SAMSUNG ELECTRONICS CO.,LTD.
% Jaesang Noh
Senior Professional, Regulatory Affairs
129, Samsung-ro, Yeongtong-gu
Suwon-si, Gyeonggi-do 16677
REPUBLIC OF KOREA

May 24, 2018

Re: K180543
Trade/Device Name: GC70, GU60A&GU60A-65, GF50, GF50A, GR40CW, and GM85
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: May 4, 2018
Received: May 7, 2018

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 (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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K180543

Device Name
GC70

Indications for Use *(Describe)*

The GC70 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.

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K180543

Device Name
GU60A, GU60A-65

Indications for Use *(Describe)*
The GU60A & GU60A-65 Digital X-ray Imaging Systems are 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K180543

Device Name
GF50

Indications for Use *(Describe)*

The GF50 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)

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Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K180543

Device Name
GF50A

Indications for Use *(Describe)*

The GF50A 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K180543

Device Name
GR40CW

Indications for Use *(Describe)*

The GR40CW Digital X-ray Imaging System is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K180543

Device Name
GM85

Indications for Use *(Describe)*
The GM85 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)

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SAMSUNG ELECTRONICS Co., Ltd.

510(k) Premarket Notification - Traditional

Section 5: 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 28, 2018

2. **Submitter**
   A. Company Name: SAMSUNG ELECTRONICS Co., Ltd.
   B. Address: 145, Pangyoyeok-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, 13530, Republic of Korea

3. **Primary Contact Persons**
   A. Name: Jaesang NOH & Chulsin KIM
   B. Title: Regulatory Affairs Senior Professional
   C. Phone Number: +82-2-2193-2444 & +82-2-2193-2437
   D. FAX Number: +82-31-200-6401
   E-Mail: jaesang.noh@samsung.com & chulsin.kim@samsung.com

4. **Secondary Contact Person**
   A. Name: Genci Omari
   B. Title: Manager, Regulatory Affairs
   C. Phone Number: 978-564-8602
   D. FAX Number: 978-560-0602
   E-Mail: gomari@samsungneurologica.com

5. **Proposed Device**

	Proposed Devices					
	#1	#2	#3	#4	#5	#6
Trade Name	GC70	GU60A&GU60A-65	GF50	GF50A	GR40CW	GM85
Device Name	GC70	GU60A&GU60A-65	GF50	GF50A	GR40CW	GM85
Common Name	Digital Diagnostic X-ray System	Digital Diagnostic X-ray System	Digital Diagnostic X-ray System	Digital Diagnostic X-ray System	Retrofit Kit	Digital Diagnostic Mobile X-ray System
Classification Name	Stationary X-ray System	Stationary X-ray System	Stationary X-ray System	Stationary X-ray System	Solid State X-ray Imager	Mobile X-ray System
Product Code	KPR	KPR	KPR	KPR	MQB	IZL
Regulation	21 CFR 892.1680	21 CFR 892.1680	21 CFR 892.1680	21 CFR 892.1680	21 CFR 892.168	21 CFR 892.1720

					0	
Feature Name	IPE, Image Post-processing Engine					

6. Predicate Devices

	Predicate Devices						
	#1	#2	#3	#4	#5	#6	#7
Device Name	GC70	GU60A&GU60A-65	GF50	GF50A	GR40CW	GM85	GC85A
Classification Name	Stationary X-ray System	Stationary X-ray System	Stationary X-ray System	Stationary X-ray System	Solid State X-ray Imager	Mobile X-ray System	Stationary X-ray System
Product Code	KPR	KPR	KPR	KPR	MQB	IZL	KPR
Regulation	21 CFR 892.1680	21 CFR 892.1680	21 CFR 892.1680	21 CFR 892.1680	21 CFR 892.1680	21 CFR 892.1720	21 CFR 892.1680
510(K)#	K163115	K173828	K140326	K151419	K153401	K171119	K172229
510(K) Decision Date	Dec., 07, 2016	Jan., 12, 2018	May, 29, 2014	Jun., 23, 2015	Dec., 21, 2015	May, 12, 2017	Nov., 22, 2017

7. Device Description

GC70, GU60&GU60A-65, GF50, GF50A, GR40CW and GM85 are 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.

