (4)

Attribute		Predicate Device #1 (GC85A, K181629)	GF85	Comparison Results
Movement	Range (mm)	280~1,850	400~1,900	Different (4)
Detector/tube servo coupling		Yes	Yes	Same
Detector	Tilting	Motorized	Motorized	Same
		-20~+90 / N/A	-20~+90 / N/A	Same
AEC		Conventional	Conventional	Same
Grid	Lines/cm	85/92	85	Same
	Grid mechanism	Stationary	Stationary	Same
	Removability	Removable	Removable	Same
Detector Support Mounting		Floor	Floor	Same
Patient Support Device		Patient handgrips, lateral support bar	Patient handgrips, lateral support bar	Same

Attribute		Predicate Device #1 (GC85A, K181629)	GF85	Comparison Results
(5) Patient Table				
Table Top	Size(mm)	2,410 X 812	2,208 X 800	Different (5)
	Range (mm)	±140	±105	Different (5)
		±480	±400	Different (5)
Table height	Mechanism	Motorized	Motorized / Fixed	Same
	Range (mm)	545 ~ 900	500 ~770 / 680 (Fixed)	Different (5)
Horizontal range of detector(mm)		688	600	Different (5)
AEC		Conventional	Conventional	Same
Grid	Lines/cm	85/92	85	Same
	Grid mechanism	Stationary	Stationary	Same

Attribute	Predicate Device #1 (GC85A, K181629)	GF85	Comparison Results
Removability	Removable	Removable	Same
Vertical Sync.	O	O / Fixed	Different (5)
Control Switch Type	Foot switch	Foot switch	Same
Maximum Patient Weight(kg) (Static, Center load)	350	350 (CFRP) / 300 (HPL)	Different (5)

Attribute	Predicate Device #1 (GC85A, K181629)			GF85		Comparison Results
(6) Collimator						
Name	SDR-OGCL80U	SDR-OGCL81U	SDR-OGCL83U	SDR-OGCL20P	SDR-OGCL21P	Different (6)
Beam Limiting Blade/Moving Method	Motorized /Manual			Motorized /Manual		Same
Manual Operation Method	Volume			Volume		Same
Collimator Rotation	±45			-90°/+180°		Different (6)
Beam Light Source	LED			LED		Same
Light Field Indicator Timer	O			O		Same
Side Lamp	O			O		Same
	Laser Module			Laser Module		Same
Field Size / SID Display	Color LCD			Color LCD		Same

Attribute	Predicate Device #2 (GM85, K222353)	GF85	Comparison Results
(7) Detector			
Name	S4335-W S4343-W S3025-W S4335-AW S4343-AW S4335-AWM S4343-AWM S3025-AW S3025-AWM F4335-AW	S4335-AW S4343-AW S4335-AWM S4343-AWM S3025-AW S3025-AWM F4335-AW	Same

Attribute	Predicate Device #1 (GC85A, K181629)	GF85	Comparison Results
(8) Weight Distribution Cap			
W x L x H (mm)	505 X 553 X 37.0	505 X 553 X 37.0	Same

Attribute	Predicate Device #1 (GC85A, K181629)	GF85	Predicate Device #2 (GM85, (K222353)	Comparison Results
(9) Software Features				
Feature Names	S-Share	S-Share	S-Share	Same
	S-Enhance	S-Enhance	S-Enhance	Same
	SimGrid	SimGrid	SimGrid	Same
	-	PEM	PEM	Same
	QAP	QAP	QAP	Same
	Bone Suppression	Bone Suppression	Bone Suppression	Same
	Remote View	Remote View	Remote View	Same
	Smart Stitching	Smart Stitching	-	Same
	-	Mirror View	Mirror View	Same
	-	RFID	RFID..	Same
	-	Vision Live	-	Different (7)
	-	Vision Stitching	-	Different (7)
	-	Vision Capture	-	Different (7)
	-	Virtual Remote Controller	-	Different (7)

Attribute	Predicate Device #1 (GC85A, K181629)	GF85	Predicate Device #2 (GM85, (K222353)	Comparison Results
	-	Lunit INSIGHT CXR Triage	-	Different (7)

Attribute	Predicate Device #1 (GC85A, K181629)	GF85	Predicate Device #2 (GM85, (K222353)	Comparison Results
(10) Image Post-processing Engine				
Noise reduction algorithm	Image Post-processing Engine with an advanced noise reduction algorithm	Image Post-processing Engine with an advanced noise reduction algorithm	Image Post-processing Engine with an advanced noise reduction algorithm	Same

No	Comparison Results	Discussion
(1)	High Voltage Generator	The High Voltage Generators are different from the predicate device, which have various Max. Power and Output Range for the Tube Current. They do not contribute any adverse impact to the device's safety and effectiveness.
(2)	X-ray tube	The X-ray tube are different from the predicate device, which have different Max. Anode HU. They do not contribute any adverse impact to the device's safety and effectiveness.
(3)	Tube Stand	The Tube Stand is different from the predicated device, which have different Moving Range, Vertical Tube Moving method, Tube Assembly Rotation, Moving Rail Type and Tube Support Mounting because it's a floor-mounded type in the proposed device. It does not contribute any adverse impact to the device's safety and effectiveness.
(4)	Wall Stand	The Wall Stand different from the predicate device, which have different Vertical Movement. It does not contribute any adverse impact to the device's safety and effectiveness.
(5)	Patient Table	The Patient Table is different from the predicate device, which has different Table Top, Table height, Horizontal range of detector, Vertical Sync. and Maximum Patient Weight. It does not contribute any adverse impact to the device's safety and effectiveness.
(6)	Collimator	The Collimator is different from the predicate device, which have different Collimator Rotation. It does not contribute any adverse impact to the device's safety and effectiveness.
(7)	Software	New features are provided for user convenience. It does not contribute any adverse impact to the device's safety and effectiveness.

B. Safety, EMC and Performance Data

Electrical, mechanical, environmental safety and performance testing according to standard ES 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-28, IEC 60601-2-54, ISO 14971, 21 CFR1020.30 and 21 CFR1020.31 were performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2. Wireless function was tested and

verified followed by guidance, Radio frequency Wireless Technology in Medical Devices. All test results were satisfying the standards.

C. Non-clinical data

In the non-clinical data, the basic dosimetric performance data of the proposed device and predicate device were compared and the proposed device has the similar characteristics in the exposure output and Half Value Layer even for different tube combinations. The phantom image evaluations were performed in accordance with the FDA guidance for the submission of 510(k)'s for Solid State X-ray Image Devices and were evaluated by three different professional radiologists and found to be equivalent to the predicate device. These reports show that the proposed device is substantially equivalent to the proposed devices.

D. Clinical data

This submission does not required clinical data. Testing for image quality has been conducted with image phantoms, as described above.

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. Conclusion

The non-clinical data demonstrates that the proposed device is as safe, as effective, and performs as well as the legally marketed devices indicating substantial equivalence to the predicate.