LG Electronics Inc.
Jinhwan Jun
Chief Research Engineer
222, LG-Ro
Jinwi-Myeon, Pyeongtaek-Si,
Gyeonggi-do, 17709 Korea

October 18, 2018

Re: K182348
Trade/Device Name: 14HK701G-W
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: August 22, 2018
Received: August 29, 2018

Dear Jinhwan Jun:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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,

Michael D. O'Hara For

Robert A. 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)*
K182348

Device Name

14HK701G-W

Indications for Use *(Describe)*

Flat Panel Digital X-ray Detectors are indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in general purpose diagnostic procedures all and not to be used for mammography.

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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5. 510(K) Summary

510(k) Summary

[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

July 20, 2018

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer: LG Electronics Inc.
- Address: 222, LG-ro, Jinwi-myeon, Pyeongtaek-si, Gyeonggi-do, Republic of Korea
- Contact Name: Jinhwan Jun / Chief Research Engineer
- Telephone No.: +82-31-8066-5641
- Email Address: Jinhwan.jun@lge.com
- Registration No.: 3009955829

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade/Device Name	14HK701G-W
Common Name	Flat Panel Digital X-ray Detector
Device Classification Name	Stationary X-ray System
Regulation Number	21 CFR 892.1680
Classification Product Code	MQB
Device Class	II
510(k) Review Panel	Radiology

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow;

Predicate Device 1

- 510(k) Number: K180332
- Applicant: LG Electronics Inc.
- Trade/Device Name: 17HK700G-W
- Common Name: Digital Diagnostic X-ray System
- Classification Name: System. X-ray, Stationary
- Regulation Number: 21 CFR 892.1680
- Classification Product Code: MQB
- Device Class: II
- 510(k) Review Panel: Radiology

Predicate Device 2

- 510(k) Number: K150165
- Applicant: Samsung Electronics Co., Ltd.
- Trade/Device Name: S4343-W (of GC85A)
- Common Name: Digital Diagnostic X-ray System
- Classification Name: System. X-ray, Stationary
- Regulation Number: 21 CFR 892.1680
- Classification Product Code: KPR
- Device Class: II
- 510(k) Review Panel: Radiology

The predicate devices have not been subject to a design-related recall

5. Description of the Device [21 CFR 807.92(a)(4)]

The 14HK701G-W is the solid state x-ray imager, which can generate radiographic images of any part of the body. These devices intercept x-ray photons and the scintillator (CsI:TI) emits visible spectrum photons that illuminate an array of photo-detectors that create an electrical signals. After the electrical signals are generated, it is converted to digital value, and the images are displayed on monitors. The digital value can be communicated to the operator console via wiring connection.

The 14HK701G-W consists of the following components: Flat Panel Detector, Control Box, battery Charger, 2 packs of battery, power adapter for charger, Calibration Software, power cord and cables. The 14HK701G-W can be used for general X-ray system excluding fluoroscopic, angiographic, and mammographic applications.

6. Indications for use [21 CFR 807.92(a)(5)]

Flat Panel Digital X-ray Detectors are indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures and not to be used for mammography

7. Technological Characteristics (Equivalence to Predicate Device) [21 CFR 807.92(a)(6)]

There are no significant differences in the technological characteristics of these devices compared to the predicate devices which adversely affect safety or effectiveness. Provided below is a table summarizing and comparing the technological characteristics of the 14HK701G-W and the predicate devices:

[Table 1. Comparison of Proposed Device to Predicate Device]

	Proposed Device	Predicate Device 1	Predicate Device 2
K Number	Not known	K180332	K150165
Manufacturer	LG Electronics Inc.	LG Electronics Inc.	Samsung Electronics Co., Ltd.
Trade Name	14HK701G-W	17HK700G-W	S4343-W (of GC85A)
Common Name	Flat Panel Digital X-ray Detector	Flat Panel Digital X-ray Detector	Flat Panel Digital X-ray System
Product Code	MQB	MQB	KPR
Regulation Number	21 CFR 892.1680	21 CFR 892.1680	21 CFR 892.1680
510(k) Review Panel	Radiology	Radiology	Radiology
Indications for Use	Flat Panel Digital X-ray Detectors are indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in general purpose diagnostic procedures all and not to be used for mammography.	Flat Panel Digital X-ray Detector is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.	The GC85A 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.
Detector			
Scintillator	CsI	CsI	CsI
Imaging Area	13.7 x 16.8 inches	17 x 17 inches	17 x 17 inches
Pixel Matrix	2,500 x 3,052 pixels	3,072 x 3,072 pixels	3,036 x 3,040 pixels
Pixel Pitch	140 um	140 um	140 um
High Contrast Limiting Resolution (LP/mm)	3.6 lp/mm	3.6	3.57
Communication	Wired/Wireless	Wired	Wired/Wireless
DQE	Typ.72% @0.1lp/mm	Typ.72% @0.1lp/mm	Typ.73% @0.1lp/mm
MTF	Typ.89% @0.5lp/mm	Typ.89% @ 0.5lp/mm	Typ.84% @ 0.5lp/mm
Resolution	3.6lp	3.6lp	3.57lp

