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

December 5, 2019

Re: K191864
Trade/Device Name: 21HK512D
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: PGY
Dated: September 30, 2019
Received: October 7, 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. 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 and Part 809); 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,

Michael D. O'Hara 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191864

Device Name
21HK512D

Indications for Use *(Describe)*
This Medical Monitor is intended to be used by trained medical practitioners for displaying, reviewing, and analysis of medical images. The display is not intended 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.

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

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"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

510(k) Summary

[As Required by 21 CFR 807.92]

K191864

1. Date of submission

July 5, 2019

2. Submitter's Information

- Name of Sponsor: LG Electronics Inc.
  - Address: 222, LG-ro, Cheongho-ri, Jinwi-myeon, Pyeongtaek-si, Gyeonggi-do, 17709, 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 Inc.
  - Address: 77, Sanho-daero, Gumi-si, Gyeongsangbuk-do, 39381, Republic of Korea

3. Trade Name, Common Name, Classification

- Trade Name: 21HK512D
- Common Name: Medical Monitor
- Classification:

Classification Name	Picture archiving and communications system
Classification Number	21 CFR 892.2050
Product Code	PGY
Device Class	II
Review Panel	Radiology

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4. Identification of Predicate Device(s)

The identified predicate device within this submission are shown as follow:

Predicate Device

- 510(k) Number: K153354
- Applicant: EIZO Corporation
- Classification Name: Picture archiving and communications system
- Trade Name: RadiForce RX350

5. Description of the Device

The 21HK512D is a 21.3" LCD display for medical viewing. It can be used for diagnostic viewing or normal reviewing purpose of medical images like computed tomography images, digitalized x-ray images, etc.

6. Indications for Use

This Medical Monitor is intended to be used by trained medical practitioners for displaying, reviewing, and analysis of medical images. The display is not intended for mammography.

7. Determination of Substantial Equivalence

The comparison table shows that the subject device (21HK512D) has the same intended use as the predicate one. Although the devices have some different technological characteristics, these differences do not make the subject device less safe and reliable, so the subject device fits for diagnostic use as the predicate device does. There are no significant differences in the technological characteristics of the subject device. It is substantially equivalent to a predicate device in indications for use and technology characteristics.

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	Proposed Device	Predicate Device
K Number	Not known	K153354
Manufacturer	LG Electronics Inc.	EIZO Corporation
Model Name	21HK512D	RadiForce RX350
Classification Name	Picture archiving and communications system	Picture archiving and communications system
Classification Number	21 CFR 892.2050	21 CFR 892.2050
Indications for Use	This Medical Monitor is intended to be used by trained medical practitioners for displaying, reviewing, and analysis of medical images. The display is not intended for mammography.	This product is intended to be used in displaying and viewing digital images for review, analysis and diagnosis by trained medical practitioners. It does not support the display of mammography images for diagnosis.
LCD Screen	TFT LCD	TFT LCD
Pixel Pitch	0.2115 x 0.2115 mm	0.2115 x 0.2115 mm
Resolution	2,048 x 1,536 pixels	1,536 x 2,048 pixels

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Non-Clinical Test Summary

1) Electrical Safety and Electromagnetic Compatibility

The test results demonstrated that the proposed device complies with the following standards:

- Electrical Basic Safety and Essential Performance requirements in accordance with IEC 60601-1:2005/AMD1:2012
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2 Edition 4.0:2014
- Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability in accordance with IEC 60601-1-6:2010/A1:2013

2) Software Validation

The 21HK512D contains MODERATE level of concern software. The software was designed and developed according to a software development process and was verified and validated.

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

Clinical Test Summary:

No clinical studies were considered necessary and performed.

8. Conclusion

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 21HK512D is substantially equivalent in safety and effectiveness to the predicate devices as described herein.