January 27, 2023

LG Electronics Inc.
% Daseul An
RA associate
222, LG-RO
PYEONGTAEK-SI, GYEONGGI-DO 17709
REPUBLIC OF KOREA

Re: K223546
Trade/Device Name: 14HQ721G-B
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MQB
Dated: November 25, 2022
Received: November 25, 2022

Dear Daseul An:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang 2023.01.27 11:30:39 -05'00'

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223546

Device Name
14HQ721G-B

Indications for Use *(Describe)*
The Flat Panel Digital X-ray Detector 14HQ721G-B 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.

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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510(k) Summary K223546

[As Required by 21 CFR 807.92]

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

Jan 25, 2023

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

- Name of Sponsor: LG Electronics Inc.
  - Address: 222, LG-ro, Pyeongtaek-si, Gyeonggi-do, 17709, Republic of Korea
- Name of Manufacturer: LG Electronics Inc.
  - Address: 168, Suchul-daero, Gumi-si, Gyeongsangbuk-do, 39368, Republic of Korea
- Contact Name: Daseul An / Regulatory Affairs Associate
  - Telephone No.: +82-10-8914-0116
  - Email Address: daseul.an@lge.com

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

Trade/Device/Model Name	14HQ721G-B
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 follows;

Predicate Device

- 510(k) Number: K221394
- Applicant: LG Electronics Inc.
- Trade/Device Name: 14HQ701G-B
- Common Name: Flat Panel Digital X-ray Detector
- Classification Name: Stationary X-ray System
- Regulation Number: 21 CFR 892.1680
- Classification Product Code: MQB
- 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)]

This model is an x-ray imaging device, a system that can acquire and process X-ray images as digital images. It utilizes amorphous silicon and a high-performance scintillator to ensure sharp high-definition image quality with the resolution of 3.6 lp/mm and the pixel pitches of 140 um. This device is a flat panel based X-ray image acquisition device. This device must be used in conjunction with an operating PC and an X-ray generator. This device can be used for digitizing and transferring X-ray images for radiological diagnosis. The data transmission between the Detector and PC can be enabled with a wired (cable) or wireless connection. This device does not have a dynamic exposure feature.

14HQ721G-B is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy. It is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography or dental applications.

We understand the Agency has become aware of situations where solid state detectors inserted into radiographic systems adversely impacted device performance due to improper integration.

Below is a summary of the information from the 14HQ721G-B user manuals covering key electromechanical and computer requirements needed for X-ray system interface and integration.

1. Mechanical interface requirements.
2. Computer requirements
3. Data communication interface requirements
4. Electrical power requirements
5. X-ray trigger interface requirements

Neither the 14HQ721G-B nor its software acts as an X-ray generator controller, and therefore, the device is not subject to Electronic Product Radiation Control (EPRC) performance standards and reporting requirements.

The built-in AEC (Automatic Exposure Control) in 14HQ721G-B is sensors which convert the amount of the X-ray emitted from the X-ray generator into the electric signals and deliver them to the X-ray generator connected with the X-ray detector via the control box. The X-ray generator determines for

itself whether to stop x-ray emission based on these electrical signals. The 14HQ721G-B does not directly control the X-ray generator.

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

The Flat Panel Digital X-ray Detector 14HQ721G-B 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.

7. Intended Use [21 CFR 807.92(a)(5)]

The Flat Panel Digital X-ray Detector 14HQ721G-B is a prescription device, and it is not intended to be used for mammography.

- The detector is indicated for digital imaging solution designed for general radiographic system for human anatomy
- The detector is indicated to replace film or screen based radiographic systems in all general purpose diagnostic procedures.

