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

October 23, 2018

Re: K182622
Trade/Device Name: GU60A, GU60A-65
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: 2018.10.23 17:42:12 -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)*

K182622

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)

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**
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   B. Address: 129, Samsung-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16677, Republic of Korea

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   D. FAX Number: 978-560-0602
   E. E-Mail: gomari@samsungneurologica.com

5. **Proposed Devices**
   A. Trade Name**s**: GU60A, GU60A-65
   B. Device Name**s**: GU60A, GU60A-65
   C. Common Name: Digital Diagnostic X-ray System
   D. Regulation Name: Stationary X-ray system
   E. Regulation: 21 CFR 892.1680
   F. Product Code: KPR

6. **Predicate Device**

	Predicate Device #1 (Primary Predicate)	Predicate Device #2
Device Name	GU60A, GU60A-65	GC85A
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)#	K180543	K181629
510(K) Decision Date	May 24,2018	July 20, 2018

7. **Device Description**
   The GU60A, GU60A-65 digital X-ray imaging systems are 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 GU60A, GU60A-65 digital X-ray imaging systems consist of HVG (High Voltage Generator), U-arm positioner, X-ray tube, collimator, detector, ACE (Auto Exposure Control), DAP (Dose Area Product), CIB (Control Interface Box), remote controller, grid, barcode scanner, auto-stitching stand, weight distribution cap and workstation for S-station including Image Post-processing Engine (IPE).
The difference between GU60A and GU60A-65 is that the option of their HVG is different. In detail, 50 kW and 68 kW are for GU60A and 65 KW is for GU60A-65.

The GU60A, GU60A-65 digital X-ray imaging systems were previously cleared under K180543, and some hardware options and three software features are added to the predicate device GU60A, GU60A-65. The changes are as follows:

- Two detectors
- 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 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.

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

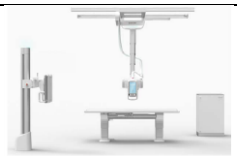
The proposed device GU60A, GU60A-65 do not alter the intended use or the fundamental scientific technology and remains within the same classification regulation for the same intended use as the predicate devices #1 and 2 because the proposed device GU60A,

GU60A-65 use the same detectors and 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 to the predicate devices, which do not show significant difference in safety and effectiveness.

Manufacturer Contents	Predicate Device #1 (Primary Predicate)	Proposed Device	Predicate Device #2	Discussion
Device Name	GU60A, GU60A-65	GU60A, GU60A-65	GC85A	
Manufacture	Samsung	Samsung	Samsung	
510(k) Number	K180543		K181629	
Appearance				Same as PD#1
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.	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

Manufacturer Contents	Predicate Device #1	Proposed Device	Predicate Device #2	Discussion
(1) Detectors (Note: All detectors were 510(k) cleared with predicate #1, #2)				

Name (Model Number)	S4335-W S4343-W S3025-W		S4335-W S4343-W S3025-W S4335-AW S4343-AW		S4335-W S4343-W S3025-W S4335-AW S4343-AW		Same as PD#2
	S4335-W	S4343-W	S4335-AW	S4343-AW	S4335-AW	S4343-AW	
Detector Type	CsI	CsI	CsI	CsI	CsI	CsI	Same
	Indirect	Indirect	Indirect	Indirect	Indirect	Indirect	Same
Detector Area	14"X17"(345mmX425mm)	17"X17"(425mmX425mm)	14"X17"(345mmX425mm)	17"X17"(425mmX425mm)	14"X17"(345mmX425mm)	17"X17"(425mmX425mm)	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		IP54		Same as PD#2
Max.load capacity	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)		400 kg for uniform load, 200 kg for local load (40 mm in diameter disk at the center)		Same as PD#2

Manufacturer Contents	Predicate Device #1	Proposed Device	Predicate Device #2	Discussion
(2) Software Feature				
Feature Names	SimGrid	SimGrid	SimGrid	Same
	-	-	S-Guide	N/A
	TLE	S-Enhance	S-Enhance	Same as PD#2
	-	PEM	PEM	Same as PD#2
	S-DAP	S-DAP	S-DAP	Same
	S-Share	S-Share	S-Share	Same
	BSI	BSI	BSI	Same
	-	Remote View	Remote View	Same as PD#2

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 detectors and software features, cleared with K181629, to the proposed device GU60A, GU60A-65 does not require clinical data.

E. Conclusions

Non-clinical data demonstrates that the proposed devices are as safe, as effective, and perform as well as the legally marketed predicate devices.