July 20, 2018

Samsung Electronics Co., Ltd.
% Jaesang Noh
Senior Professional, Regulatory Affairs
129, Samsung-ro, Yeongtong-gu
Suwon-si, Gyeonggi-do 16677
REPUBLIC OF KOREA

Re: K181629
Trade/Device Name: GC85A
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: June 15, 2018
Received: June 20, 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 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 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)*

K181629

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.

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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:** June 15, 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**
   A. Name: Genci Omari
   B. Title: Manager, Regulatory Affairs
   C. Phone Number: 978-564-8602
   D. FAX Number: 978-560-0602
   E. E-Mail: gomari@samsungneurologica.com

5. **Proposed Device**
   A. Trade Name: GC85A
   B. Device Name: GC85A
   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
Device Name	GC85A	GM85
Classification Name	Stationary X-ray System	Mobile X-ray System
Product Code	KPR	IZL
Regulation	21 CFR 892.1680	21 CFR 892.1720
510(K)#	K172229	K171119
510(K) Decision Date	Nov., 22, 2017	May, 12, 2017

7. Device Description

The GC85A 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 GC85A digital X-ray imaging system was previously cleared with K172229, and through this premarket notification, we would like to add more configurations in the previously cleared GC85A as three High Voltage Generators and two detectors are newly added, and three software features are newly added as stated below.
S-Enhance is renamed from Tube & Line Enhancement (TLE), which was cleared before with the predicate device GM85 at K171119, to enhance visibility of tubes and lines and provide enhanced images separately from original images. In this submission, the scope of S-Enhance is expanded from tubes and lines on chest images to foreign body (e.g. tubes, lines and needles) and urinary stones on chest, abdomen, and L-spine. And Pediatric Exposure Management (PEM), which was cleared before with the predicate device GM85 at K171119, is subdivided patient size and exposure conditions especially for pediatric patients based on weight and protocols, and Remote View to enable the images on the device is being displayed on the remote monitor. It was determined that the level of concern for the software contained in the GC85A digital X-ray imaging system was Moderate in accordance with the FDA guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Device".

8. Intended Use

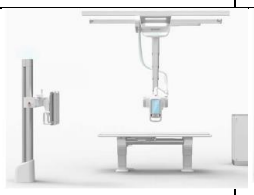
The GC85A Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.

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

The proposed device GC85A apply software features as S-Enhance and Pediatric Exposure, which were cleared with K171119, and Remote View to GC85A product which was cleared with K172229 without changes in technical characteristics, materials, energy sources and biocompatibility such as X-ray Tube Assembly except of high voltage generator and detector. Optional high voltage generators and detectors which were improved durability and dust/water-resistance are added to GC85A.

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

A. Comparing with Predicate Device

Specification	Predicate Device #1	Proposed Device	Predicate Device #2	Discussion
Device Name	GC85A	GC85A	GM85	
Manufacturer	SAMSUNG ELECTRONICS Co., Ltd.	SAMSUNG ELECTRONICS Co., Ltd.	SAMSUNG ELECTRONICS Co., Ltd.	
510(k) Number	K172229	None	K171119	
Appearances				Same as PD#1
Intended Use	The GC85A digital X-ray imaging system is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.	The GC85A Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.	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#1

Manufacturer Contents		GC85A (K172229)	GC85A				GM85 (K171119)	Discussion
(1)High Voltage Generator								
Max. Power		82kW	82kW	52kW	80kW	50kW	32kW / 40kW	Difference(1)
Output RANGE	Tube Voltage	40-150kV	40-150kV	v40-150kV	40-150kV	40-150kV	40-150kV	Same
	Tube Curr	10-1000mA	10-1000	10-640	10-1000	10-630m	10 - 500mA	Difference(2)

Manufacturer Contents		GC85A (K172229)	GC85A				GM85 (K171119)	Discussion
	ent		mA	mA	mA	A		
	Exposure Time	1msec-10sec	1msec-10sec	1msec-10sec	1msec-10sec	1msec-10sec	1msec-10sec	Same
AEC (Automatic Exposure Control)		Yes	Yes				-	Same as PD#1
APR (Anatomically Programmed Radiography)		Yes	Yes				-	Same as PD#1

