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

November 22, 2017

Re: K172229
Trade/Device Name: GC85A
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: October 19, 2017
Received: October 20, 2017

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,

Michael D. O'Hara 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)*

K172229

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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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 20, 2017

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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4. **Secondary Contact Person**
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5. **Proposed Device**
   A. Trade Name: GC85A
   B. Device Name: GC85A
   C. Common Name: Digital Diagnostic X-ray System
   D. Classification Name: Stationary X-ray System
   E. Product Code: KPR
   F. Regulation: 21 CFR 892.1680

6. **Predicate Devices**

	Predicate Device
Device Name	GC85A
Classification Name	Stationary X-ray System
Product Code	KPR
Regulation	21 CFR 892.1680
510(K)#	K160997
510(K) Decision Date	July 6, 2016

7. Device Description

The GC85A digital X-ray imaging system is 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 device before being sent to the S-Station (Operation Software) and saved in DICOM file, a standard for medical imaging. The captured images are sent to the Picture Archiving & Communication System (PACS) server, and can be used for reading images.

The Image Post-processing Engine is exclusively installed in S-station, which is a Samsung Digital X-ray Operation Software for Samsung Digital X-ray System. It has an image processing algorithm to improve an acquired image and previously cleared with K160997.

The proposed Image Post-processing Engine is upgraded with employing an advanced noise reduction algorithm to improve image quality. The proposed Engine is shown of a post-processed image as substantially equivalent as the image by the predicate Image Post-processing Engine at a certain low dose level.

This submission is intended to get 510(k) clearance for GC85A with the proposed engine by which the substantially equivalent PA radiograph for average adult chest can be taken using the 50% dose reduction 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 new GC85A also was not studied with pediatric patients. 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 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 has the same hardware characteristics as the predicate device (K160997) and includes an upgraded Image Post-processing engine. It does not have significant changes in materials, energy source or technological characteristics compared to the predicate device.

A. Comparing with Predicate Device

Specification	Predicate Device	Proposed Device	Discussion
Device Name	GC85A	GC85A	-

Manufacturer	SAMSUNG ELECTRONICS co., ltd.	SAMSUNG ELECTRONICS co., ltd.	-
510(k) Number	K160997	None	-
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.	Same
Image Post-Processing engine			
Noise reduction algorithm	Image Post-processing Engine with a conventional noise reduction algorithm	Image Post-processing Engine with an advanced noise reduction algorithm	Different(1)

No	Differences	Explanation
(1)	Image Post-processing Engine with an advanced noise reduction algorithm	The Image Post-processing Engine is upgraded with employing an advanced noise reduction algorithm which optimizes the degree of noise reduction for improvement of image quality according to the noise distribution and the structural information of a digital radiographic image. While the upgraded Image Post-processing Engine is shown a substantially equivalent image and safe as same as the predicate device's one, it can be taken by the 50% dose reduction comparing with the predicate Image Post-processing Engine.

10. 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.

11. 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 Image Post-processing Engine was evaluated with a semi-anatomical chest phantom at a various radiation dose. SNR and CNR were measured to determine image quality with the images taken using the proposed engine or the predicated engine. Overall images using the proposed engine make it easy to distinguish between background and the object and is clearer than images using the predicated engine. The

qualitative side including usefulness was validated by a radiographer using clinical images which was proved in 'Clinical data' section.

12. Clinical data

Phantom image evaluations were performed in accordance with FDA guidance for the submission of 510(k)'s for Solid State X-ray Imaging Devices. They were evaluated by professional radiologists and found to be equivalent to the predicate device.

The proposed engine was validated with anthropomorphic chest phantom images and clinical images by three professional radiologists. Anthropomorphic chest phantom images were scored by Bureau of Radiological Health (BRH) method and inter-observer agreement was calculated. Clinical image evaluations were performed to support phantom study results under the patient informed consent. Total 78 in-vivo data set of chest PA images were evaluated by three experienced radiologists, covering subject's BMI from 15 to 33. Seven anatomical landmarks were evaluated for image quality assessment by three readers, including 18 cases of featured lung lesions of chest PA images, consolidations, nodules and interstitial markings. The images using the proposed engine taken at 50% reduction in radiation dose are substantially equivalent to those using the predicated engine without sacrificing diagnostic confidence.

13. 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.