July 20, 2018

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

Re: K181626
Trade/Device Name: GM85
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: June 18, 2018
Received: June 20, 2018

Dear Soeun Chang:

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 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,

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)*
K181626

Device Name
GM85

Indications for Use *(Describe)*
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.

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:** June 18, 2018

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: SOEUN CHANG & CHUNSIN KIM
   B. Title: Regulatory Affairs, Senior Professional
   C. Phone Number: +82-2-2193-2436 & +82-2-2193-2437
   D. FAX Number: +82-31-200-1601
   E-Mail: soeun.chang@samsung.com & chulsin.kim@samsung.com

4. **Secondary Contact Person**
   A. Name: Genci Omari
   B. Title: Manager, Regulatory Affairs
   C. Phone Number: 978-564-8602
   D. FAX Number: 978-560-0602
   E-Mail: gomari@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
   F. Regulation: 21 CFR 892.1720

6. **Predicate Devices**

	Predicate Device
Device Name	GM85
Classification Name	MobileX-ray system.
Product Code	IZL
Regulation	21 CFR 892.1720
510(K)#	K180543
510(K) Decision Date	May 24, 2018

7. Device Description

The GM85 Digital Mobile X-ray imaging 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 on the S-Station, which is the Operation Software (OS) of Samsung Digital Diagnostic X-ray System, and save in DICOM file, a standard for medical imaging. The captured images are tuned up by an Image Post-processing Engine (IPE) which is exclusively installed in S-Station, and send to the Picture Archiving & Communication System (PACS) sever for reading images.

The GM85 Digital Mobile X-ray imaging System was previously cleared with K180543, and through this premarket notification, we would like to add more configurations in the previously cleared GM85 as a fixed column type and two detectors are newly added, and three software features are newly added as stated below.
S-Enhance is renamed from Tube & Line Enhancement (TLE), which was cleared before with GM85 at K171119, to enhance visibility of tubes and lines and provide enhanced images separately from original images. In this submission, the scope of S-Enhance is expanded from tubes and lines on chest images to foreign body (e.g. tubes, lines and needles) and urinary stones on chest, abdomen, and L-spine. And Manual Stitching to capture a body part that is larger than the detector's by capturing multiple images and Remote View function to remote access to view the current image on the workstation through a web browser. It was determined that the level of concern for the software contained in the GM85 Digital Mobile X-ray imaging System was Moderate in accordance with the FDA guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Device".

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, has the same technological characteristics and hardware as its original predicate device, GM85 (K180543), and added a new fixed column type, new types of detectors and image processing technology(S-Enhance, Manual stitching, and Remote View). It does not have significant changes in materials, energy source or technological characteristics compared to the predicated device.

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

A. Comparing with Predicate Device

The proposed device is shown as its parts are identical or equivalent with predicate device while some differences are made as below, which does not show significant difference in safety and effectiveness.

Specification	Predicate Device	Proposed Device	Discussion
Device Name	GM85	GM85	-
Manufacturer	SAMSUNG ELECTRONICS	SAMSUNG ELECTRONICS	-
510(k) Number	K180543	-	-
Appearances		  [C-Type*] [F-Type**] *Collapsible column type (C-Type) **Fixed column type (F-Type)	Difference(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.	Same

Manufacturer Contents		Predicate Device	GM85	Discussion
(1)High Voltage Generator				
Type		High Frequency	High Frequency	-
Max. Power		32kW / 40kW	32kW / 40kW	Same
Output RANGE	kVp Range	40 to 150kVp	40 to 150kVp	Same
	mA Range	10 - 500mA	10 - 500mA	Same
	Exposure Time	1msec-10sec	1msec-10sec	Same

Manufacturer Contents		Predicate Device	GM85		Discussion
			C-type	F-type	
(2)Tube assembly					
Moving Range	Horizontal	793~1355mm	793~1355mm		Same
	Vertical	550~2030mm	550~2030mm	550~2030 or 1850mm	Difference(2)
Rotation Range	Column	±315°	±315°		Same
	Tube (Arm axis)	±180°	±180°		Same
	Tube (Tube axis)	-30°~90°	-30°~90°		Same
Tube	Model	LUC-13L, XRR-3332X	LUC-13L, XRR-3332X		Same
	Focal spot	0.6/1.2mm	0.6/1.2mm		Same
	Target Angle	14°	14°		Same

Manufacturer Contents		Predicate Device	GM85		Discussion
			C-type	F-type	
	Target Material	Rhenium-tungsten faced molybdenum	Rhenium-tungsten faced molybdenum		Same
	Nominal Tube Voltage	150kVp	150kVp		Same
	Max.Anode HU	300kHU	300kHU		Same
Collimator		Automatic SDR-OGCL40U 212 X 306 X 179mm	Automatic SDR-OGCL40U 212 X 306 X 179mm	Manual SDR-OGCL41U 222 X 271 X 140mm	Difference(3)

