LG Electronics Inc.
Hanseul Park
RA Specialist
71, Magokjungang 8-ro, Gangseo-gu
Seoul, 07795
Korea, South

Re: K233599

March 18, 2024

Trade/Device Name: X-Clever (ASHK100G)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: February 2, 2024
Received: February 2, 2024

Dear Hanseul Park:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jessica Lamb
Assistant Director
DHT8B: Division of Radiologic 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233599

Device Name

X-Clever (ASHK100G)

Indications for Use *(Describe)*

Software used in a device that saves, enlarges, reduces, views as well as analyzes, transfers and prints medical images. (excluding fluoroscopic, angiographic, and 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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510(K) Summary

510(k) Summary

[As Required by 21 CFR 807.92]

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

February 01, 2024

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

- Name of Sponsor: LG Electronics Inc.
  - Address: 71, Magokjungang 8-ro, Gangseo-gu Seoul, 07795, Republic of Korea
  - Contact Name: Hanseul Park / Regulatory Affairs Specialist
  - Telephone No.: +82-10-9490-2109
  - Email Address: hs.park@lge.com

- Name of Manufacturer: LG Electronics Inc.
  - Address: 168, Suchul-daero, Gumi-si, Gyeongsangbuk-do, 39368, Republic of Korea

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

Product Name	LG Acquisition Workstation Software
Model Name	ASHK100G
Trade Name	X-Clever
Classification Name	Picture archiving and communication system
Regulation Number	21 CFR 892.2050
Classification Product Code	LLZ
Product Code Name	System, Image Processing, Radiological
Device Class	II
510k 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

- 510(k) Number: K212137
- Applicant: LG Electronics Inc.
- Trade/Device Name: ASHK100G
- Classification Name: Picture archiving and communications system
- Regulation Number: 21 CFR 892.2050
- Classification Product Code: LLZ
- Device Class: II
- 510(k) Review Panel: Radiology

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

LG Acquisition Workstation Software ASHK100G is a diagnostic software for final post-processed X-ray images of body parts of actual patients acquired through the integration of digital X-ray detectors (DXD+ASHK100G; refer to below list for the compatible LG DXD series) and X-ray generators. By integrating the [MWL] and the [PACS] server, this software can be used to check the information and images of the patients' body parts in real time in an HIS (Hospital Information System) based environment.

<Compatible LG DXD Series>

Company Name	Model name	
LG Electronics	17HK700G-W	17HK700G-WP
	14HK701G-W	14HK701G-WP
	17HK701G-W	17HK701G-WP
	10HQ701G-B	10HQ701G-BP
	14HQ701G-B	14HQ701G-BP
	14HQ901G-B	14HQ901G-BP
	17HQ701G-B	17HQ701G-BP
	17HQ901G-B	17HQ901G-BP
	14HQ721G-B	14HQ721G-BP

[NOTE] All the DXD models are FDA-510(k)-cleared, and the names of DXD models integrated with ASHK100G include "P" at the end.

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

Software used in a device that saves, enlarges, reduces, views as well as analyzes, transfers and prints medical images. (excluding fluoroscopic, angiographic, and mammographic applications.)

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

ASHK100G is medical software. It digitalizes the signal sent from the detector and displays the x-ray image. Also, it can enter patient information, shot information, and other necessary references for convenience.

Compared with the predicate device, the technological characteristics of the proposed device are substantially equivalent to those of the predicate device. The proposed device is functionally similar to the predicate device. The table below presents comparisons for each device:

[Table. Comparison of Proposed Device to Predicate Device]

	Proposed Device	Predicate Device	SE Note
K Number	K233599	K212137	-
Manufacturer	LG Electronics Inc.	LG Electronics Inc.	-
Model name	ASHK100G	ASHK100G	-
Product Code	LLZ	LLZ	Same
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Same
510(k) Review Panel	Radiology	Radiology	Same
Indications for Use	Software used in a device that saves, enlarges, reduces, views as well as analyzes, transfers and prints medical images. (excluding fluoroscopic, angiographic, and mammographic applications.)	Software used in a device that saves, enlarges, reduces, views as well as analyzes, transfers and prints medical images. (excluding fluoroscopic, angiographic, and mammographic applications.)	Same
SW Version	3.06.XX	3.01.XX	Different

