Samsung Electronics Co., Ltd.
Jaesang Noh
Senior Professional, Regulatory Affairs
129, Samsung-Ro, Yeongtong-Gu,
Suwon-Si, 16677 KR

October 24, 2018

Re: K182647
Trade/Device Name: GC70
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR
Dated: September 21, 2018
Received: September 24, 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,

Michael D. O'hara -S

Digitally signed by Michael D. O'hara -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300226759, cn=Michael D. O'hara -S
Date: 2018.10.24 07:38:20 -04'00'

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)*

K182647

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.

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SAMSUNG ELECTRONICS Co., Ltd.

510(k) Premarket Notification - Special

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:** September 21, 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 Person**
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4. **Secondary Contact Person**
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   B. Title: Manager, Regulatory Affairs
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   D. FAX Number: 978-560-0602
   E. E-Mail: gomari@samsungneurologica.com

5. **Proposed Device**
   A. Trade Name: GC70
   B. Device Name: GC70
   C. Common Name: Digital Diagnostic X-ray System
   D. Regulation Name: Stationary X-ray system
   E. Product Code: KPR
   F. Regulation: 21 CFR 892.1680

6. **Predicate Devices**

	Predicate Device #1	Predicate Device #2 (Primary Predicate)
Device Name	GC85A	GC70
Classification Name	Stationary X-ray System	Stationary X-ray System
Product Code	KPR	KPR
Regulation	21 CFR 892.1680	21 CFR 892.1680
510(K)#	K181629	K180543
510(K) Decision Date	July 20, 2018	May 24, 2018

7. Device Description

The GC70 digital X-ray imaging system is a stationary x-ray system designed for general radiography and 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 GC70 digital X-ray imaging system consists of HVG (High Voltage Generator), ceiling suspension, X-ray tube, collimator, detector, wall stand, patient table, ACE (Auto Exposure Control), DAP (Dose Area Product), CIB (Control Interface Box), remote controller, grid, foot switch, barcode scanner, auto-stitching stand, weight distribution cap and workstation for S-station including Image Post-processing Engine (IPE).

The GC70 digital X-ray imaging system was previously cleared under K180543, and some hardware options and three software features are added to the predicate device GC70. The changes are as follows:

- Two High Voltage Generators
- Two detectors
- Slim wall stand
- Software features called as S-Enhance, PEM (Pediatric Exposure Management) and Remote View
  - The S-Enhance is optional software to improve clarity of a foreign body (e.g. tube, line) and stone in chest, abdomen and L-spine images. With a single on-screen click, the companion image is created without additional settings or x-ray exposure, streamlining the process.
  - Pediatric Exposure Management is subdivided patient size and exposure conditions especially for pediatric patients based on weight and protocols. It follows same methodologies to define preset of patient size compare to preset of standard patient size from predicate device but specially optimized for pediatric patients.
  - The Remote view function provided images on another PC, not just on the device.

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.

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

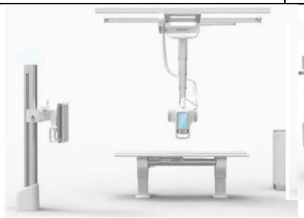
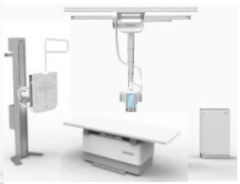
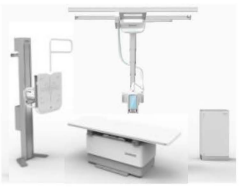
the predicate devices

The proposed device GC70 does not alter the intended use or the fundamental scientific technology and remains within the same classification regulation for the same intended use as the predicate devices #1 and 2 because the proposed device GC70 uses the same X-ray generators, the same detectors, the similar wall stand, the same software features called as S-Enhance, PEM and Remote View of the predicate device GC85A, which were cleared with K181629, as a selective option of X-ray configuration. Verification and validation testing for these changes were successfully conducted in accordance with Samsung Design Change Process.

The following tables compare the main technological characteristics of the proposed device with the predicate devices to substantiate equivalence.

A. Comparing with Predicate Devices

The components and software features added to the proposed device are identical or similar to the predicate devices, which do not show significant difference in safety and effectiveness.

Specification	Predicate Device #1	Predicate Device #2 (Primary Predicate)	Proposed Device	Discussion
Device Name	GC85A	GC70	GC70	
Manufacturer	SAMSUNG ELECTRONICS Co., Ltd.	SAMSUNG ELECTRONICS Co., Ltd.	SAMSUNG ELECTRONICS Co., Ltd.	
510(k) Number	K181629	K180543	None	
Appearances				Same as PD#2
Intended Use	The GC85A digital X-ray imaging system is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.	The 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#2