An IPE operates, from the input image, the roles of a region-of-interest extraction, tone-scale mapping, noise reduction and texture restoration. The IPE employing an advanced noise reduction algorithm is shown that the image quality of PA radiograph for average adult chest, exposed at the condition of 50% lower dose at Entrance Skin Exposure (ESE) in comparison with the condition of the conventional noise reduction algorithm, is substantially equivalent. It was cleared with K172229 that using the IPE is able to reduce dose of 50% for chest PA of average adult in GC85A.

This submission is purposed to get 510(k) clearance for expanding the scope of the claim, cleared with K172229, from GC85A to the proposed devices, Samsung x-ray systems.

The IPE, a software which has no relation with imaging chain, is applied to the proposed devices and it is evaluated that images acquired by a various imaging chain are

substantially equivalent to GC85A in a non-clinical evaluation.

The proposed devices with the IPE employing an advanced noise reduction algorithm are able to reduce dose of 50% for chest PA of average adult for marketing purpose.

This claim is based on a limited study of an anthropomorphic phantom that simulates the x-ray properties of an average size adult, and on a small clinical study at one facility. Only routine PA chest radiography was studied, and results for larger-size adults (body mass index) greater than 30 was not studied to statistical significance. The pediatric patients was not studied and the clinical site is responsible for determining whether the particular radiographic imaging needs are not impacted by such x-ray dose reduction.

8. Intended Use

The GC70 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 GU60A & GU60A-65 Digital X-ray Imaging Systems are 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.

GF50 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 GF50A 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 GR40CW Digital X-ray Imaging System is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. This device is not intended for mammographic applications.

The GM85 Digital Mobile 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 devices compared with the predicate devices

The proposed devices, GC70, GU60&GU60A-65, GF50, GF50A, GR40CW and GM85, apply the IPE with employing an advanced noise reduction algorithm, which was cleared with K172229, to GC70, GU60&GU60A-65, GF50, GF50A, GR40CW and GM85 products which were cleared with respectively K163115, K173828, K140326, K151419, K153401 and K171119 without changes in technical characteristics.
There is identical and nothing changed in technological characteristic between the predicate and proposed devices.

A. Compared with Predicate Devices

Specification		Proposed Device #1		Predicate Device #7	Discussion
Device Name		GC70		GC85A	
Manufacturer		SAMSUNG ELECTRONICS Co., Ltd.		SAMSUNG ELECTRONICS Co., Ltd.	
510(k) Number		None		K172229	
Intended Use		The GC70 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.	Same as PD#1
High Voltage Generator					
Type		High Frequency		High Frequency	Same as PD#1
Max. Power		82kW	52kW	82kW	Same as PD#1
Output RANGE	Tube Voltage	40-150kV	40-150kV	40-150kV	Same as PD#1
	Tube Current	10-1000mA	10-640mA	10-1000mA	Same as PD#1
	Exposure Time	1msec-10sec	1msec-10sec	1msec-10sec	Same as PD#1
AEC (Automatic Exposure Control)		Yes		Yes	Same as PD#1
APR (Anatomically Programmed Radiography)		Yes		Yes	Same as PD#1
X-ray tube					
Name		E7869X	E7252X	E7869X	Same as PD#1
kV range		40-150kV	40-150kV	40-150kV	Same as PD#1
Max. Power	Large focus	100kW	75kW	100kW	Same as PD#1
	Small focus	40kW	27kW	40kW	Same as PD#1
Max. mA	Large focus	1000mA	1000mA	1000mA	Same as PD#1
	Small focus	500mA	400mA	500mA	Same as PD#1
Anode target material		Rhenium-Tungsten	Rhenium-Tungsten	Rhenium-Tungsten	Same as PD#1