	Proposed Device	Predicate Device	SE Note
Processor	Intel 6th gen i5 or higher	Intel 6th gen i5	Different
RAM	8GB or higher	8GB or higher	Same
Hard Disk	512 GB or greater recommended	512 GB or greater recommended	Same
Network	Dual Ethernet 100/1000Mbps	Dual Ethernet 100/1000Mbps	Same
Operation Software	Microsoft Windows 10, 11 (64 bit)	Microsoft Windows 8.1(64 bit) Microsoft Windows 10(64 bit)	Different
Resolution	1920 x 1080, 3840 x 2160	1920 x 1080, 3840 x 2160	Same
Generator Control protocol	Yes (can control detailed exam options, such as the level of dose on each examination)	Yes (can control detailed exam options, such as the level of dose on each examination)	Same
Image Processing	Yes (Add Wide Dynamic View (WDV) algorithm)	Yes	Different
Windowing	Yes (review mode has a function of control the image window level)	Yes (review mode has a function of control the image window level)	Same
Image formatting	Yes (1x1,1x2,2x2,3x3)	Yes (1x1,1x2,2x2,3x3)	Same
Electronic zoom	Yes (Magnifying and optimizing accurate ROI(region of interest) area)	Yes (Magnifying and optimizing accurate ROI(region of interest) area)	Same
Image rotation	Yes (90 degree rotation and free rotation per degree)	Yes (90 degree rotation and free rotation per degree)	Same
Image annotation	Yes (Review mode support applying detailed annotation immediately)	Yes (Review mode support applying detailed annotation immediately)	Same
Image Stitch	Yes (auto-stitch function and allow manual control options on detailed position and brightness/contrast)	Yes (auto-stitch function and allow manual control options on detailed position and brightness/contrast)	Same
DICOM Worklist	Yes (archive work orders automatically)	Yes (archive work orders automatically)	Same
DICOM Store	Yes	Yes	Same

	Proposed Device	Predicate Device	SE Note
DICOM Print	Yes	Yes	Same
Measurement tools	Advanced tools are added: Cobb angle, Cardiothoracic ratio, Acetabular depth ratio, Sharp angle	Basic tools available: Angle and Ruler	Different

The proposed device is an updated version of the predicate device, with improvements and changes made to the operations software, image processing algorithm, and measurement tools.

More specifically, as shown in the above comparison table, the following items of the proposed device are different from the predicate device: Software version, Processor, Operation software, Image processing algorithm, and Advanced measurement tools. Software version, Processor and operation software have been updated from the predicate device, and the software has been validated accordingly. In terms of image processing algorithm, the proposed device has undergone a performance testing to assess the new WDV algorithm.

The newly added advanced measurement tools have been validated and verified by the software validation.

Based on those reviews, it has been determined that these changes do not have any negative impact on the safe and effective use of the product.

8. Non-Clinical Test Summary [21 CFR 807.92(b)(1)]

The following data were provided in support of the substantial equivalence determination:

1) Software Validation

The ASHK100G belongs to a Basic Documentation Level. 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 Device Software Functions (June 14, 2023)

2) Cybersecurity

Cybersecurity documents are provided in accordance with the below FDA guidance:

- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (September 27, 2023)
- Postmarket Management of Cybersecurity in Medical Devices (December 28, 2016)

3) Performance Test

- Performance for WDV (Wide Dynamic View)
- Compatibility with Generator Test

- Compatibility with LG DXD

The performance test report for the addition of the Wide Dynamic View (WDV) algorithm, as well as the compatibility tests with LG DXD (Digital X-ray Detector) and generators, have been submitted as part of the nonclinical tests.

The performance test results indicate that the WDV algorithm enhances the performance of the proposed medical device by normalizing tissue through the creation of a regional map based on image location and distribution characteristics. This leads to more natural and consistent images compared to those that rely solely on residual and image brightness signal composition. Despite the inclusion of algorithms with a high operation quantity, the optimization process has minimized the increase in image processing time.

In conclusion, the addition of the WDV feature has not had any negative impact on the performance and safety of the proposed device.

The compatibility tests with LG DXDs and generators also confirm that the proposed device can interface and control the Console workstation and DXDs in real-time without any functional bugs. Additionally, safety trials have been conducted to ensure that values cannot be set beyond the limitations.

9. Clinical Test Summary [21 CFR 807.92(b)(2)]

No clinical studies were considered necessary and performed.

The main improvement in the proposed device, as compared to the predicate, is the addition of the WDV algorithm to the existing imaging processing. It is important to note that this update does not require clinical testing. Instead, the performance test for the WDV algorithm includes clinical opinions on the images processed with WDV. Therefore, a separate clinical study is not applicable in this case.

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

Based on the information provided in this premarket notification and in accordance with the Federal Food, Drug, and Cosmetic Act, 21 CFR Part 807, LG Electronics Inc. has determined that there are no significant differences between the proposed device and the predicate device that would negatively impact its use. The proposed device has been shown to be as safe and effective as the predicate version previously cleared in K212137. It shares the same intended

use and similar technological characteristics, with any differences supported by performance testing. Therefore, the technological variances between the proposed device and its predicate device do not raise any new concerns regarding safety or effectiveness, and the proposed device can be considered substantially equivalent to the predicate device.