Manufacturer Contents	Predicate Device		GM85		Discussion
(3) Detector					
Name	S4335-W S4343-W S3025-W		S4335-W S4343-W S3025-W S4335-AW S4343-AW		Difference(4)
	S4335-W	S4343-W	S4335-AW	S4343-AW	
Detector Type	CsI	CsI	CsI	CsI	Same
	Indirect	Indirect	Indirect	Indirect	Same
Detector Area	14"X17" (345mmX425mm)	17"X17" (425mmX425mm)	14"X17" (345mmX425mm)	17"X17" (425mmX425mm)	Same
Number of pixels	2466X3040	3036X3040	2466X3040	3036X3040	Same
Pixel Pitch(um)	140	140	140	140	Same
High Contrast Limiting Resolution (LP/mm)	3.57	3.57	3.57	3.57	Same
Communication	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Same
Dust/Water-resistance	IPx1		IP54		Difference(4)-1
Max.load capacity	150 kg for uniform load, 100 kg for local load (40 mm in diameter disk at the center)		400 kg for uniform load, 200 kg for local load (40 mm in diameter disk at the center)		Difference(4)-2

Manufacturer Contents	Predicate Device	GM85	Discussion
(4) Grid			
Lines/cm	84.6	84.6	Same
Grid mechanism	Stationary	Stationary	Same
Removability	Removable	Removable	Same
(5) Weight Distribution Cap			
Model Name	SDR-OGWD80U	SDR-OGWD80U	Same
Size(mm)	505x553x37.4	505x553x37.4	Same
(6) Software Features			
SimGrid	SimGrid	SimGrid	Same

Manufacturer Contents	Predicate Device	GM85	Discussion
Tube & Line Enhancement(TLE) / S-Enhance	TLE* *FDA-cleared(K171119)	S-Enhance	Difference(5)
Pediatric Exposure Management(PEM)	PEM	PEM	Same
S-DAP (Dose Area Product)	S-DAP	S-DAP	Same
S-Align	S-Align	S-Align	Same
S-Share	S-Share	S-Share	Same
Bone Suppression Image(BSI)	BSI	BSI	Same
Remote View	-	Remote View	Difference(6)
Manual Stitching	-	Manual Stitching	Difference(7)

No	Differences	Explanation
(1)	Appearances	The proposed device GM85 adds newly a fixed column type in comparison with the predicated device's one that has only collapsible column type. The fixed column type has two options about the column's height, 1,800mm and 1,980mm. It does not contribute any adverse impacts to the device's image quality. The variety of column's types can be more helpful to choose the right equipment for fitting user's needs.
(2)	Moving Range (Vertical)	The vertical moving range of proposed device GM85 varies depending on the column type.
(3)	Collimator	The proposed device GM85 has different types of collimator depending on column type. The collapsible column type has the same collimator(automatic, SDR-OGCL40U) applied to the predicate device and the fixed column type has the new type of collimator(manual, SDR-OGCL41U) which does not contribute any adverse impacts to the device's image quality.
(4)-1	Detector Dust/Water-resistance	The new detectors which are added to the GM85 device have better dust/water-resistance than the predicate device's dust/water-resistance and this change does not contribute any adverse impact to the device's safety and effectiveness.
(4)-2	Detector Max.load capacity	The new detectors which are added to the GM85 device have higher max load capacity than the predicate device's max load capacity and this change does not contribute any adverse impact to the device's safety and effectiveness.
(5)	Tube & Line Enhancement(TLE) / S-Enhance	Tube & Line Enhancement (TLE), which was cleared with K171119, is to enhance visibility of tubes and lines on chest images and provide enhanced images separately from original images. TLE is renamed as S-Enhance, expanding its coverage and scope in this proposed device. S-Enhance is expanded from tubes and lines on chest images to foreign body (e.g. tubes, lines and needles) and urinary stones on chest, abdomen, and L-spine. This change is considered low risk and does not

		contribute any adverse impact to the device's safety and effectiveness.
(6)	Remote View	The function of Remote View, which allows remote access to view the current image on the workstation through a web browser, is applied to the GM85 and this change does not contribute any adverse impact to the device's safety and effectiveness.
(7)	Manual Stitching	Manual Stitching can capture a body part that is larger than the detector's area by capturing multiple images. This function is considered low risk and 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 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 new types of detectors that have equivalent image characteristics as the existing ones. Specific description is added to make it clear with the non-clinical data and phantom image evaluation report. And those detectors evaluated by Software System Test Case for verification and validation.

The S-Enhance is same image processing technology as TLE of predicate device GM85 (K171119) and extends the applicable body parts to chest, abdomen, and L-spine so it shows no difference in non-clinical testing data such as TLC and CER measurements from TLE of the predicate device GM85 (K171119).

Manual Stitching is optional software to capture a body part that is larger than the detector's area and evaluated Software System Test Case for verification and validation.

D. Clinical data

In clinical data, phantom image evaluations of the new types of detectors and S-Enhance were performed in accordance with FDA guidance for the submission of 510(k)'s for Solid State X-ray Imaging Devices. Anthropomorphic phantom images were provided; these images were not necessary to establish substantial equivalence based on the modifications to the device (note X-ray flat-panel detector similar to the predicate detector) but they provide further evidence in addition to the performance data to show

that the complete system works as intended. They were evaluated by a professional radiologist and found to be equivalent to the predicate devices. There is no significant difference in the average score considering the standard deviation of image quality evaluation between the proposed device and the predicate device and it is confirmed that S-Enhance is able to generate a companion image which provide clear visibility for foreign bodies such as lines, tubes, and needles, and urinary stones in chest, abdomen, and L-spine protocol in addition to the original images. Therefore, these changes do not affect either the safety or the effectiveness, compared to the predicated device.

E. Conclusions

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