Collimator							
Name	SDR-OGCL83U			SDR-OGCL80U	SDR-OGCL83U		Same as PD#1
Overall Size(mm)	H212 X W306 X D179			H212 X W300 X D179	H212 X W306 X D179		Same as PD#1
Beam Limiting Blade Moving Method	Motorized /Manual			Motorized /Manual	Motorized /Manual		Same as PD#1
Manual Operation Method	Volume			Volume	Volume		Same as PD#1
Collimator Rotation	±45			±45	±45		Same as PD#1
Beam Light Source	LED			LED	LED		Same as PD#1
Light Field Indicator Timer	O			O	O		Same as PD#1
Side Lamp	O			O	O		Same as PD#1
	Laser Module			Laser Module	Laser Module		Same as PD#1
Field Size / SID Display	Color LCD			Color LCD	Color LCD		Same as PD#1
Detector							
Name	S4335-W	S4343-W	S3025-W	S4335-W	S4343-W	S3025-W	Same as PD#1
Detector Type	CsI	CsI	CsI	CsI	CsI	CsI	Same as PD#1
	Indirect	Indirect	Indirect	Indirect	Indirect	Indirect	Same as PD#1
Detector Area	14"X17" (345mmX425mm)	17"X17" (425mmX425mm)	10”X12” (245mmX295mm)	14"X17" (345mmX425mm)	17"X17" (425mmX425mm)	10”X12” (245mmX295mm)	Same as PD#1
Number of pixels	2466X3040	3036X3040	1750X2108	2466X3040	3036X3040	1750X2108	Same as PD#1
Pixel Pitch(um)	140	140	140	140	140	140	Same as PD#1
High Contrast Limiting Resolution (LP/mm)	3.57	3.57	3.57	3.57	3.57	3.57	Same as PD#1
Communication	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Same as PD#1
Image Post-processing Engine							
Noise reduction algorithm	Image Post-processing Engine with an advanced			Image Post-processing Engine with an advanced			Same as PD#7

	noise reduction algorithm	noise reduction algorithm	

Specification		Proposed Device #2		Predicate Device #7	Discussion
		GU60A	**GU60A-65**		
Device Name		GU60A & GU60A-65		GC85A	
Manufacturer		SAMSUNG ELECTRONICS Co., Ltd.		SAMSUNG ELECTRONICS Co., Ltd.	
510(k) Number		None		K172229	
Intended Use		The GU60A & GU60A-65 Digital X-ray Imaging Systems are 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.	Same as PD#2
High Voltage Generator					
Type		High Frequency		High Frequency	Same as PD#2
Max. Power		50kW/68kW	65kW	82kW	Same as PD#2
Output RANGE	Tube Voltage	40 to 150kVp	40 to 150kVp	40-150kV	Same as PD#2
	Tube Current	10 - 630mA/ 10 - 800mA	10 - 800mA	10-1000mA	Same as PD#2
	Exposure Time	1msec-6.3sec/ 1msec-10sec	1msec-6.3sec	1msec-10sec	Same as PD#2
X-ray tube					
Name		E7252X		E7869X	Same as PD#2
kV range		40-150kV		40-150kV	Same as PD#2
Max. Power	Large focus	75kW		100kW	Same as PD#2
	Small focus	27kW		40kW	Same as PD#2
Max. mA	Large focus	1000mA		1000mA	Same as PD#2
	Small focus	400mA		500mA	Same as PD#2
Anode target material		Rhenium-Tungsten		Rhenium-Tungsten	Same as PD#2
Collimator					

Name	SDR-OGCL82U			SDR-OGCL80U	SDR-OGCL83U		Same as PD#2
Overall Size(mm)	H212 X W306 X D179			H212 X W300 X D179	H212 X W306 X D179		Same as PD#2
Beam Limiting Blade Moving Method	Motorized /Manual			Motorized /Manual	Motorized /Manual		Same as PD#2
Manual Operation Method	Volume			Volume	Volume		Same as PD#2
Collimator Rotation	±45			±45	±45		Same as PD#2
Beam Light Source	LED			LED	LED		Same as PD#2
Light Field Indicator Timer	O			O	O		Same as PD#2
Side Lamp	O			O	O		Same as PD#2
	Laser Module			Laser Module	Laser Module		Same as PD#2
Field Size / SID Display	Color LCD			Color LCD	Color LCD		Same as PD#2
Detector							
Name	S4335-W	S4343-W	S3025-W	S4335-W	S4343-W	S3025-W	Same as PD#2
Detector Type	CsI	CsI	CsI	CsI	CsI	CsI	Same as PD#2
	Indirect	Indirect	Indirect	Indirect	Indirect	Indirect	Same as PD#2
Detector Area	14"X 17" (345 mmX 425mm)	17"X 17" (425 mmX 425mm)	10”X12” (245 mmX 295mm)	14"X 17" (345 mmX 425mm)	17"X17" (425 mmX 425mm)	10”X12” (245 mmX 295mm)	Same as PD#2
Number of pixels	2466 X3040	3036 X3040	1750 X2108	2466 X3040	3036 X3040	1750 X2108	Same as PD#2
Pixel Pitch(um)	140	140	140	140	140	140	Same as PD#2
High Contrast Limiting Resolution (LP/mm)	3.57	3.57	3.57	3.57	3.57	3.57	Same as PD#2
Communication	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Same as PD#2
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			Same as PD#7

