DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 30, 2017

LG Electronics
Jinhwan Jun
Chief Research Engineer
222, LG-ro, Cheongho-ri, Jinwi-myeon
Pyeongtaek-si, Gyeonggi-do, 17709 Republic of Korea

Re: K170899
Trade/Device Name: 27HJ713S
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: March 17, 2017
Received: March 27, 2017

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

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)*

K170899

Device Name

27HI713S

Indications for Use *(Describe)*

This 27HJ713S 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. This product does not support 3D.

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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Gyeonggi-do, Republic of Korea
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510(k) Number: K170899

510(k) Summary

[As Required by 21 CFR 807.92]

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

March 17, 2017

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: Same as sponsor
  - Address: Same as sponsor

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

- Trade Name: 27HJ713S
- Common Name: Monitor
- Classification:

Classification Name	Endoscope and Accessories
Classification Number	21 CFR 876.1500
Product Code	GCJ
Device Class	II
Review Panel	General & Plastic Surgery

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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: K113203
- Applicant: SONY ELECTRONICS, INC.
- Classification Name: Endoscope and Accessories
- Trade Name: SONY LMD-2451MT LCD MONITOR

5. Description of the Device [21 CFR 807.92(a)(4)]

The 27HJ713S is a color video monitor intended to display viewable medical images transmitted by standard video signals. In particular, the device is intended for use as part of a visualisation system in endoscopic surgery.

6. Indications for Use [21 CFR 807.92(a)(5)]

This 27HJ713S 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. This product does not support 3D.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

There are no significant differences in the technological characteristics of this device compared to the predicate device which adversely affect safety or effectiveness. Provided below is a table summarizing and comparing the technological characteristics of the 27HJ713S and the predicate device:

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

510(k) Number: K170899

	Proposed Device	Predicate Device
K Number	Not known K170899	K113203
Manufacturer	LG Electronics	SONY ELECTRONICS, INC.
Model Name	27HJ713S	SONY LMD-2451MT LCD MONITOR
Classification Name	Endoscope and Accessories	Endoscope and Accessories
Classification Number	21 CFR 876.1500	21 CFR 876.1500
Indications for Use	This 27HJ713S 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. This product does not support 3D.	The Sony LMD-2451MT LCD Monitor is intended to provide 3D and 2D) color video displays of images from surgical endoscopic/laparoscopic camera systems and other compatible medical imaging systems. The LMD-2451IMT is a widescreen, highdefinition, medical grade monitor for real-time use during minimally invasive surgical procedures and is suitable for use in hospital operating rooms, surgical centers, clinics, doctors' offices and similar medical environments.
LCD Screen	TFT LCD	TFT LCD
Pixel Pitch	0.1554 x 0.1554 mm	0.3114 x 0.3114 mm
Resolution	3,840 x 2,160 pixels	1920 x 1080 pixels
Monitor Size (W x H x D)	654.4 x 410.9 x 58.0 mm	650.0 x 419.0 x 58.0 mm
Weight	7.7 kg	8.5 kg

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510(k) Number: K170899

Non-Clinical Test Summary

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:
Testing to confirm compliance with the safety requirements of standard AAMI ES60601-1
Testing to confirm compliance with EMC requirements of standard IEC 60601-1-2

2) Software Validation
The 27HJ713S 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. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

There are no significant differences between 27HJ713S and the predicate device, K113203 that would adversely affect the use of the product. It is substantially equivalent to these devices in indications for use and technology characteristics.

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

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 27HJ713S is substantially equivalent in safety and effectiveness to the predicate devices as described herein.