June 12, 2026

Lg Electronics.Inc
Wonhi Lee
RA Specialist
168, Suchul-Daero
Gumi-Si, Gyeongsangbuk-do 39368
Republic Of Korea

Re: K261213
Trade/Device Name: Medical Monitor (40HT513D)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: PGY
Dated: April 14, 2026
Received: April 14, 2026

Dear Wonhi Lee:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, Ph.D.
Assistant Director
Imaging Science 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261213

Please provide the device trade name(s).

Medical Monitor (40HT513D)

Please provide your Indications for Use below.

This Medical Monitor is indicated for use in displaying radiological images and enhancing the image quality for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☒ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #: K261213

510(k) Summary

Prepared on: 2026-04-14

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	LG Electronics Inc.
Applicant Address	168, Suchul-daero Gumi-si Gyeongsangbuk-do 39368 Korea, Republic of
Applicant Contact Telephone	+82-1091523670
Applicant Contact	Mr. Wonhi Lee
Applicant Contact Email	wonhi.lee@lge.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Medical Monitor (40HT513D)
Common Name	Medical image management and processing system
Classification Name	Display, Diagnostic Radiology
Regulation Number	892.2050
Product Code(s)	PGY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K232127	32HL512D	PGY

Device Description Summary

21 CFR 807.92(a)(4)

40HT513D is a curved screen display and has a TFT Liquid Crystal Display module with without LED driver. The matrix employs a-Si thin film transistor as the active element. It is a transmissive type display operating in the normally black mode. It has a 40 inch diagonally measured active display area with WUHD resolution (5120 horizontal by 2160 vertical pixel array). Each pixel is divided into red, green and blue sub-pixels or dots which are arranged in vertical stripes. Gray scale or the brightness of the sub-pixel color is determined with a 8-bit gray scale signal for each dot, thus, presenting a palette of more than 16.78 Million colors. It has been designed to apply eDP (HBR2, 5.4Gbps) interface.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

This Medical Monitor is indicated for use in displaying radiological images and enhancing the image quality for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography.

Indications for Use Comparison

21 CFR 807.92(a)(5)

<Indication Comparison>
When comparing the indications for use statements, the terminology demonstrates that the proposed device shares the same indications for use as the predicate device. Therefore, it supports the determination of substantial equivalence between the proposed device and predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The comparison table shows the proposed device (40HT513D) has shares the same indications for use as the predicate device. Although there are some differences, they do not compromise the safety and performance of the proposed device. The major change includes its

module, which has been verified and validated through physical laboratory testing conducted according to the FDA Guidance, “Display Devices for Diagnostic Radiology”.
Based on the physical laboratory test results and software validation reports, all the differences between the proposed and predicate device do not raise any concerns regarding safety and effectiveness of the device.
Therefore, the proposed device is substantially equivalent to the predicate device in terms of its indications for use and technological characteristics.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

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

1) Electrical Safety and Electromagnetic Compatibility
Bench tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:
- IEC60601-1 Edition 3.2 2020-08
  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC60601-1-2 Edition 4.1 2020-09
  Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC TR 60601-4-2 Edition 1.0 2016-05
  Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

2) Software Validation
40HT513D contain software that belongs to Basic Documentation Level. The software was designed and developed according to a software development process and was verified and validated according to IEC 62304. Software information is provided in accordance with FDA guidance:
- The content of premarket submissions for Device Software Functions (June 14, 2023)

3) Performance Testing
The major change includes its module, which has been verified and validated through physical laboratory testing conducted according to the FDA Guidance, “Display Devices for Diagnostic Radiology”.

No clinical studies were considered necessary, and therefore, none were conducted.

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 adversely affect its effectiveness and safety. The proposed device has been proved to be as safe and effective as the predicate devices, which was previously cleared in K232127. They shares the same indications for use and similar technological characteristics, with any differences supported by software validation reports that demonstrate the proposed device's safety and effectiveness. Therefore, the technological differences 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 devices.