December 7, 2018

Samsung Electronics Co., LTD.
Jaesang Noh
Senior Professional, Regulatory Affairs
129, Samsung-Ro, Yeongtong-Gu
Suwon-Si, 16677 Republic of Korea

Re: K182183
Trade/Device Name: GC70, GU60A, GU60A-65, GF50, GR50A ; GR40CW ; GM85 ; GC85A
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR, MQB, IZL
Dated: July 31, 2018
Received: August 13, 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Robert A. 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)*
K182183

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.

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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)*
K182183

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)

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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)*
K182183

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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Indications for Use

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Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K182183

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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Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K182183

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)*

K182183

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)*
K182183

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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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:** July 31, 2018

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 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	#7
Trade Name	GC70	GU60A& GU60A-65	GF50	GF50A	GR40CW	GM85	GC85A
Device Name	GC70	GU60A& GU60A-65	GF50	GF50A	GR40CW	GM85	GC85A
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	Digital Diagnostic X-ray System
Regulation Name	Stationary X-ray System	Stationary X-ray System	Stationary X-ray System	Stationary X-ray System	Stationary X-ray System	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

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)#	K180543	K180543	K180543	K180543	K181631	K181626	K181629
510(K) Decision Date	May 24, 2018	May 24, 2018	May 24, 2018	May 24, 2018	July 20, 2018	July 20, 2018	July 20, 2018

7. Device Description

GC70, GU60&GU60A-65, GF50, GF50A, GR40CW, GM85 and GC85A 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, SAMSUNG digital X-ray operation software, and sent to the Picture Archiving & Communication System (PACS) sever for reading images.

The 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 (hereinafter "new IPE") 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 (hereinafter "old IPE"), is substantially equivalent. It was cleared with K172229 that using the new IPE is able to reduce dose of 50% for chest PA of average adult in the proposed device, GC85A. The scope of the claim, 50% dose reduction by using the new IPE, was expanded at K180543, from GC85A to GC70, GU60&GU60A-65, GF50, GF50A, GR40CW and GM85. In K180543, it was evaluated that the IPE had no relation with imaging chain and the images acquired by a various imaging chain were substantially equivalent to GC85A (K172229).

This submission is purposed to get 510(k) clearance for expanding the scope of the dose reduction claims, the chest PA of average adult to abdominal radiograph of adult, cleared with K172229 and K180543, and chest, abdomen and skull of pediatric populations.

The principles of operation and technological characteristics of the proposed devices and the predicate devices are the same. The proposed device is identical to the predicate devices since there are the same devices including the new IPE; however, Samsung would like to expand dose reduction claims to the adult's abdominal radiograph, and the chest, abdomen and skull of pediatric populations for marketing purposes.

The non-clinical and clinical image evaluations show that the proposed devices with the new IPE employing and advanced noise reduction algorithm are able to reduce x-ray dose up to 47.5% for abdominal radiographs of average adult and up to 45% for pediatric abdomen, 15.5% for pediatric chest, and up to 27% for pediatric skull exams, compared with radiation doses needed to obtain similar image quality using the old IPE on the same x-ray systems.

Note: The dose reduction claim is based on non-clinical (phantom) testing and on clinical testing conducted at one medical site with a specific x-ray imaging system and specific technique factors. In practice, the values of dose reduction may vary accordingly. The clinical site is responsible for determining whether the particular radiographic imaging needs are not impacted by such x-ray dose reduction. The pediatric subgroup, neonate under 1 month old, was not studied.

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.

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.

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

The proposed devices, GC70, GU60&GU60A-65, GF50, GF50A, GR40CW, GM85 and GC85A, are identical to the predicate devices recently cleared with K180543 (GC70, GU60&GU60A-65, GF50 and GF50A), K181631 (GR40CW), K181626 (GM85) and K181629 (GC85A), including the new IPE with employing an advanced noise reduction algorithm.

