January 28, 2025

LG Electronics Inc.
Hanseul Park
RA Specialist
168, Suchul-daero
Gumi-si, Gyeongsangbuk-do 39368
Korea, South

Re: K243439
Trade/Device Name: Medical Monitor (27HS714S)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: October 31, 2024
Received: November 6, 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.

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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2025.01.28 18:37:10 -05'00'

for Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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.*

510(k) Number *(if known)*
K243439

Device Name
Medical Monitor (27HS714S)

Indications for Use *(Describe)*
This medical monitor is intended to provide color video displays and images from medical equipment which include laparoscopy and endoscopy systems for surgery and various medical imaging systems.

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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510(k) #: K243439

# 510(k) Summary

Prepared on: 2025-01-22

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | LG Electronics Inc. |
| Applicant Address | 168, Suchul-daero Gumi-si Gyeongsangbuk-do 39368 Korea, South |
| Applicant Contact Telephone | +82-1094902109 |
| Applicant Contact | Mrs. Hanseul Park |
| Applicant Contact Email | hs.park@lge.com |
| Correspondent Name | LG Electronics Inc. |
| Correspondent Address | 168, Suchul-daero Gumi-si Gyeongsangbuk-do 39368 Korea, South |
| Correspondent Contact Telephone | +82-1094902109 |
| Correspondent Contact | Mrs. Hanseul Park |
| Correspondent Contact Email | hs.park@lge.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Medical Monitor (27HS714S) |
| Common Name | Endoscope and accessories |
| Classification Name | Laparoscope, General & Plastic Surgery |
| Regulation Number | 876.1500 |
| Product Code(s) | GCJ |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K241402 | 32HR734S | GCJ |

## Device Description Summary

21 CFR 807.92(a)(4)

27HS714S LCD monitor is intended to provide color video displays of images from surgical endoscope, laparoscopic camera system and other compatible medical imaging systems. This Medical Monitor has multiple video interface ports such as Display port, HDMI, DVI and SDI. This monitor displays color video and images from medical equipment which include various medical imaging systems. This monitor can be covered over 99% of the sRGB spectrum.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

This medical monitor is intended to provide color video displays and images from medical equipment which include laparoscopy and endoscopy systems for surgery and various medical imaging systems.

## 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 indications for use, display technology, power, video signal and input video signals are identical to the predicate device.
The differences in specifications include:
- Pixel pitch: 0.1554 mm x 0.1554 mm (Predicate: 0.18159 mm x 0.18159 mm)
- Resolution: SDI (Display Port) 3840 x 2160 mm @ 60 Hz (Predicate: No recommended resolution for SDI)
- Maximum power consumption: 120 W (Predicate: 130 W)
- Output video signals: SDI OUT x 4, DVI-D OUT x 1, DP OUT x 1 (Predicate: SDI OUT x 4, HDMI OUT x 1)

These differences do not affect the safe and effective use of the device. The performance of 27HS714S has been validated in the software validation report. In addition, the safety of 27HS714S has been confirmed through the test according to IEC 60601-1 and 60601-1-2. Those reports confirm that all the differences between the proposed and predicate devices do not affect safety and effectiveness of the device.
Therefore, the proposed device is substantially equivalent to the predicate device in terms of 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
27HS714S 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)

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 negatively impact its effectiveness and safety. The proposed device has been proved to be as safe and effective as the predicate device, which was previously cleared in K241402. 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 device.