	Proposed Device	Predicate Device 1	Predicate Device 2
Anatomical Sites	General	General	General
Exposure Mode	Manual, Auto(AED)	Manual, Auto(AED)	Manual, Auto(AED)
Wireless	Standard: 802.11 a/b/g/n/ac compliance Frequency: 2.4 GHz/5GHz Bandwidth: 20MHz/40MHz/80MHz MIMO: 2x2		
Rating	100-240V~, 50/60Hz	100-240V~, 50/60Hz	100-240V~, 50/60Hz

There are no significant differences between the 14HK701G-W and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, operational principles and intended use. The proposed device, 14HK701G-W has been tested about electrical safety, EMC and performance, and the software has been validated. In addition, the clinical data has been provided to support the substantial equivalence to the predicate devices.

The predicate device 2 (K150165) is the X-ray system but the proposed device provides only a detector. The proposed device is substantially equivalent to the previously cleared detector which is provided as part of the complete imaging system, K150165.

The technological characteristics of the subject detector 14HK701G-W are similar to the predicate 17HK700G-W, and the only major difference is the smaller detector size.

8. Integration Specifications / Requirements for 14HK701G-W

The proposed device is provided with the recommended generator specification as follows:

No.	Item	Specification
1	Power frequency	50Hz ~ 60Hz
2	KV	40kVp ~ 150kVp
3	mA Range	10 to 500mA
4	Exposure Time	0.001 to 4sec
5	mAs Range	0.1 to 500mAs
6	Accuracy	kV < ±(1%+1kV), mA < ±(3%+1mA)

9. Non-Clinical Test summary

The 14HK701G-W comply with voluntary standards for electrical safety, electromagnetic compatibility. The following data were provided in support of the substantial equivalence determination:

1) Electrical Safety, Electromagnetic Compatibility and Performance:

The 14HK701G-W comply with the electrical safety and electromagnetic compatibility requirements established by the standards.

Standards No.	Standards Organization	Standard Title	Version	Publication Year
ES60601-1	AAMI	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)	ES60601-1: 2005(R)2012 and A1:2012	2014
60601-1-2	IEC	Medical Electrical Equipment - Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	60601-1-2 Edition 4.0 2014-02	2016
-	FDA	Radio Frequency Wireless Technology in Medical Devices	August 14	2013

2) Software Validation

The 14HK701G-W contains MODERATE level of concern software as firmware. The software was designed and developed according to a software development process and was verified and validated. Software information is provided in accordance with FDA guidance:

- The content of premarket submissions for software contained in medical devices, on May 11, 2005

3) Biocompatibility

- ISO 10993-1 and series, Biological evaluation of medical devices

4) Performance Test

Imaging performance test has been conducted according to:

- IEC 62220-1, Medical Electrical Equipment – Characteristics of Digital X-ray Imaging Devices – Part 1-1: Determination of the Detective Quantum Efficiency – Detectors Used in Radiographic Imaging.

5) Cybersecurity

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, on October2, 2014
- Postmarket Management of Cybersecurity in Medical Devices, on December 28, 2016

6) Label

- CFR Part 801
- Pediatric Information for X-ray Imaging Device Premarket Notifications, on November 28, 2017

10. Clinical Test Summary

Clinical data has been provided according to FDA guidance document "Guidance for the Submission of 510(k)s for Solid Sate X-ray Imaging Devices". The data was not necessary to establish substantial equivalence based on the modifications to the device but provided further evidence in addition to the laboratory performance data to show that the device works as intended.

11. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

There are no significant differences between 14HK701G-W and the predicate devices, K150165 and K180332 that would adversely affect the use of the product. It is substantially equivalent to these devices in indications for use and technology characteristics.

12. Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification LG Electronics, concludes that the 14HK701G-W is substantially equivalent in safety and effectiveness to the predicate devices as described herein.