Manufacturer Contents		GC85A (K181629)				GC70 (K180543)		GC70				Discussion
(1)High Voltage Generator												
Model Number		GXR-82	GXR-52	ZR75PN80	ZR75PN50	GXR-82	GXR-52	GXR-82	GXR-52	ZR75PN80	ZR75PN50	
Max. Power		82kW	52kW	80kW	50kW	82kW	52kW	82kW	52kW	80kW	50kW	Same as PD#1&2
Output RANGE	Tube Voltage	40-150kV	v40-150kV	40-150kV	40-150kV	40-150kV	v40-150kV	40-150kV	v40-150kV	40-150kV	40-150kV	Same as PD#1&2
	Tube Current	10-1000mA	10-640mA	10-1000mA	10-630mA	10-1000mA	10-640mA	10-1000mA	10-640mA	10-1000mA	10-630mA	Same as PD#1&2
	Exposure Time	1msec-10sec	1msec-10sec	1msec-10sec	1msec-10sec	1msec-10sec	1msec-10sec	1msec-10sec	1msec-10sec	1msec-10sec	1msec-10sec	Same as PD#1&2
AEC (Automatic Exposure Control)		Yes				Yes		Yes				Same
APR (Anatomically Programmed Radiography)		Yes				Yes		Yes				Same

Manufacturer Contents		GC85A (K181629)		GC70 (K180543)	GC70		Discussion
(2) Wall Stand							
Model number		SDR-OGST80U	SDR-OGST73A/B	SDR-OGST73A/B	SDR-OGST73A/B	SDR-OGST73C	SDR-OGST73A/B is the same as PD#1&2 and SDR-OGST73C is new
Vertical Movement	Mechanism	Motorized	Motorized	Motorized	Motorized	Motorized	Same
	Range(mm)	280~1850	412~1838	412~1838	412~1838	280~1850	Same as PD#1&2
Detector/tube servo coupling		Yes	Yes	Yes	Yes	Yes	Same

Manufacturer Contents			GC85A (K181629)		GC70 (K180543)	GC70		Discussion
Detector	Tilting	Motorized	Motorized	Motorized	Motorized	Motorized	None	SDR-OGST73A/B is the same as PD#1&2 and SDR-OGST73C is new
		-20~+90	-20~+90	-30~+90	-30~+90	-30~+90	None	SDR-OGST73A/B is the same as PD#1&2 and SDR-OGST73C is new
AEC			Conventional	Conventional	Conventional	Conventional	Conventional	Same
Grid	Lines/cm		85/92	85/92	85/92	85/92	85/92	Same
	Grid mechanism		Stationary	Stationary	Stationary	Stationary	Stationary	Same
	Removability		Removable	Removable	Removable	Removable	Removable	Same
Detector Support Mounting			Floor	Floor	Floor	Floor	Floor	Same
Patient Support Device			Patient handgrips, lateral support bar	Patient handgrips, lateral support bar	Patient handgrips, lateral support bar	Patient handgrips, lateral support bar	Patient handgrips, lateral support bar	Same

Manufacturer Contents	GC85A (K181629)		GC70 (K180543)		GC70		Discussion
(3) Detector							
Name (Model Number)	S4335-W S4343-W S3025-W S4335-AW S4343-AW		S4335-W S4343-W S3025-W		S4335-W S4343-W S3025-W S4335-AW S4343-AW		Same as PD#1
	S4335-AW	S4343-AW	S4335-W	S4343-W	S4335-AW	S4343-AW	
Detector Type	CsI	CsI	CsI	CsI	CsI	CsI	Same
	Indirect	Indirect	Indirect	Indirect	Indirect	Indirect	Same
Detector Area	14"X17"(345m	17"X17"(425m	14"X17"(345m	17"X17"(425m	14"X17"(345m	17"X17"(425m	Same

Manufacturer Contents	GC85A (K181629)		GC70 (K180543)		GC70		Discussion
	mX425 mm)	mX425 mm)	mX425 mm)	mX425 mm)	mX425 mm)	mX425 mm)	
Number of pixels	2466X 3040	3036X 3040	2466X 3040	3036X 3040	2466X 3040	3036X 3040	Same
Pixel Pitch(um)	140	140	140	140	140	140	Same
High Contrast Limiting Resolution (LP/mm)	3.57	3.57	3.57	3.57	3.57	3.57	Same
Communication	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Same
Dust/Water-resistance	IP54		IPx1		IP54		Same as PD#1
Max.load capacity	400 kg for uniform load, 200 kg for local load (40 mm in diameter disk at the center)		150 kg for uniform load, 100 kg for local load (40 mm in diameter disk at the center)		400 kg for uniform load, 200 kg for local load (40 mm in diameter disk at the center)		Same as PD#1

Manufacturer Contents	GC85A (K181629)	GC70 (K180543)	GC70	Discussion
(4) Software Features				
Feature Names	SimGrid	SimGrid	SimGrid	Same
	S-Guide	S-Guide	S-Guide	Same
	S-Enhance		S-Enhance	Same as PD#1
	PEM	-	PEM	Same as PD#1
	S-DAP	S-DAP	S-DAP	Same
	S-Align	S-Align	S-Align	Same
	S-Share	S-Share	S-Share	Same
	BSI	BSI	BSI	Same
	Remote View	-	Remote View	Same as PD#1

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, 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

Non-clinical testing data was provided in conformance to the FDA “Guidance for the Submission of 510(k)’s for Solid-State X-ray Imaging Devices”, which includes MTF and DQE measurements as tested by IEC 62220-1. The verification and validation for the software features added to the proposed device were also conducted and reviewed in accordance with internal design change procedure. As a result, requirement specifications were met and the proposed device shows no difference in non-clinical testing data such as MTF and DQE measurements from the predicate device.

D. Clinical data

The application of these hardware options and software features, cleared with K181629, to the proposed device GC70 do not require clinical data.

E. Conclusions

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