A. Compared with Predicate Devices

Specification		Proposed Device #1		Predicate Device #1 (PD #1)		Discussion
Device Name		GC70		GC70		
Manufacturer		SAMSUNG ELECTRONICS Co., Ltd.		SAMSUNG ELECTRONICS Co., Ltd.		
510(k) Number		None		K180543		
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 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.		Same as PD#1
High Voltage Generator						
Type		High Frequency		High Frequency		Same as PD#1
Max. Power		82kW	52kW	82kW	52kW	Same as PD#1
Output RANGE	Tube Voltage	40-150kV	40-150kV	40-150kV	40-150kV	Same as PD#1
	Tube Current	10-1000mA	10-640mA	10-1000mA	10-640mA	Same as PD#1
	Exposure Time	1msec-10sec	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	E7252X		Same as PD#1
kV range		40-150kV	40-150kV	40-150kV	40-150kV		Same as PD#1
Max. Power	Large focus	100kW	75kW	100kW	75kW		Same as PD#1
	Small focus	40kW	27kW	40kW	27kW		Same as PD#1
Max. mA	Large focus	1000mA	1000mA	1000mA	1000mA		Same as PD#1
	Small focus	500mA	400mA	500mA	400mA		Same as PD#1
Anode target material		Rhenium-Tungsten	Rhenium-Tungsten	Rhenium-Tungsten	Rhenium-Tungsten		Same as PD#1
Collimator							
Name		SDR-OGCL83U		SDR-OGCL83U			Same as PD#1
Overall Size(mm)		H212 X W306 X D179		H212 X W306 X D179			Same as PD#1
Beam Limiting Blade Moving Method		Motorized /Manual		Motorized /Manual			Same as PD#1
Manual Operation Method		Volume		Volume			Same as PD#1
Collimator Rotation		±45		±45			Same as PD#1
Beam Light Source		LED		LED			Same as PD#1
Light Field Indicator Timer		O		O			Same as PD#1
Side Lamp		O		O			Same as PD#1
		Laser Module		Laser Module			Same as PD#1
Field Size / SID Display		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 noise reduction algorithm			Image Post-processing Engine with an advanced noise reduction algorithm			Same as PD#1
Claim of dose reduction	50% dose reduction for chest PA of average adult			50% dose reduction for chest PA of average adult			Same as PD #1
	Up to 47.5% dose reduction for abdominal radiographs of adult			-			Different(1)
	Up to 45% dose reduction for pediatric abdomen, 15.5% for pediatric chest, and up to 27% for pediatric skull exams			-			Different(2)

Specification	Proposed Device #2		Predicate Device #2 (PD #2)		Discussion
	GU60A	GU60A-65	GU60A	GU60A-65	
Device Name	GU60A & GU60A-65		GU60A & GU60A-65		
Manufacturer	SAMSUNG ELECTRONICS Co., Ltd.		SAMSUNG ELECTRONICS Co., Ltd.		
510(k) Number	None		K180543		
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 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.		Same as PD#2
High Voltage Generator					
Type	High Frequency		High Frequency		Same as PD#2

Max. Power		50kW/68kW	65kW	50kW/68kW	65kW	Same as PD#2
Output RANGE	Tube Voltage	40 to 150kVp	40 to 150kVp	40 to 150kVp	40 to 150kVp	Same as PD#2
	Tube Current	10 - 630mA/ 10 - 800mA	10 - 800mA	10 - 630mA/ 10 - 800mA	10 - 800mA	Same as PD#2
	Exposure Time	1msec-6.3sec/ 1msec-10sec	1msec-6.3sec	1msec-6.3sec/ 1msec-10sec	1msec-6.3sec	Same as PD#2
X-ray tube						
Name		E7252X		E7252X		Same as PD#2
kV range		40-150kV		40-150kV		Same as PD#2
Max. Power	Large focus	75kW		75kW		Same as PD#2
	Small focus	27kW		27kW		Same as PD#2
Max. mA	Large focus	1000mA		1000mA		Same as PD#2
	Small focus	400mA		400mA		Same as PD#2
Anode target material		Rhenium-Tungsten		Rhenium-Tungsten		Same as PD#2
Collimator						
Name		SDR-OGCL82U		SDR-OGCL82U		Same as PD#2
Overall Size(mm)		H212 X W306 X D179		H212 X W306 X D179		Same as PD#2
Beam Limiting Blade Moving Method		Motorized /Manual		Motorized /Manual		Same as PD#2
Manual Operation Method		Volume		Volume		Same as PD#2
Collimator Rotation		±45		±45		Same as PD#2
Beam Light Source		LED		LED		Same as PD#2
Light Field Indicator Timer		O		O		Same as PD#2
Side Lamp		O		O		Same as PD#2
		Laser Module		Laser Module		Same as PD#2
Field Size / SID Display		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#2
Claim of dose reduction	50% dose reduction for chest PA of average adult			50% dose reduction for chest PA of average adult			Same as PD #2
	Up to 47.5% dose reduction for abdominal radiographs of adult			-			Different(1)
	Up to 45% dose reduction for pediatric abdomen, 15.5% for pediatric chest, and up to 27% for pediatric skull exams			-			Different(2)