Specification		Proposed Device #3	Predicate Device #7	Discussion
Device Name		GF50	GC85A	
Manufacturer		SAMSUNG ELECTRONICS Co., Ltd.	SAMSUNG ELECTRONICS Co., Ltd.	
510(k) Number		None	K172229	
Intended Use		The GF50 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.	Same as PD#3
High Voltage Generator				
Type		High Frequency	High Frequency	Same as PD#3
Max. Power		52kW	82kW	Same as PD#3
Output RANGE	Tube Voltage	40-150kV	40-150kV	Same as PD#3
	Tube Current	10-640mA	10-1000mA	Same as PD#3
	Exposure Time	1msec-10sec	1msec-10sec	Same as PD#3
AEC (Automatic Exposure Control)		Yes	Yes	Same as PD#3
APR (Anatomically Programmed Radiography)		Yes	Yes	Same as PD#3
X-ray tube				
Name		E7252X	E7869X	Same as PD#3
kV range		40-150kV	40-150kV	Same as PD#3
Max. Power	Large focus	75kW	100kW	Same as PD#3
	Small focus	27kW	40kW	Same as PD#3
Max. mA	Large focus	1000mA	1000mA	Same as PD#3
	Small focus	400mA	500mA	Same as PD#3
Anode target material		Rhenium-Tungsten	Rhenium-Tungsten	Same as PD#3

Collimator					
Name	SDR-OGCL50D	SDR-OGCL80U		SDR-OGCL83U	Same as PD#3
Overall Size(mm)	H185 X W213 X D180	H212 X W300 X D179		H212 X W306 X D179	Same as PD#3
Beam Limiting Blade Moving Method	Manual	Motorized /Manual		Motorized /Manual	Same as PD#3
Manual Operation Method	Volume	Volume		Volume	Same as PD#3
Collimator Rotation	±45	±45		±45	Same as PD#3
Beam Light Source	Halogen Lamp	LED		LED	Same as PD#3
Light Field Indicator Timer	O	O		O	Same as PD#3
Side Lamp	O	O		O	Same as PD#3
	Laser Module	Laser Module		Laser Module	Same as PD#3
Field Size / SID Display	Color LCD	Color LCD		Color LCD	Same as PD#3
Detector					
Name	S4335-W	S4335-W	S4343-W	S3025-W	Same as PD#3
Detector Type	CsI	CsI	CsI	CsI	Same as PD#3
	Indirect	Indirect	Indirect	Indirect	Same as PD#3
Detector Area	14"X17" (345mmX425mm)	14"X17" (345mmX425mm)	17"X17" (425mmX425mm)	10”X12” (245mmX295mm)	Same as PD#3
Number of pixels	2466X3040	2466X3040	3036X3040	1750X2108	Same as PD#3
Pixel Pitch(um)	140	140	140	140	Same as PD#3
High Contrast Limiting Resolution (LP/mm)	3.5	3.57	3.57	3.57	Same as PD#3
Communication	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Same as PD#3
Image Post-processing Engine					
Noise reduction algorithm	Image Post-processing Engine with an advanced	Image Post-processing Engine with an advanced			Same as PD#7

