



August 12, 2024

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

Re: K241402
Trade/Device Name: Medical Monitor (32HR734S)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: May 17, 2024
Received: May 17, 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,

TANISHA L.
HITHE -S



Digitally signed by
TANISHA L. HITHE -S
Date: 2024.08.12
18:48:53 -04'00'

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

Indications for Use

510(k) Number (if known)

K241402

Device Name

Medical Monitor (32HR734S)

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.

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510(k) Summary

Prepared on: 2024-08-08

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	LG Electronics Inc.
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Correspondent Contact	Mrs. HANSEUL PARK
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Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Medical Monitor (32HR734S)
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
K170899	27HJ713S	GCJ
K231066	CuratOR EX3242-FD	GCJ

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

32HR734S 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 DP, HDMI, DVI, SDI input. This monitor displays color video and images from medical equipment which include various medical imaging systems. This monitor can be covered over 100% 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 primary predicate devices. Therefore, it supports the determination of substantial equivalence between the proposed device and predicate devices.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

<Difference between Subject and Predicate Devices>

The comparison tables show some differences in specifications such as maximum resolution available at SDI, connectors, and physical specifications. However, these differences do not affect the safe and effective use of the device. The performance of 32HR734S device has been validated as per the software validation report. In addition, its safety has been confirmed through tests conducted in accordance with IEC 60601-1 and 60601-1-2 standards.

The major change is the addition of "CLONE SCREEN" available in HDMI OUT, which also have been validated in the software validation report. Based on the software validation report, 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 devices 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

32HR734S 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 devices that would negatively impact its effective use and safety. The proposed device has been proved to be as safe and effective as the predicate devices, which were previously cleared in K170899 and K231066. 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 devices do not raise any new concerns regarding safety or effectiveness, and the proposed device can be considered substantially equivalent to the predicate devices.