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 443-742
REPUBLIC OF KOREA

February 19, 2015

Re: K150097
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: January 14, 2015
Received: January 20, 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)*

K150097

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.

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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:** January 14, 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
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   D. FAX Number: 978-750-6677
   E-Mail: ngujar@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**
   A. Manufacturer: SAMSUNG ELECTRONICS Co., Ltd.
   B. Trade Name: GM60A
   C. Device Name: GM60A-32S, GM60A-40S
   D. Classification Name: Mobile X-ray system
   E. Product Code: IZL
   F. 510(k) Number: K142492
   G. 510(k) Decision Date: December 17, 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 Substantial Equivalence Discussion

The proposed GM60A adds a new detector (S3025-W) to the predicate device GM60A (K142492), and it has same materials, energy source or technological characteristics compare to the predicate device. The S3025-W detector has same pixel pitch and resolution from those detectors (S4343-W & S4335-W) used for the predicate device, and has just in differences of size. Comparisons of the following technological characteristics were assessed and the results demonstrate the substantial equivalence to the predicates.

Specification	Proposed Device	Predicate Device	Discussion
Device Name	GM60A	GM60A	
Manufacturer	SAMSUNG ELECTRONICS	SAMSUNG ELECTRONICS	
510(k) Number	N/A	K142492	
Appearances			Same
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.	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.	Same

Manufacturer Contents		GM60A	GM60A(K142492)	Discussion
(1)High Voltage Generator				
Type		High Frequency	High Frequency	Same
Max. Power		32kW / 40kW	32kW / 40kW	Same
Output RANGE	kVp Range	40 to 150kVp	40 to 150kVp	Same
	mA Range	10 to 500mA	10 to 500mA	Same

Manufacturer Contents		GM60A	GM60A(K142492)	Discussion
	Exposure Time	1msec-10sec	1msec-10sec	Same

Manufacturer Contents		GM60A	GM60A(K142492)	Discussion
(2)Tube assembly				
Moving Range	Horizontal	700~1250	700~1250	Same
	Vertical	550~2020 / 550~1890(Option)	550~2020 / 550~1890(Option)	Same
Rotation Range	Column	±315°	±315°	Same
	Tube(Arm axis)	±180°	±180°	Same
	Tube(Tube axis)	-30°~90°	-30°~90°	Same
Collimator		RALCO R221 DHHS	RALCO R221 DHHS	Same

Manufacturer Contents	GM60A			GM60A(K142492)		Discussion
(3) Detectors *NOTE: S3025-W detector as an option is added in the list of detectors that are S4335-W, S4343-W (cleared with K142492).						
Name	S4335-W	S4343-W	S3025-W	S4335-W	S4343-W	Different(1)
Detector Type	CsI	CsI	CsI	CsI	CsI	Same
	Indirect	Indirect	Indirect	Indirect	Indirect	Same
Detector Area	14"X17" (345mmX425mm)	17"X17" (425mmX425mm)	10"X12" (245mmX295mm)	14"X17" (345mmX425mm)	17"X17" (425mmX425mm)	Different(2)
Number of pixels	2466X3040	3036X3040	1750X2108	2466X3040	3036X3040	
Pixel Pitch(um)	140	140	140	140	140	Same
High Contrast Limiting Resolution (LP/mm)	3.57	3.57	3.57	3.57	3.57	Same
Communication	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Same
(4) Grid						
Lines/cm	84.6			84.6		Same
Grid mechanism	Stationary			Stationary		Same
Removability	Removable			Removable		Same

Note	Differences	Explanation
(1)	New detector,S3025-W, is included	Small size of new detector, S3025-W is included as an option.
(2)	Detector area is different from those of predicate device also number of pixels.	Detector area and number of pixels are different from those of predicate device but new detector has same technical characteristics, pixel pitch and resolution of detectors of predicate device. The new detector has just differences in size from predicate device and these differences do not contribute any adverse impacts to the predicate 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. In clinical data, the proposed GM60A 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 60601-1-2:2007. Wireless function was tested and verified followed by guidance, Radio frequency Wireless Technology in Medical Devices. All test results were satisfied as the standard.

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

Clinical images were provided; these images were not necessary to establish substantial equivalence based on the modifications to the device but they provide further evidence in addition to the laboratory performance data to show that the complete system works as intended. These images were evaluated by a radiologist with equivalent U.S. board certification and found to be equivalent to the predicate device.

13. Conclusions

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

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