DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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SAMSUNG ELECTRONICS Co., Ltd. June 23, 2015
% Chulsin Kim
Regulatory Affairs Manager
129, Samsung-ro, Yeongtong-gu
Suwon-si, Gyeonggi-do 443-742
REPUBLIC OF KOREA

Re: K151419
Trade/Device Name: GF50A
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: May 27, 2015
Received: May 28, 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,

Robert A Ochs

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

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)*

K151419

Device Name
GF50A

Indications for Use *(Describe)*

The GF50A 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:** May 27, 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
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4. **Secondary Contact Person**
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   B. Title: Regulatory Affairs Manager
   C. Phone Number: 978-564-8503
   D. FAX Number: 978-750-6677
   E-Mail: ngujar@samsungneurologica.com
5. **Proposed Device**
   A. Trade Name: GF50A
   B. Device Name: GF50A
   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 Device**
   A. Manufacturer: SAMSUNG ELECTRONICS Co., Ltd.
   B. Device Name: XGEO GF50
   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
   G. 510(k) Number: K140326
   H. 510(k) Decision Date: May 28, 2014

7. **Device Description**

The GF50A digital X-ray imaging system consists of High voltage generator (HVG), Tube Stand, Wall Bucky Stand, Patient table, Detector, X-ray tube, Collimator, Automatic Exposure Control(AEC), Dose Area Product(DAP), Control Interface Box (CIB), Grid and Barcode scanner.

This 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.

8. **Intended Use**

The GF50A 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 GF50A has a High voltage generator different from the one the predicate device has, which does not have significant change in materials, energy source or technological characteristics compared to the predicate device, XGEO GF50 (K140326).

Comparisons with technological characteristics were assessed and the results demonstrate the substantial equivalence to the predicates.

Manufacturer Contents		XGEO GF50 (K140326)	GF50A	Discussion
(1)High Voltage Generator				
Type		High Frequency	High Frequency	Same
Max. Power		52kW	40kW	Differences(1)
Output RANGE	Tube Voltage	40-150kV	40-125kV	Differences(2)
	Tube Current	10-640mA	10-500mA	Differences(3)
	Exposure Time	1msec-10sec	1msec-10sec	Same

A. Differences Explanation

No.	Differences	Explanation
(1)	HVG Max Power	Proposed medical device's HVG has lower max power than the predicate device's max power, and the lower max power does not contribute any adverse impacts to the device's safety and performance.
(2)	Tube Voltage	Proposed medical device's HVG has lower Tube voltage than the predicate device's Tube voltage, and the lower Tube voltage does not contribute any adverse impacts to the device's safety and performance.
(3)	Tube Current	Proposed medical device's HVG has lower Tube current than the predicate device's Tube current, and the lower Tube current does not

		contribute any adverse impacts to the device's safety and performance.

In non-clinical data, the proposed detector shows curves and measurements of MTF and DQE that do not differ from the predicate device, and the proposed GF50A has been shown a substantially equivalent to 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 device shows no difference in non-clinical testing data such as MTF and DQE measurements from the predicate device.

12. Clinical data

Not required since the difference of Max Power, Tube Voltage and Current of HVG does not affect the clinical images of the detector which was cleared with the predicate device.

13. Conclusions

The results of the non-clinical data demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed device identified in paragraph 6.