LG Electronics
℅ Jinhwan Jun
Chief Research Engineer
222, Lg-ro, Cheongho-ri
Jinwi-myeon Pyeongtaek-si,
17709 Gyeonggi-do
REPUBLIC OF KOREA

May 30, 2019

Re: K191188
Trade/Device Name: ASHK100G
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 30, 2019
Received: May 3, 2019

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. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K191188

Device Name
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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

222, LG-ro, Cheongho-ri, Jinwi-myeon, Pyeongtaek-si,
Gyeonggi-do, Republic of Korea
Tel: +82-31-8066-5641

5. 510(K) Summary

222, LG-ro, Cheongho-ri, Jinwi-myeon, Pyeongtaek-si,
Gyeonggi-do, Republic of Korea
Tel: +82-31-8066-5641

510(k) Summary

K191188

[As Required by 21 CFR 807.92]

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

April 30, 2019

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

- Name of Sponsor: LG Electronics
  - Address: 222, LG-ro, Cheongho-ri, 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
- Name of Manufacturer: LG Electronics
  - Address: 77, Sanho-daero, Gumi-si, Gyeongsangbuk-do, Republic of Korea, 3938

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

Trade Name (Model Name)	ASHK100G
Product Name	LG Acquisition Workstation Software
Device Classification Name	Picture archiving and communications 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

222, LG-ro, Cheongho-ri, Jinwi-myeon, Pyeongtaek-si,
Gyeonggi-do, Republic of Korea
Tel: +82-31-8066-5641

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: K160579
- Applicant: Rayence Co., Ltd.
- Trade Name: XmaruView V1, Xmaru Chiroview, Xmaru Podview and Xmaru PACS
- Common Name: Radiological Image Processing System
- 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)]

ASHK100G is digital radiography operating console software. ASHK100G provides an integrated solution for X-ray projection. It integrates with the digital detector. Furthermore, ASHK100G acquires and processes images. In addition, it complies with DICOM standards and is able to transmit and receive data with the PACS system, and print images through the DICOM printer.

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.)

222, LG-ro, Cheongho-ri, Jinwi-myeon, Pyeongtaek-si,
Gyeonggi-do, Republic of Korea
Tel: +82-31-8066-5641

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, ASHK100G, are substantially equivalent to those of the predicate device. The proposed device is functionally similar to the predicate device.

	Proposed Device	Predicate Device
K Number	Not known	K160579
Manufacturer	LG Electronics	Rayence Co., Ltd.
Trade Name	ASHK100G	XmaruView V1, Xmaru Chiroview, Xmaru Podview and Xmaru PACS
Common Name	Radiological Image Processing System	Medical Image Processing Software
Product Code	LLZ	LLZ
Regulation Number	21 CFR 892.2050	21 CFR 892.2050
510(k) Review Panel	Radiology	
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.)	XmaruView V1(Xmaru Chiroview or Xmaru Podview) software carries out the image processing and administration of medical X-ray data which includes adjustment of window leveling, rotation, zoom, and measurements. XmaruView V1(Xmaru Chiroview or Xmaru Podview) is not approved for mammography and is meant to be used by qualified medical personnel only. XmaruView V1(Xmaru Chiroview or Xmaru Podview) is complying with DICOM standards to assure optimum communications between network systems. Xmaru PACS receives, stores, searches and views the diagnostic image data from imaging modalities in DICOM compliant. Xmaru PACS is capable of communicating with electronic medical records systems, hospital information

222, LG-ro, Cheongho-ri, Jinwi-myeon, Pyeongtaek-si,
Gyeonggi-do, Republic of Korea
Tel: +82-31-8066-5641

	Proposed Device	Predicate Device
		systems, and radiology information system via DICOM standard. XmaruView V1(Xmaru Chiroview or Xmaru Podview) and Xmaru PACS can be packaged together or offered as a stand-alone imaging solution to be installed in a PC for trained medical professionals.
Processor	Intel® Core i5 or higher	Intel® Core i3 or higher
RAM	8GB or higher	4GB or higher
Hard Disk	min. 500GByte	min. 80GByte
Network	100MBit or 1GBit	100MBit or 1GBit
Operation Software	Microsoft Windows 7(64 bit) Microsoft Windows 8(64 bit) Microsoft Windows 10(64 bit)	Microsoft Windows 7(32 bit / 64 bit) Professional Microsoft Windows 8 Professional or Enterprise
Resolution	min. 1920 x 1080	min. 1280 x 768
Generator Control protocol	YES	YES
Image Processing	Yes	Yes
Windowing	Yes	Yes
Image formatting	Yes (1x1,2x2,3x3,4x4)	Yes (1x1,1x2,2x1,2x2,3x3)
Electronic zoom	Yes	Yes
Image rotation	Yes	Yes
Image annotation	Yes	Yes
Image Stitch	Yes	Yes
DICOM Worklist	Yes	Yes
DICOM Store	Yes	Yes
DICOM Print	Yes	Yes
SW Ver.	ver. 1.0	XmaruView V1(Xmaru Chiroview or Xmaru Podview) - 2.0 Xmaru PACS - 1.

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

The software information of ASHK100G is provided in accordance with FDA guidance: The content of premarket submissions for software contained in medical devices, on May 11, 2005.

222, LG-ro, Cheongho-ri, Jinwi-myeon, Pyeongtaek-si,
Gyeonggi-do, Republic of Korea
Tel: +82-31-8066-5641

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

This section is not applicable

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

There are no significant differences between ASHK100G and the predicate devices, K160579 that would adversely affect the use of the product. It is substantially equivalent to these devices in indications for use and technology characteristics.

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

There are no significant differences between the ASHK100G and the predicate device(s) 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.