DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 12, 2017

Samsung Electronics Co., Ltd.
% Chulsin Kim
Regulatory Affairs Manager
129, Samsung-ro, Yeongtong-gu
Suwon-si, 16677 Gyeonggi-do
REPUBLIC OF KOREA

Re: K171119
Trade/Device Name: GM85
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL, MQB
Dated: April 7, 2017
Received: April 14, 2017

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,

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)*

K171119

Device Name
GM85

Indications for Use *(Describe)*
The GM85 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.

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:** April 7, 2017

2. **Submitter**
   A. Company Name: SAMSUNG ELECTRONICS Co., Ltd.
   B. Address: 129, Samsung-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16677, 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: Director, Regulatory & Quality
   C. Phone Number: 978-564-8503
   D. FAX Number: 978-750-6677
   E-Mail: ngujar@samsungneurologica.com

5. **Proposed Device**
   A. Trade Name: GM85
   B. Device Name: GM85
   C. Common Name: Digital Diagnostic Mobile X-ray System
   D. Classification Name: Mobile X-ray System
   E. Product Code: IZL & MQB
   F. Regulation: 21 CFR 892.1720

6. **Predicate Devices**

	Predicate Device #1	Predicate Device #2
Device Name	GM85	GC70
Classification Name	MobileX-ray system.	Stationary X-ray System
Product Code	IZL	KPR
Regulation	21 CFR 892.1720	21 CFR 892.1680
510(K)#	K162278	K163115
510(K) Decision Date	November 15, 2016	December 07, 2016

7. Device Description

The GM85 Digital Mobile X-ray imaging System is the equipment that captures 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 Bone Suppression Image (BSI) 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 BSI software option suppresses bone anatomy to enhance visualization of chest pathology in a companion image that is delivered in addition to the original diagnostic image.
The BSI option is 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 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.

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

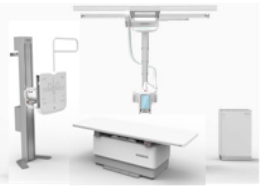
The proposed device GM85 applies a post-image processing software feature as BSI (Bone Suppression Image), which was cleared with K163115, to the predicate device GM85 (K162278) without changes in technical characteristics, materials, energy sources and biocompatibility such as High Voltage Generator(HVG), X-ray Tube Assembly and Detectors.

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 BSI is applied, which does not show significant difference in safety and effectiveness.

Specification	Predicate Device #1	Proposed Device	Predicate Device #2	Discussion
Device Name	GM85	GM85	GC70	
Manufacturer	SAMSUNG ELECTRONICS co., ltd.	SAMSUNG ELECTRONICS co., ltd.	SAMSUNG ELECTRONICS co., ltd.	
510(k) Number	K162278	-	K163115	

Appearances				Same as PD#1
Intended Use	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.	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.	The GC70 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 as PD#1

Manufacturer Contents	Predicate Device #1	Proposed Device GM85	Predicate Device #2	Discussion
Software Feature				
SimGrid	SimGrid	SimGrid	SimGrid	Same as PD#1
Tube & Line Enhancement(TLE)	TLE	TLE	-	Same as PD#1
Pediatric Exposure Management(PEM)	PEM	PEM	-	Same as PD#1
S-DAP	S-DAP	S-DAP	S-DAP	Same
S-Align	S-Align	S-Align	S-Align	Same as PD#1
S-Share	S-Share	S-Share	S-Share	Same
BSI	-	BSI	BSI	Same as PD#2

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 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 has same detectors so it shows no difference in non-clinical testing data such as MTF and DQE measurements from the predicate device #1 and #2. BSI installed in S-Station of GM85 has been verified and validated through GM85

Software System Test Case.

D. Clinical data

The application of BSI, cleared with K163115, to the proposed device GM85 does not require clinical data.

E. Conclusions

The non-clinical demonstrates that the proposed device is as safe, as effective, and performs as well as the legally marketed predicate devices.