Specification	Proposed Device #3	Predicate Device #3 (PD #3)	Discussion
Device Name	GF50	GF50	
Manufacturer	SAMSUNG ELECTRONICS Co., Ltd.	SAMSUNG ELECTRONICS Co., Ltd.	
510(k) Number	None	K180543	
Intended Use	The GF50 Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy by a qualified/trained	The GF50 Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy by a qualified/trained	Same as PD#3

		doctor or technician. This device is not intended for mammographic applications.	doctor or technician. This device is not intended for mammographic applications.	
High Voltage Generator				
Type		High Frequency	High Frequency	Same as PD#3
Max. Power		52kW	52kW	Same as PD#3
Output RANGE	Tube Voltage	40-150kV	40-150kV	Same as PD#3
	Tube Current	10-640mA	10-640mA	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	E7252X	Same as PD#3
kV range		40-150kV	40-150kV	Same as PD#3
Max. Power	Large focus	75kW	75kW	Same as PD#3
	Small focus	27kW	27kW	Same as PD#3
Max. mA	Large focus	1000mA	1000mA	Same as PD#3
	Small focus	400mA	400mA	Same as PD#3
Anode target material		Rhenium-Tungsten	Rhenium-Tungsten	Same as PD#3
Collimator				
Name		SDR-OGCL50D	SDR-OGCL50D	Same as PD#3
Overall Size(mm)		H185 X W213 X D180	H185 X W213 X D180	Same as PD#3
Beam Limiting Blade Moving Method		Manual	Manual	Same as PD#3
Manual Operation Method		Volume	Volume	Same as PD#3
Collimator Rotation		±45	±45	Same as PD#3
Beam Light Source		Halogen Lamp	Halogen Lamp	Same as PD#3

Light Field Indicator Timer	O	O	Same as PD#3
Side Lamp	O	O	Same as PD#3
	Laser Module	Laser Module	Same as PD#3
Field Size / SID Display	Color LCD	Color LCD	Same as PD#3
Detector			
Name	S4335-W	S4335-W	Same as PD#3
Detector Type	CsI	CsI	Same as PD#3
	Indirect	Indirect	Same as PD#3
Detector Area	14"X17" (345mmX425mm)	14"X17" (345mmX425mm)	Same as PD#3
Number of pixels	2466X3040	2466X3040	Same as PD#3
Pixel Pitch(um)	140	140	Same as PD#3
High Contrast Limiting Resolution (LP/mm)	3.5	3.5	Same as PD#3
Communication	Wired / Wireless	Wired / Wireless	Same as PD#3
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#3
Claim of dose reduction	50% dose reduction for chest PA of average adult	50% dose reduction for chest PA of average adult	Same as PD #3
	Up to 47.5% dose reduction for abdominal radiographs of adult	-	Different(1)
	Up to 45% dose reduction for pediatric abdomen, 15.5% for pediatric chest, and up to 27% for pediatric skull exams	-	Different(2)

Specification	Proposed Device #4	Predicate Device #4 (PD #4)	Discussion
Device Name	GF50A	GF50A	
Manufacturer	SAMSUNG ELECTRONICS Co., Ltd.	SAMSUNG ELECTRONICS Co., Ltd.	
510(k) Number	None	K180543	

