May 31, 2019

Nanjing Jusha Display Technology Co., Ltd
Zilong Liang
Certification Manager
Suite A, 8/F, Bldg 1, No. 301, Hanzhongmen St.
Nanjing International Service Outsourcing Mansion
Nanjing, China 210036

Re: K190831
Trade/Device Name: E240AG LCD Monitor, E240A LCD Monitor, JUSHA-E240AG LCD Monitor, JUJSHA-E240A LCD Monitor, C230A LCD Monitor, JUSHA-C230A LCD Monitor, C230M LCD Monitor, JUSHA-C230M LCD Monitor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 1, 2019
Received: April 1, 2019

Dear Zilong Liang:

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); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Jennifer R. Stevenson
Acting Division 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190831

Device Name
E240AG, C230A, C230M, E240A, JUSHA-E240AG, JUSHA-C230A, JUSHA-C230M, JUJSHA-E240A LCD Monitor

Indications for Use *(Describe)*
The E240AG LCD Monitor is intended to provide 2D color video displays of images from surgical endoscopic/ laparoscopic camera systems and other compatible medical imaging systems. The E240AG is a widescreen, high definition, 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.

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.

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	December 2,2018
Submitter:	Nanjing Jusha Display Technology Co., Ltd Add: 301, Hanzhongmen Street, 8F Block A, No.1, Nanjing International Service Outsourcing Mansion, Nanjing, 210036 China
Primary Contact Person:	Zilong Liang Certification Manager Nanjing Jusha Display Technology Co., Ltd Tel: +86-25- 83305050 Fax: +86-25- 58783271
Secondary Contact Person:	Dongdong Li Quality Manager Nanjing Jusha Display Technology Co., Ltd Tel: +86-25- 83305050 Fax: +86-25- 58783271
Device Trade Name:	E240AG, C230A, C230M, E240A, JUSHA-E240AG, JUSHA-C230A, JUSHA-C230M, JUJSHA-E240A LCD Monitor
Common/Usual Name:	LCD Monitor
Classification Name: Product Code:	Endoscope and Accessories GCJ
Predicate Device(s):	Sony LMD-2451MT LCD Monitor, K 113203
Device Description:	The E240AG, C230A, C230M, E240A, JUSHA-E240AG, JUSHA-C230A, JUSHA-C230M, JUJSHA-E240A LCD Monitor is intended primarily for use in a medical

	environment for displaying images captured during minimally invasive surgical procedures. The monitor features a 23.8-inch widescreen LCD display panel and employs full WUXGA high-definition (HID) performance. In addition to digital signals, the E240AG accepts analog signals and converts them to digital signals. The E240AG LCD Monitor is designed with the flexibility to support a variety of formats with two built-in option slots to select, expand, and change input/output signals.
Intended Use:	The E240AG, C230A, C230M, E240A, JUSHA-E240AG, JUSHA-C230A, JUSHA-C230M, JUJSHA-E240A LCD Monitor is intended to provide 2D color video displays of images from surgical endoscopic/laparoscopic camera systems and other compatible medical imaging systems. The E240AG is a widescreen, high-definition, 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.
Technological characteristic and Substantial equivalence:	The E240AG, C230A, C230M, E240A, JUSHA-E240AG, JUSHA-C230A, JUSHA-C230M, JUJSHA-E240A LCD Monitor has the same overall purpose and function as the predicate device cited above. Both of the devices are intended to provide color video displays of images from surgical camera systems, primarily in endoscopic/laparoscopic applications.
Performance Testing:	Testing of the E240AG, C230A, C230M, E240A, JUSHA-E240AG, JUSHA-C230A, JUSHA-C230M, JUJSHA-E240A LCD Monitor demonstrated that the device is in compliance with applicable requirements of recognized standards for electromagnetic compatibility and electrical safety.

Conclusion:	Based on the similarities in overall purpose and function, the E240AG LCD Monitor has demonstrated substantial equivalence to the cited predicate device and any differences do not affect the safety or effectiveness of the device.

12.1 Product Comparison

This comparison identifies the similarities and differences of the proposed E240AG LCD Monitor device to the legally marketed predicate Sony LMD-2451MT LCD Monitor device to which substantial equivalency is claimed.