	noise reduction algorithm	noise reduction algorithm	

Specification		Proposed Device #4	Predicate Device #7	Discussion
Device Name		GF50A	GC85A	
Manufacturer		SAMSUNG ELECTRONICS Co., Ltd.	SAMSUNG ELECTRONICS Co., Ltd.	
510(k) Number		None	K172229	
Intended Use		The GF50A 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.	Same as PD#4
High Voltage Generator				
Type		High Frequency	High Frequency	Same as PD#4
Max. Power		40kW	82kW	Same as PD#4
Output RANGE	Tube Voltage	40-125kV	40-150kV	Same as PD#4
	Tube Current	10-500mA	10-1000mA	Same as PD#4
	Exposure Time	1msec-10sec	1msec-10sec	Same as PD#4
AEC (Automatic Exposure Control)		Yes	Yes	Same as PD#4
APR (Anatomically Programmed Radiography)		Yes	Yes	Same as PD#4
X-ray tube				
Name		E7252X	E7869X	Same as PD#3
kV range		40-150kV	40-150kV	Same as PD#3
Max. Power	Large focus	75kW	100kW	Same as PD#3
	Small focus	27kW	40kW	Same as PD#3
Max. mA	Large focus	1000mA	1000mA	Same as PD#3
	Small focus	400mA	500mA	Same as PD#3

Anode target material	Rhenium-Tungsten	Rhenium-Tungsten			Same as PD#3
Collimator					
Name	SDR-OGCL50D	SDR-OGCL80U	SDR-OGCL83U		Same as PD#4
Overall Size(mm)	H185 X W213 X D180	H212 X W300 X D179	H212 X W306 X D179		Same as PD#4
Beam Limiting Blade Moving Method	Manual	Motorized /Manual	Motorized /Manual		Same as PD#4
Manual Operation Method	Volume	Volume	Volume		Same as PD#4
Collimator Rotation	±90	±45	±45		Same as PD#4
Beam Light Source	Halogen Lamp	LED	LED		Same as PD#4
Light Field Indicator Timer	O	O	O		Same as PD#4
Side Lamp	O	O	O		Same as PD#4
	Laser Module	Laser Module	Laser Module		Same as PD#4
Field Size / SID Display	Color LCD	Color LCD	Color LCD		Same as PD#4
Detector					
Name	S4335-W	S4335-W	S4343-W	S3025-W	Same as PD#4
Detector Type	CsI	CsI	CsI	CsI	Same as PD#4
	Indirect	Indirect	Indirect	Indirect	Same as PD#4
Detector Area	14"X17" (345mmX425mm)	14"X17" (345mmX425mm)	17"X17" (425mmX425mm)	10”X12” (245mmX295mm)	Same as PD#4
Number of pixels	2466X3040	2466X3040	3036X3040	1750X2108	Same as PD#4
Pixel Pitch(um)	140	140	140	140	Same as PD#4
High Contrast Limiting Resolution (LP/mm)	3.5	3.57	3.57	3.57	Same as PD#4
Communication	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Same as PD#4
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	Same as PD#7

Specification	Proposed Device #5				Predicate Device #7			Discussion
Device Name	GR40CW				GC85A			
Manufacturer	SAMSUNG ELECTRONICS Co., Ltd.				SAMSUNG ELECTRONICS Co., Ltd.			
510(k) Number	None				K172229			
Intended Use	The GR40CW Digital X-ray Imaging System is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. 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.			Same as PD#5
Detector								
Name	S4335-W	S4335-WV	S4343-W	S3025-W	S4335-W	S4343-W	S3025-W	Same as PD#5
Detector Type	CsI	Gd_2O_2S	CsI	CsI	CsI	CsI	CsI	Same as PD#5
	Indirect	Indirect	Indirect	Indirect	Indirect	Indirect	Indirect	Same as PD#5
Detector Area	14"X17"(345mmX425mm)	14"X17"(345mmX425mm)	17"X17"(425mmX425mm)	10”X12”(245mmX295mm)	14"X17"(345mmX425mm)	17"X17"(425mmX425mm)	10”X12”(245mmX295mm)	Same as PD#5
Number of pixels	2466X3040	2466X3040	3036X3040	1750X2108	2466X3040	3036X3040	1750X2108	Same as PD#5
Pixel Pitch(um)	140	140	140	140	140	140	140	Same as PD#5
High Contrast Limiting Resolution (LP/mm)	3.57	3.5	3.57	3.57	3.57	3.57	3.57	Same as PD#5
Communication	Wir	Wir	Wir	Wir	Wired	Wired	Wired	Same as PD#5

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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			Same as PD#7