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 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.	Same as PD#4
High Voltage Generator				
Type		High Frequency	High Frequency	Same as PD#4
Max. Power		40kW	40kW	Same as PD#4
Output RANGE	Tube Voltage	40-125kV	40-125kV	Same as PD#4
	Tube Current	10-500mA	10-500mA	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	E7252X	Same as PD#4
kV range		40-150kV	40-150kV	Same as PD#4
Max. Power	Large focus	75kW	75kW	Same as PD#4
	Small focus	27kW	27kW	Same as PD#4
Max. mA	Large focus	1000mA	1000mA	Same as PD#4
	Small focus	400mA	400mA	Same as PD#4
Anode target material		Rhenium-Tungsten	Rhenium-Tungsten	Same as PD#4
Collimator				
Name		SDR-OGCL50D	SDR-OGCL50D	Same as PD#4
Overall Size(mm)		H185 X W213 X D180	H185 X W213 X D180	Same as PD#4
Beam Limiting Blade Moving Method		Manual	Manual	Same as PD#4

Manual Operation Method	Volume	Volume	Same as PD#4
Collimator Rotation	±90	±90	Same as PD#4
Beam Light Source	Halogen Lamp	Halogen Lamp	Same as PD#4
Light Field Indicator Timer	O	O	Same as PD#4
Side Lamp	O	O	Same as PD#4
	Laser Module	Laser Module	Same as PD#4
Field Size / SID Display	Color LCD	Color LCD	Same as PD#4
Detector			
Name	S4335-W	S4335-W	Same as PD#4
Detector Type	CsI	CsI	Same as PD#4
	Indirect	Indirect	Same as PD#4
Detector Area	14"X17" (345mmX425mm)	14"X17" (345mmX425mm)	Same as PD#4
Number of pixels	2466X3040	2466X3040	Same as PD#4
Pixel Pitch(um)	140	140	Same as PD#4
High Contrast Limiting Resolution (LP/mm)	3.5	3.5	Same as PD#4
Communication	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#4
Claim of dose reduction	50% dose reduction for chest PA of average adult	50% dose reduction for chest PA of average adult	Same as PD #4
	Up to 47.5% dose reduction for abdominal radiographs of adult	-	Different(1)
	Up to 45% dose reduction for pediatric abdomen, 15.5% for pediatric chest, and up to 27% for pediatric skull exams	-	Different(2)

Specification	Proposed Device #5	Predicate Device #5 (PD #5)	Discussion
Device Name	GR40CW	GR40CW	

Manufacturer	SAMSUNG ELECTRONICS Co., Ltd.				SAMSUNG ELECTRONICS Co., Ltd.				
510(k) Number	None				K181631				
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 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.				Same as PD#5
Detector									
Name	S4335-W/S4335-AW	S4335-WV/S4335-AWV	S4343-W/S4343-AW	S3025-W	S4335-W/S4335-AW	S4335-WV/S4335-AWV	S4343-W/S4343-AW	S3025-W	Same as PD#5
Detector Type	CsI	Gd_2O_2S	CsI	CsI	CsI	Gd_2O_2S	CsI	CsI	Same as PD#5
	Indirect	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)	14"X17"(345mmX425mm)	17"X17"(425mmX425mm)	10”X12”(245mmX295mm)	Same as PD#5
Number of pixels	2466X3040	2466X3040	3036X3040	1750X2108	2466X3040	2466X3040	3036X3040	1750X2108	Same as PD#5
Pixel Pitch(um)	140	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	3.5	3.57	3.57	Same as PD#5
Communication	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Same as PD#5
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#5
Claim of dose reduction	50% dose reduction for chest PA of average adult	50% dose reduction for chest PA of average adult	Same as PD #5
	Up to 47.5% dose reduction for abdominal radiographs of adult	-	Different(1)
	Up to 45% dose reduction for pediatric abdomen, 15.5% for pediatric chest, and up to 27% for pediatric skull exams	-	Different(2)

