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

January 12, 2018

Re: K173828
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: December 19, 2017
Received: December 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)*
K173828

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 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 :** November 30, 2017
2. **Submitter**
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   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: Ninad Gujar
   B. Title: Director, Regulatory & Quality
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   D. FAX Number: 978-750-6677
   E-Mail: ngujar@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** | **Predicate Device #2** |
|---|---|---|
| Device Name | GU60A & GU60A-65 | 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)# | K151685 | K171119 |
| 510(K) Decision Date | July 17, 2015 | May 12, 2017 |

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.

The GU60A & GU60A-65 digital X-ray imaging systems is stationary, and it was previously cleared under K151685. The software features cleared with K171119, SimGrid, BSI (Bone Suppression Image) and TLE (Tube & Line Enhancement), is added to the predicate x-ray system (K151685).

The software features called as SimGrid, BSI (Bone Suppression Image) and TLE (Tube & Line Enhancement) is a post-image processing software option which provides companion images to assist diagnosis in addition to the images obtained from normal diagnosis protocol.
The SimGrid software option is able to compensate the contrast loss due to scatter radiations, primarily acquisitions without a physical anti-scatter grid.
The BSI software option suppresses bone anatomy and the TLE software option enhances visibility of tube and catheter features in a companion image that is delivered in addition to the original diagnostic image.
These software features are designed to be exclusively installed in S-station, SAMSUNG digital X-ray operation software, while it uses the radiological image as an input and do not depend on how the image is acquired or which radiology device is used.

**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 apply a post-image processing software feature as SimGrid, TLE (Tube & Line Enhancement), S-DAP and BSI (Bone Suppression Image), which was cleared with K171119, to GU60A & GU60A-65 product which were cleared with K151685 without changes in technical characteristics, materials, energy sources and biocompatibility such as X-ray Tube Assembly and Detectors except of high voltage generator. Optional high voltage generator is added to GU60A model.

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

A. Comparing with Predicate Device #1 and #2

The proposed device is shown as its parts are identical or equivalent with predicate device #1 or #2 while the software features called as SimGrid, BSI, TLE and S-DAP are applied, which does not show significant difference in safety and effectiveness.

| Manufacturer Contents | Predicate Device #1 | Proposed Device | Predicate Device #2 | Discussion |
|---|---|---|---|---|
| Device Name | GU60A & GU60A-65 | GU60A & GU60A-65 | GM85 | |
| Manufacture | Samsung | Samsung | Samsung | |
| 510(k) Number | K151685 | | K171119 | |

| | | | | |
|---|---|---|---|---|
| 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 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** | **Predicate Device #1** | **Proposed Device** | | **Predicate Device #2** | **Discussion** |
|---|---|---|---|---|---|
| High voltage generator | | | | | |
| Model | GU60A | GU60A | | - | Same as PD#1 |
| Phase | 3 phase | 3 phase | | - | Same as PD#1 |
| Frequency | 50/60 Hz | 50/60 Hz | | - | Same as PD#1 |
| Line voltage | 400/480 VAC ±10% | 400/480 VAC ±10% | | - | Same as PD#1 |
| Power rating | 50kW | 50kW | 68kW | - | Difference(1) |
| kV range | 40 ~ 150 kV | 40 ~ 150 kV | | - | Same as PD#1 |
| mA range | 10 ~ 630 mA | 10 ~ 630 mA | 10 ~ 800 mA | - | Difference(2) |
| Time range | 1.0 ms ~ 6.3sec | 1.0 ms ~ 6.3sec | 1.0 ms ~ 10sec | - | Difference(3) |

| **Manufacturer Contents** | **Predicate Device #1** | **Proposed Device** | **Predicate Device #2** | **Discussion** |
|---|---|---|---|---|
| Software Feature | | | | |
| BSI | - | BSI | BSI | Same as PD#2 |
| SimGrid | - | SimGrid | SimGrid | Same as PD#2 |

| | | | | |
|---|---|---|---|---|
| Tube & Line Enhancement (TLE) | - | TLE | TLE | Same as PD#2 |
| S-DAP | - | S-DAP | S-DAP | Same as PD#2 |
| S-Share | S-Share | S-Share | S-Share | Same |

| No | Differences | Explanation |
|---|---|---|
| (1) | Power rating | Optional HVG which is added to the GU60A device has higher max power than the predicate device's max power and the higher max power does not contribute any adverse impact to the device's safety and effectiveness. |
| (2) | mA range | Optional HVG which is added to the GU60A device has higher max current than the predicate device's max current and the higher max current does not contribute any adverse impact to the device's safety and effectiveness. |
| (3) | Time range | Optional HVG which is added to the GU60A device has longer max time than the predicate device's max time and the longer max time 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 devices show no difference in non-clinical testing data such as MTF and DQE measurements from the predicate device.

D. Clinical data

The application of SimGrid, TLE, S-DAP and BSI, cleared with K171119, 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.