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

There are no significant differences in the technological characteristics of the proposed device compared to the predicate device which would adversely affect safety or effectiveness. Provided below is a table summarizing and comparing the technological characteristics of the 14HQ721G-B and the predicate device:

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

	Proposed Device	Predicate Device	Note
K Number	K223546	K221394	-
Manufacturer	LG Electronics Inc.	LG Electronics Inc.	Same
Trade Name	14HQ721G-B	14HQ701G-B	-
Common Name	Flat Panel Digital X-ray Detector	Flat Panel Digital X-ray Detector	Same
Product Code	MQB	MQB	Same
Regulation Number	21 CFR 892.1680	21 CFR 892.1680	Same
510(k) Review Panel	Radiology	Radiology	Same
Indications for Use	The Flat Panel Digital X-ray Detector 14HQ721G-B 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 Flat Panel Digital X-ray Detector 14HQ701G-B 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.	Same
Intended use	The Flat Panel Digital X-ray Detector 14HQ721G-B is a prescription device, and it is not intended to be used for mammography. - The detector is indicated for digital imaging solution designed for general radiographic system for human anatomy - The detector is indicated to replace film or screen based radiographic systems in all general purpose diagnostic procedures.	The Flat Panel Digital X-ray Detector 14HQ701G-B is a prescription device, and it is not intended to be used for mammography. - The detector is indicated for digital imaging solution designed for general radiographic system for human anatomy - The detector is indicated to replace film or screen based radiographic systems in all general purpose diagnostic procedures.	Same
Detector			
Scintillator	CsI	CsI	Same
Imaging Area	14 x 17 inches	14 x 17 inches	Same
Pixel Matrix	2,500 x 3,052 pixels	2,500 x 3,052 pixels	Same

	Proposed Device	Predicate Device	Note
Pixel Pitch	140 um	140 um	Same
High Contrast Limiting Resolution (LP/mm)	3.6 lp/mm	3.6 lp/mm	Same
Communication	Wired/Wireless	Wired/Wireless	Same
DQE	Typ.66% @0.1lp/mm	Typ.66% @0.1lp/mm	Equivalent
MTF	Typ.84% @0.5lp/mm	Typ.84% @0.5lp/mm	Equivalent
Resolution	3.6lp	3.6lp	Same
Anatomical Sites	General	General	Same
Exposure Mode	Manual, Auto (AED)	Manual, Auto (AED)	Same
Built-in AEC	O	X	Different
Semi Dynamic mode	O	O	Same
Wireless	Standard: 802.11 a/b/g/n/ac compliance Frequency: 2.4 GHz/5GHz Bandwidth: 20MHz/40MHz/80MHz MIMO: 2x2	Standard: 802.11 a/b/g/n/ac compliance Frequency: 2.4 GHz/5GHz Bandwidth: 20MHz/40MHz/80MHz MIMO: 2x2	Same
Rating	24V ⎓ 2.1A	24V ⎓ 2.1A	Same
Gap Analysis	The difference from the predicate device (14HQ701G-B) is the addition of the built-in AEC mode and the software update, which would not adversely affect the safety and the effectiveness of the product. The software update includes the addition of the AEC mode. The proposed device (14HQ721G-B) has shown similar performance (DQE, MTF) as the predicate device. Therefore, the proposed device is substantially equivalent to the predicate device.		

*** Semi Dynamic mode is a function that can transmit five images per second to the PC.*

There are no significant differences between the 14HQ721G-B and the predicate device that would adversely affect the use of the product. It is concluded that the 14HQ721G-B is substantially equivalent to the predicate devices in design, function, materials, operational principles and intended use. The electrical safety test, EMC test and the performance test were conducted on the proposed devices, and the software was validated.

In this submission, clinical testing was not conducted, since nonclinical information is sufficient to show the substantial equivalence of the proposed devices to the predicate devices for the modifications.

9. Non-Clinical Test summary

The 14HQ721G-B complies 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 14HQ721G-B complies 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) [Including Amendment 2 (2021)]	ES60601-1: 2005(R)2012 & A1:2012 [Incl. AMD2:2021]	2021
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	2014
-	FDA	Radio Frequency Wireless Technology in Medical Devices	August 14	2013
-	FDA	Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices	September 1	2016

2) Software Validation

The 14HQ721G-B includes the software of MODERATE level of concern as a firmware. The difference from the predicate device is the addition of the AEC mode. The software was designed and developed according to the internal 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 was conducted according to:

- IEC 62220-1-1, 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 October 18, 2018
- 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. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

There are no significant differences between 14HQ721G-B and the predicate device, K221394 that would adversely affect the use of the product. The proposed device is substantially equivalent to the predicate device in indications for use and technology characteristics.

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

In accordance with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification of LG Electronics, it is concluded that the 14HQ721G-B is substantially equivalent in safety and effectiveness to the predicate device as described herein.