Specification		Proposed Device #6	Predicate Device #6 (PD #6)	Discussion
Device Name		GM85	GM85	
Manufacturer		SAMSUNG ELECTRONICS Co., Ltd.	SAMSUNG ELECTRONICS Co., Ltd.	
510(k) Number		None	K181626	
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 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.	Same as PD#6
High Voltage Generator				
Type		High Frequency	High Frequency	Same as PD#6
Max. Power		32kW / 40kW	32kW / 40kW	Same as PD#6
Output RANGE	Tube Voltage	40 to 150kVp	40 to 150kVp	Same as PD#6
	Tube Current	10 – 500mA	10 – 500mA	Same as PD#6
	Exposure Time	1msec-10sec	1msec-10sec	Same as PD#6
AEC (Automatic		No	No	Same as PD#6

Exposure Control)						
APR (Anatomically Programmed Radiography)		Yes		Yes		Same as PD#6
X-ray tube						
Name		XRR-3332X	LUC-13L	XRR-3332X	LUC-13L	Same as PD#6
kV range		40-150kV	40-150kV	40-150kV	40-150kV	Same as PD#6
Max. Power	Large focus	46kW	45kW	46kW	45kW	Same as PD#6
	Small focus	20kW	19kW	20kW	19kW	Same as PD#6
Max. mA	Large focus	600mA	600mA	600mA	600mA	Same as PD#6
	Small focus	300mA	260mA	300mA	260mA	Same as PD#6
Anode target material		Rhenium-Tungsten	Rhenium-Tungsten	Rhenium-Tungsten	Rhenium-Tungsten	Same as PD#6
Collimator						
Name		SDR-OGCL40U	SDR-OGCL41U	SDR-OGCL40U	SDR-OGCL41U	Same as PD#6
Overall Size(mm)		H212 X W306 X D179	H222 X W271 X D140	H212 X W306 X D179	H222 X W271 X D140	Same as PD#6
Beam Limiting Blade Moving Method		Motorized /Manual	Manual	Motorized /Manual	Manual	Same as PD#6
Manual Operation Method		Volume	Volume	Volume	Volume	Same as PD#6
Collimator Rotation		+90/-180	+90/-90	+90/-180	+90/-90	Same as PD#6
Beam Light Source		LED	LED	LED	LED	Same as PD#6
Light Field Indicator Timer		O	O	O	O	Same as PD#6
Side Lamp		O	O	O	O	Same as PD#6
		Laser Module	Laser Module	Laser Module	Laser Module	Same as PD#6
Field Size / SID Display		Color LCD	Scale Mark	Color LCD	Scale Mark	Same as PD#6
Detector						
Name		S4335-W/ S4335-AW	S4343-W/ S4343-AW	S3025-W	S4335-W/ S4335-AW	S4343-W/ S4343-AW	S3025-W	Same as PD#6
Detector Type		CsI	CsI	CsI	CsI	CsI	CsI	Same as PD#6
		Indirect	Indirect	Indirect	Indirect	Indirect	Indirect	Same as PD#6

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"X 17" (425 mmX 425mm)	10”X12” (245 mmX 295mm)	Same as PD#6
Number of pixels	2466 X3040	3036 X3040	1750 X2108	2466 X3040	3036 X3040	1750 X2108	Same as PD#6
Pixel Pitch(um)	140	140	140	140	140	140	Same as PD#6
High Contrast Limiting Resolution (LP/mm)	3.57	3.57	3.57	3.57	3.57	3.57	Same as PD#6
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#6
Claim of dose reduction	50% dose reduction for chest PA of average adult			50% dose reduction for chest PA of average adult			Same as PD #6
	Up to 47.5% dose reduction for abdominal radiographs of adult			-			Different(1)
	Up to 45% dose reduction for pediatric abdomen, 15.5% for pediatric chest, and up to 27% for pediatric skull exams			-			Different(2)

