



Food and Drug Administration
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SAMSUNG ELECTRONICS Co., Ltd.
% ChulSin Kim
Regulatory Affairs Manager
129, Samsung-ro, Yeongtong-gu,
Suwon-si, Gyeonggi-do 443-742
REPUBLIC OF KOREA

July 17, 2015

Re: K151685
Trade/Device Name: GU60A & GU60A-65
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: June 23, 2015
Received: June 24, 2015

Dear Chulsin Kim:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. A faint, semi-transparent "FDA" watermark is visible behind the signature.

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151685

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.

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** : June 19, 2015
2. **Submitter**
 - A. Company Name: SAMSUNG ELECTRONICS Co., Ltd.
 - B. Address: 129, Samsung-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, 443-742, Republic of Korea
3. **Primary Contact Person**
 - A. Name: ChulSin Kim
 - B. Title: Regulatory Affairs Manager
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 - E-Mail: chulsin.kim@samsung.com
4. **Secondary Contact Person**
 - A. Name: Ninad Gujar
 - B. Title: Regulatory Affairs Manager
 - C. Phone Number: 978-564-8503
 - D. FAX Number: 978-750-6677
 - E-Mail: ngujar@samsungneurologica.com
5. **Proposed Devices**
 - A. Trade Names: GU60A & GU60A-65
 - B. Device Names: GU60A & GU60A-65
 - C. Common Name: Digital Diagnostic X-ray System
 - D. Classification Name: **Stationary X-ray System**
 - E. Regulation: 21 CFR 892.1680
 - F. Product Code: KPR
6. **Predicate Device**
 - A. Manufacturer: SAMSUNG ELECTRONICS Co., Ltd.
 - B. Device Name: XGEO GU60A
 - C. Common Name: Digital Diagnostic X-ray System
 - D. Classification Name: **Stationary X-ray System**
 - E. Regulation: 21 CFR 892.1680
 - F. Product Code: KPR
 - G. 510(k) Number: K140332
 - H. 510(k) Decision Date: May 28,2014
7. **Device Description**

The GU60A & GU60A-65 digital X-ray imaging systems are to be used to take and store image for diagnosis of patients. It consists of HVG(High voltage generator), U-arm positioner, Detector, X-ray tube, Collimator, AEC(Auto Exposure Control), DAP(Dose Area Product), CIB(Control Interface Box), Remote controller, Grid, Barcode scanner and Auto-stitching stand.

These systems 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 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.

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 GU60A & GU60A-65 add two detectors (S4335-W & S3025-W), already cleared with K150165, to the list of detector of predicate device XGEO GU60A (K140332), and GU60A-65 has a HVG (High Voltage Generator) which have no significant difference in materials, energy source or technological characteristics compared to the predicate device. Comparisons of the following technological characteristics were assessed and the results demonstrate the substantial equivalence to the predicate device.

Manufacturer Contents	XGEO GU60A (K140332)	GU60A & GU60A-65			Discussion
(4) Detector *NOTE: S4335-W and S3025-W were already cleared with K150165.					
Name	S4343-W	S4343-W	S4335-W	S3025-W	
Detector type	Csl	Csl	Csl	Csl	Same
	Indirect	Indirect	Indirect	Indirect	Same
Detector area	17"X17" (425mmX425mm)	17"X17" (425mmX425mm)	14"X17" (345mmX425mm)	10"X12" (245mmX295mm)	Difference(1)
Number of pixels	3,036 x 3,040	3,036 x 3,040	2,466 x 3,040	1,750 x 2,108	Difference(2)
Pixel pitch(um)	140	140	140	140	Same
High contrast limiting resolution(lp/mm)	3.57	3.57	3.57	3.57	Same
Communication	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Same

Manufacturer Contents	XGEO GU60A (K140332)	GU60A	GU60A-65	Discussion	
(3) High Voltage Generator					
Type	High Frequency	High Frequency		Same	
Max. Power	50kW	50kW	65kW	Difference(3)	
Output RANGE	Tube Voltage	40-150kV	40-150kV	Same	
	Tube Current	10-630mA	10-630mA	10-800mA	Difference(4)
	Exposure Time	1msec-6.3sec	1msec-6.3sec		Same
AEC (Automatic Exposure Control)	Yes	Yes		Same	
APR (Anatomically Programmed Radiography)	Yes	Yes		Same	

A. Differences Explanation

No	Differences	Explanation
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(1)	Detector Area	Proposed medical device's S4335-W and S3025-W detectors have smaller area than the predicate device's detectors while technical specification is identical among them such as type & pixel pitch, and the smaller area does not contribute any adverse impacts to the device's safety and performance.
(2)	Number of pixels Resolution and pixel pitch of detector	Proposed medical device's S4335-W and S3025-W detector have smaller detector area. Therefore, the proposed medical device's numbers of pixels is smaller than the predicate device's detectors while pixel pitch is identical among them, and the smaller number of pixels does not contribute any adverse impacts to the device's safety and performance.
(3)	HVG Max Power	Proposed GU60A-65's HVG has higher max power than the predicate device's max power, and the higher max power does not contribute any adverse impacts to the device's safety and performance.
(4)	HVG Tube Current Range	Proposed GU60A-65's HVG has higher max tube current than the predicate device's max tube current, and the higher max tube current does not contribute any adverse impacts to the device's safety and performance.

The proposed GU60A & GU60A-65 devices have the same intended use, and the differences among the predicate device and the proposed devices do not introduce any new potential safety & performance risks, and the proposed devices are substantially equivalent to and performs as well as the predicate device.

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 devices show no difference in non-clinical testing data such as MTF and DQE measurements from the predicate device.

12. Clinical data

A Clinical images review report is prepared in accordance with FDA guidance for the submission of 510(k)'s for Solid State X-ray Imaging Devices, which shows the equivalent diagnostic capability to the predicate device.

13. Conclusions

The results of non-clinical and clinical data demonstrate that the proposed devices are as safe, as effective, and perform as well as the legally marketed device.

14. Samsung Electronics Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.