Manufacturer Contents	GC85A (K172229)		GC85A		GM85 (K171119)		Discussion
(2) Detector							
Name	S4335-W S4343-W S3025-W		S4335-W S4343-W S3025-W S4335-AW S4343-AW		S4335-W S4343-W S3025-W		Difference(3)
	S4335-W	S4343-W	S4335-AW	S4343-AW	S4335-W	S4343-W	
Detector Type	CsI	CsI	CsI	CsI	CsI	CsI	Same
	Indirect	Indirect	Indirect	Indirect	Indirect	Indirect	Same
Detector Area	14"X17" (345mm X425mm)	17"X17" (425mm X425mm)	14"X17" (345mm X425mm)	17"X17" (425mm X425mm)	14"X17" (345mm X425mm)	17"X17" (425mm X425mm)	Same
Number of pixels	2466X3040	3036X3040	2466X3040	3036X3040	2466X3040	3036X3040	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	IPx1		IP54		IPx1		Difference(3)-1
Max.load capacity	150 kg for uniform load, 100 kg for local load (40 mm in diameter disk at		400 kg for uniform load, 200 kg for local load (40 mm in diameter disk at		150 kg for uniform load, 100 kg for local load (40 mm in diameter disk at		Difference(3)-2

Manufacturer Contents	GC85A (K172229)	GC85A	GM85 (K171119)	Discussion
	the center)	the center)	the center)	

Manufacturer Contents	GC85A (K172229)	GC85A	GM85 (K171119)	Discussion
(3) Software Features				
Feature Names	SimGrid	SimGrid	SimGrid	Same
	S-Guide	S-Guide	-	Same as PD#1
	-	S-Enhance	TLE	Difference(4)
	-	PEM	PEM	Same as PD#2
	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	-	Difference(5)

No	Differences	Explanation
(1)	HVG Power rating	Optional HVGs which are added to the GC85A device have lower max power than the predicate device's max power and these changes do not contribute any adverse impact to the device's safety and effectiveness.
(2)	HVG mA range	Optional HVGs which are added to the GC85A device have lower max current than the predicate's max current and these changes do not contribute any adverse impact to the device's safety and effectiveness.
(3)-1	Dust/Water-resistance	The new detectors which are added to the GC85A device have better dust/water-resistance than the predicate device's dust/water-resistance and this change does not contribute any adverse impact to the device's safety and effectiveness.
(3)-2	Max.load capacity	The new detectors which are added to the GC85A device have higher max load capacity than the predicate device's

		max load capacity and this change does not contribute any adverse impact to the device's safety and effectiveness.
(4)	S-Enhance	S-Enhance is renamed from Tube & Line Enhancement (TLE), which was cleared with K171119, is to enhance visibility of tubes and lines and provide enhanced images separately from original images. This software feature is applied to the GC85A with the scope of application for S-Enhance, which is expanded from tubes and lines on chest images to foreign body (e.g. tubes, lines and needles) and urinary stones on chest, abdomen and L-spine images. This change is considered low risk and does not contribute any adverse impact to the device's safety and effectiveness.
(5)	Remote View	The function of Remote View, which allows remote access to view the current image on the workstation through a web browser, is applied to the GC85A and this change does not contribute any adverse impact to the device's safety and effectiveness.

B. Safety, EMC and Performance Data

Electrical, mechanical, environmental safety and performance testing according to standard ES 60601-1,IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-28, IEC 60601-2-54, 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 proposed device shows no difference in non-clinical testing data such as MTF and DQE measurements form the predicate device.

D. Clinical data

Phantom image evaluations for the new detector and S-Enhance were performed in accordance with FDA guidance for the submission of 510(k)'s for Solid State X-ray Imaging Devices. Anthropomorphic phantom images were provided; these images were not necessary to establish substantial equivalence based on the modifications to the device (note X-ray flat-panel detector similar to the predicate detector) but they provide further evidence in addition to the performance data to show that the complete system works as intended. They were evaluated by professional radiologists and found to be equivalent to the predicate devices. There is no significant difference in the average score considering the standard deviation of image quality evaluation between the proposed device and the predicate device and it is confirmed that S-Enhance is able to generate a companion image which provide clear visibility for foreign bodies such as lines, tubes, and

needles, and urinary stones in chest, abdomen, and L-spine protocol in addition to the original images. Therefore, these changes do not affect either the safety or the effectiveness, compared to the predicated device.

E. Conclusions

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