Specification	Proposed Device #7	Predicate Device #7 (PD #7)	Discussion
Device Name	GC85A	GC85A	
Manufacturer	SAMSUNG ELECTRONICS Co., Ltd.	SAMSUNG ELECTRONICS Co., Ltd.	
510(k) Number	None	K181629	
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	The GC85A Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy by a qualified/trained	Same as PD#7

		doctor or technician. This device is not intended for mammographic applications.				doctor or technician. This device is not intended for mammographic applications.			
High Voltage Generator									
Type		High Frequency				High Frequency			Same as PD#7
Max. Power		82kW	52kW	80kW	50kW	82kW	52kW	80kW	50kW	Same as PD#7
Output RANGE	Tube Voltage	40-150 kV	v40-150 kV	40-150 kV	40-150 kV	40-150 kV	v40-150 kV	40-150 kV	40-150 kV	Same as PD#7
	Tube Current	10-1000mA	10-640 mA	10-1000mA	10-630 mA	10-1000mA	10-640 mA	10-1000mA	10-630 mA	Same as PD#7
	Exposure Time	1msec-10sec	1msec-10sec	1msec-10sec	1msec-10sec	1msec-10sec	1msec-10sec	1msec-10sec	1msec-10sec	Same as PD#7
AEC (Automatic Exposure Control)		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Same as PD#7
APR (Anatomically Programmed Radiography)		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Same as PD#7
X-ray tube									
Name		E7869X	E7252X	E7869X	E7252X	Same as PD#7			
kV range		40-150kV	40-150kV	40-150kV	40-150kV	Same as PD#7			
Max. Power	Large focus	100kW	75kW	100kW	75kW	Same as PD#7			
	Small focus	40kW	27kW	40kW	27kW	Same as PD#7			
Max. mA	Large focus	1000mA	1000mA	1000mA	1000mA	Same as PD#7			
	Small focus	500mA	400mA	500mA	400mA	Same as PD#7			
Anode target material		Rhenium-Tungsten	Rhenium-Tungsten	Rhenium-Tungsten	Rhenium-Tungsten	Same as PD#7			
Collimator									
Name		SDR-OGCL80U	SDR-OGCL83U	SDR-OGCL80U	SDR-OGCL83U	Same as PD#7			
Overall Size(mm)		H212 X W300 X D179	H212 X W306 X D179	H212 X W300 X D179	H212 X W306 X D179	Same as PD#7			
Beam Limiting Blade Moving Method		Motorized /Manual	Motorized /Manual	Motorized /Manual	Motorized /Manual	Same as PD#7			
Manual Operation Method		Volume	Volume	Volume	Volume	Same as PD#7			

Collimator Rotation	±45		±45	±45		±45	Same as PD#7
Beam Light Source	LED		LED	LED		LED	Same as PD#7
Light Field Indicator Timer	O		O	O		O	Same as PD#7
Side Lamp	O		O	O		O	Same as PD#7
	Laser Module		Laser Module	Laser Module		Laser Module	Same as PD#7
Field Size / SID Display	Color LCD		Color LCD	Color LCD		Color LCD	Same as PD#7
Detector							
Name	S4335-W/ S4335-AW	S4343-W/ S4343-AW	S3025-W	S4335-W/ S4335-AW	S4343-W/ S4343-AW	S3025-W	Same as PD#7
Detector Type	CsI	CsI	CsI	CsI	CsI	CsI	Same as PD#7
	Indirect	Indirect	Indirect	Indirect	Indirect	Indirect	Same as PD#7
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"X 17" (425 mmX 425mm)	10”X12” (245 mmX 295mm)	Same as PD#7
Number of pixels	2466 X3040	3036 X3040	1750 X2108	2466 X3040	3036 X3040	1750 X2108	Same as PD#7
Pixel Pitch(um)	140	140	140	140	140	140	Same as PD#7
High Contrast Limiting Resolution (LP/mm)	3.57	3.57	3.57	3.57	3.57	3.57	Same as PD#7
Communication	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Same as PD#7
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
Claim of dose reduction	50% dose reduction for chest PA of average adult			50% dose reduction for chest PA of average adult			Same as PD #7
	Up to 47.5% dose reduction for abdominal radiographs of adult			-			Different(1)
	Up to 45% dose reduction for pediatric abdomen, 15.5% for			-			Different(2)