Specification		Proposed Device #6		Predicate Device #7	Discussion
Device Name		GM85		GC85A	
Manufacturer		SAMSUNG ELECTRONICS Co., Ltd.		SAMSUNG ELECTRONICS Co., Ltd.	
510(k) Number		None		K172229	
Intended Use		The GM85 Digital Mobile 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.	Same as PD#6
High Voltage Generator					
Type		High Frequency		High Frequency	Same as PD#6
Max. Power		32kW / 40kW		82kW	Same as PD#6
Output RANGE	Tube Voltage	40 to 150kVp		40-150kV	Same as PD#6
	Tube Current	10 – 500mA		10-1000mA	Same as PD#6
	Exposure Time	1msec-10sec		1msec-10sec	Same as PD#6
AEC (Automatic Exposure Control)		No		Yes	Same as PD#6
APR (Anatomically Programmed Radiography)		Yes		Yes	Same as PD#6
X-ray tube					
Name		XRR-3332X	LUC-13L	E7869X	Same as PD#6

kV range		40-150kV	40-150kV	40-150kV			Same as PD#6
Max. Power	Large focus	46kW	45kW	100kW			Same as PD#6
	Small focus	20kW	19kW	40kW			Same as PD#6
Max. mA	Large focus	600mA	600mA	1000mA			Same as PD#6
	Small focus	300mA	260mA	500mA			Same as PD#6
Anode target material		Rhenium-Tungsten	Rhenium-Tungsten	Rhenium-Tungsten			Same as PD#6
Collimator							
Name		SDR-OGCL40U		SDR-OGCL80U	SDR-OGCL83U		Same as PD#6
Overall Size(mm)		H212 X W306 X D179		H212 X W300 X D179	H212 X W306 X D179		Same as PD#6
Beam Limiting Blade Moving Method		Motorized /Manual		Motorized /Manual	Motorized /Manual		Same as PD#6
Manual Operation Method		Volume		Volume	Volume		Same as PD#6
Collimator Rotation		+90/-180		±45	±45		Same as PD#6
Beam Light Source		LED		LED	LED		Same as PD#6
Light Field Indicator Timer		O		O	O		Same as PD#6
Side Lamp		O		O	O		Same as PD#6
		Laser Module		Laser Module	Laser Module		Same as PD#6
Field Size / SID Display		Color LCD		Color LCD	Color LCD		Same as PD#6
Detector							
Name		S4335-W	S4343-W	S3025-W	S4335-W	S4343-W	S3025-W	Same as PD#6
Detector Type		CsI Indirect	CsI Indirect	CsI Indirect	CsI Indirect	CsI Indirect	CsI Indirect	Same as PD#6
								Same as PD#6
Detector Area		14"X17" (345mmX425mm)	17"X17" (425mmX425mm)	10”X12” (245mmX295mm)	14"X17" (345mmX425mm)	17"X17" (425mmX425mm)	10”X12” (245mmX295mm)	Same as PD#6
Number of pixels		2466X3040	3036X3040	1750X2108	2466X3040	3036X3040	1750X2108	Same as PD#6
Pixel Pitch(um)		140	140	140	140	140	140	Same as PD#6
High Contrast		3.57	3.57	3.57	3.57	3.57	3.57	Same as PD#6

Limiting Resolution (LP/mm)							
Communication	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Same as PD#6
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			Same as PD#7

10. Safety and EMC

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, ISO14971, 21CFR1020.30 and 21CFR1020.31 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.

11. Verification of Software and Non-clinical data

The quantitative assessment of image quality was conducted with the images of TOR CDR radiography phantom and TO20 contrast detail phantom taken at a various exposure condition with different Samsung X-ray imaging systems. Modulation Transfer Function (MTF), Contrast to Noise (CNR) and visibility of the images were measured and compared. As a result of comparison, the image quality produced at the same dose level by different Samsung was same. This testing shows that the image quality produced by the subject devices and predicate GC85A are substantially equivalent when used at the same dose levels. Therefore, the IPE is capable of providing the same dose reduction in AP adult chest radiographs for the proposed devices as it does for the predicate GC85A.

12. Clinical data

This submission does not required clinical data.

13. Conclusions

The non-clinical data demonstrates that the IPE in the proposed devices, operating not depending on Samsung digital x-ray systems, is as safe, as effective, and performs as well as the legally marketed predicate devices.