DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Samsung Electronics Co., Ltd.
% Chulsin Kim
Regulatory Affairs Manager
129, Samsung-ro
Yeongtong-gu
Suwon-si, Gyeonggi-do, 443742
REPUBLIC OF KOREA

December 17, 2014

Re: K142492
Trade/Device Name: GM60A-32S, GM60A-40S
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: November 20, 2014
Received: November 24, 2014

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 A. 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)*
K142492

Device Name
GM60A-32S, GM60A-40S

Indications for Use *(Describe)*
The GM60A 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.

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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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 19, 2014
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**
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4. **Secondary Contact Person**
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   B. Title: Vice President Regulatory & Quality Assurance
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   E-Mail: dfickett@samsungneurologica.com

5. **Identification Device**
   A. Trade Name: GM60A
   B. Device Name: GM60A-32S, GM60A-40S
   C. Common Name: Digital Diagnostic Mobile X-ray System
   D. Classification Name: Mobile X-ray System
   E. Product Code: IZL
   F. Regulation: 21 CFR 892.1720

6. **Predicate Device**
   6.1 Predicate Device I

A. Manufacturer: Sedecal, Inc. SEDECAL SA
B. Device Name: Easy Moving Plus, SM-XXHF-YY
C. Classification Name: Mobile X-ray system, Solid State X-Ray Imager(Flat Panel/Digital Imager)
D. Product Code: IZL
E. 510(k) Number: K090322
F. 510(k) Decision Date: March 17, 2009

6.2 Predicate Device II

G. Manufacturer: SAMSUNG ELECTRONICS Co., Ltd.
H. Trade Name: XGEO GC80
I. Classification Name: System, X-ray, Stationary
J. Product Code: KPR
K. 510(k) Number: K140334
L. 510(k) Decision Date: May 28, 2014

7. Device Description

The GM60A Digital Mobile X-ray imaging system consists of High voltage generator (HVG), X-ray tube, Collimator, Detector, DAP 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 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 GM60A 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.

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

The GM60A' system does not have significant changes in materials, energy source or

technological characteristics compared to the predicate device, Easy moving plus(K090322), and the detectors that GM60A uses are same as the one that the predicate device of XGEO GC80(K140334) uses. Comparisons of the following technological characteristics were assessed and the results demonstrate the substantial equivalence to the predicates.

Specification	Predicate Device I	Proposed Device	Predicate Device II	Discussion
Device Name	Sedecal Easy moving plus	GM60A	XGEO GC80	
Manufacturer	Sedecal SA	SAMSUNG ELECTRONICS	SAMSUNG ELECTRONICS	
510(k) Number	K090322	N/A	K140334	
Appearances				Same
Intended Use	Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.	The GM60A 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.	The XGEO GC80 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

Manufacturer Contents		Sedecal Easy moving plus (K090322)	GM60A	XGEO GC80 (K140334)	Discussion
(1)High Voltage Generator					
Type		High Frequency	High Frequency	High Frequency	Same
Max. Power		20/32/40/50kW	32kW / 40kW	80kW	Same as K090322
Output RANGE	kVp Range	40 to 150kVp	40 to 150kVp	40 to 150kVp	Same
	mA Range	20kW : 10 to 320mA 32/40/50kW : 10 to 500mA	10 to 500mA	10-1000mA	Same as K090322
	Exposure Time	1msec-10sec	1msec-10sec	1msec-6.3sec	Same or above

Manufacturer Contents		Sedecal Easy moving plus (K090322)	GM60A	XGEO GC80 (K140334)	Discussion
(2)Tube assembly					
Moving Range	Horizontal	700~1250	700~1250	1030~3030	Same as K090322
	Vertical	550~2020 550~1890 (Option)	550~2020 550~1890 (Option)	△1,840	Same as K090322
Rotation Range	Column	±315°	±315°	-157° ~ +183°	Same or better
	Tube(Arm axis)	±180°	±180°	±120°	Same or better
	Tube(Tube axis)	-30°~90°	-30°~90°	N/A	Same or better
Collimator		RALCO R221 DHHS	RALCO R221 DHHS	SAMSUNG Electronics	Same as K090322

Manufacturer Contents	Sedecal Easy moving Plus(K090322)	GM60A		XGEO GC80 (K140334)		Discussion
(3) Detectors						
Name	Canon CXDI-50G	S4335-W	S4343-W	S4335-W	S4343-W	
Detector Type	GOS	CsI	CsI	CsI	CsI	Same or better
	Indirect	Indirect	Indirect	Indirect	Indirect	Same
Detector Area	14"X17" (353mmX430mm)	14"X17" (345mmX425mm)	17"X17" (425mmX425mm)	14"X17" (345mmX425mm)	17"X17" (425mmX425mm)	Similar
Number of pixels	2208X2688	2466X3040	3036X3040	2466X3040	3036X3040	Same or better
Pixel Pitch(um)	160	140	140	140	140	
High Contrast Limiting Resolution (LP/mm)	N/A	3.57	3.57	3.57	3.57	
Communication	Wired	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Same or better
(4) Grid						
Lines/cm	40	84.6		84.6		Same or better
Grid mechanism	Stationary	Stationary		Stationary		Same
Removability	Removable	Removable		Removable		Same

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 60601-1-2:2007. Wireless function was tested and verified followed by guidance, Radio frequency Wireless Technology in Medical Devices. All test results were satisfied.

11. Non-clinical data

In non-clinical data, MTF and DQE were tested and measured by IEC 62220-1. The proposed device shows same curves and measurements of MTF and DQE than the predicate device (K140334) at all spatial frequencies tested.

12. Clinical data

In clinical data, clinical images were obtained 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.

13. Conclusions

The non-clinical and clinical data that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph 6, above.

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