	pediatric chest, and up to 27% for pediatric skull exams		

No	Differences	Explanation
(1)	Up to 47.5% dose reduction for abdominal radiographs of adult	The claim for dose reduction of abdominal radiographs of adult is added to the proposed devices. The proposed devices with the new IPE employing and advanced noise reduction algorithm are able to reduce x-ray dose up to 47.5% for abdominal radiographs of average adult, compared with radiation doses needed to obtain similar image quality using the old IPE on the same x-ray systems.
(2)	Up to 45% dose reduction for pediatric abdomen, 15.5% for pediatric chest, and up to 27% for pediatric skull exams	The claims for dose reduction of pediatric population are added to the proposed devices. The proposed devices with the new IPE employing and advanced noise reduction algorithm are able to reduce x-ray dose up to 45% for pediatric abdomen, 15.5% for pediatric chest, and up to 27% for pediatric skull exams, compared with radiation doses needed to obtain similar image quality using the old IPE on the same x-ray systems.

B. 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.

C. Non-clinical data

The quantitative assessment of image quality was conducted with the images of TOR CDR radiography phantom taken at a various exposure condition using GM85. Contrast to Noise Ratio (CNR), Detail Compacted Contrast (DCC) and Modulation Transfer Functions (MTF) of the images were measured and compared. As a result of comparison, CNR was measured highly under the condition of the new IPE in comparison with the old IPE and the other image quality metrics such as DCC and MTF of the new IPE were equivalent to those of the old IPE. The non-clinical data shows that images using the new IPE make it easy to distinguish between background and the object, and is clearer than images using the old IPE. Ant it says that the performance of the new IPE is robustness with regard to the variation of X-ray exposure factors such as kVp values and 0.1 mm Cu filter on/off.

D. Clinical data

i. Abdominal radiograph for adult

GC85A as a representative device of the proposed devices was validated with anthropomorphic phantom images and clinical images by three and two professional radiologists respectively. Anthropomorphic phantom images captured at different radiation exposures were scored by the 5-point grading scale in consideration of anatomical regions and physical parameters. Clinical images captured at two different radiation exposures were also scored by the 5-point grading scale for the assessment of overall image quality such as sharpness and visualization for the anatomical regions.

The anthropomorphic phantom image study shows that the new IPE with an advanced noise reduction algorithm retained the quality of images captured at 47.5% reduced exposure in comparison with the old IPE. In detail, we performed a paired t-test comparison between each lower dose image and the reference image; the old IPE maintained the image quality at as low as 0.4 mGy, while the new IPE maintained the image quality at as low as 0.21 mGy. We derived the dose reduction 47.5% by calculating (0.4-0.21)/0.4*100. We confirmed that it was possible to reduce the dose in clinical images as well.

Based on the evaluation of anthropomorphic phantom images, the new IPE enables to reduce the dose of 47.5%.

ii. Pediatric population

GC85A as a representative device of the proposed devices were evaluated using a validated noise simulation tool in pursue of dose optimization with the new IPE relative to the old IPE for chest, abdomen and skull of pediatric populations.

Dose reduction performance was calculated by a statistical method based on a clinical trial. Three experienced pediatric radiologists assessed the series of dose-simulated images to decide the optimal dose for each patient. The optimal dose means the lowest dose at which image quality is still appropriate for diagnosis. On the whole, image processed by new IPE could achieve lower optimal dose than the old IPE. We analyzed the difference between the optimal doses for old IPE and new IPE images.

Based on the evaluation, the performance of the new IPE shows that the images using the new IPE taken at up to 45% reduction for pediatric abdomen, 15.5% for pediatric chest, and up to 27% pediatric skull in radiation dose are substantially equivalent of those using the old IPE without sacrificing diagnostic confidence, although dose reduction rate is various in accordance with protocols such as chest, abdomen and skull and pediatric sub-population.

E. Conclusions

There is no difference between the proposed devices and the predicate devices in technical and physical characteristics.

Differences in the devices do not alter the intended use/indications. The non-clinical and clinical data demonstrate that the proposed devices are as safe, as effective, and performs as well as the legally marketed predicate devices.