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	Sony LMD-2451MT	E240AG, C230A, C230M, E240A, JUSHA-E240AG, JUSHA-C230A, JUSHA-C230M, JUJSHA-E240A LCD Monitor	
510(k) Number	K113203	/	
Display Performance/Specifications			
Screen technology	24” TFT LCD Panel	23.8” TFT LCD Panel	Same
Viewing angle （H,V）	Horizontal 178°,Vertical 178° (the contrast ratio ≥ 10 :1)	Horizontal 178°,Vertical 178° (the contrast ratio ≥ 10 :1)	Same
Resolution	1920×1200	1920×1080	Different Resolution design due to the different panel size.
Display area	518.4×324.0 mm	527.04 ×296.46mm	Different Display area design due to the different panel size.
Contrast Ratio(typ)	1000:1	1000:1	Same

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	Sony LMD-2451MT	E240AG, C230A, C230M, E240A, JUSHA-E240AG, JUSHA-C230A, JUSHA-C230M, JUJSHA-E240A LCD Monitor	
510(k) Number	K113203	/	
Recommended brightness	300cd/m^2	300cd/m^2	Same
Pixel Pitch	0.27×0.27 mm	0.27×0.27 mm	Same
Backlighting	LED backlight	LED backlight	Same
grayscale	1024	1024	Same
Response time	14ms	14ms	Same
Sensor	Backlight sensor	Backlight sensor	Same
Video Signal Input			
Input signals	BNC、DVI、SDI、Y/C(S-Video)、YPbPr、RGBS、HD15	VGA、DVI-A/D、SDI、Y/C(S-Video)、YPbPr、RGBS、CVBS	The differences caused by different signals interface type used in the medical display, the E240AG has VGA&CVBS ,This only shows the signals interface type is different, nothing to do with the display function
Input terminational	1 DVI-D Dual Link 1 HDMI Port	1 DVI-D Dual Link 1 HDMI Port	Same
Display controller	Off the shelf	Off the shelf	Same
Video Signal Output			

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	Sony LMD-2451MT	E240AG, C230A, C230M, E240A, JUSHA-E240AG, JUSHA-C230A, JUSHA-C230M, JUJSHA-E240A LCD Monitor	
510(k) Number	K113203	/	
Output signals	BNC、DVI、SDI、Y/C(S-Video)、YPbPr、RGBS、HD15	DVI-D、SDI、Y/C (S-Video)、YPbPr、RGBS、CVBS	The differences caused by different signals interface type used in the medical display, the E240AG has VGA&CVBS ,This only shows the signals interface type is different, nothing to do with the display function
Power Related Specification			
Power Requirement	100 V - 240 Vac ±10%, 50/60 Hz 1.53 A - 0.58 A	100 - 240 Vac ±10%, 47-63 Hz 1.4 - 0.6A	Same
Power Consumptions/Save Mode	125W/less than 0.7W	35W/less than 0.5W	The differences caused by different adapter and components used in the medical display,the E240AG has lower power consumptions,This only shows the power consumption is different, nothing to do with the display function
Miscellaneous Features/Specifications			

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	Sony LMD-2451MT	E240AG, C230A, C230M, E240A, JUSHA-E240AG, JUSHA-C230A, JUSHA-C230M, JUJSHA-E240A LCD Monitor	
510(k) Number	K113203	/	
Dimensions w/o stand (W x H x D)	With stand: 602.4×454×302mm Without stand: 602.4×386.2×110 mm	With stand: 565.3x238x460.3mm Without stand: 565.3x65x375.3mm	Different housing design due to the different panel size.
Indication for use	The Sony LMD-2451MT LCD Monitor is intended to provide 3D and 2Dcolor video displays of images from surgical endoscopic/laparoscopic camera systems and other compatible medical imaging systems. The LMD-2451MT is a widescreen, high-definition, 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.	The E240AG, C230A, C230M, E240A, JUSHA-E240AG, JUSHA-C230A, JUSHA-C230M, JUJSHA-E240A LCD Monitor is intended to provide 2D color video displays of images from surgical endoscopic/laparoscopic camera systems and other compatible medical imaging systems. The E240AG is a widescreen, high-definition, 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.	Same

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	Sony LMD-2451MT	E240AG, C230A, C230M, E240A, JUSHA-E240AG, JUSHA-C230A, JUSHA-C230M, JUJSHA-E240A LCD Monitor	
510(k) Number	K113203	/	
Applicable standard	1 IEC 60601-1Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance 1988+A1 : 1991 + A2:1995 2 IEC 60601-1-2 Edition 3:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.	1 IEC 60601-1:2012 Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance. 2 IEC 60601-1-2:2014, Medical electrical equipment-Part 1-2:General requirements for basic safety and essential performance-Collateral Standard:Electromagnetic disturbances-Requirements and tests	Same

PERFORMANCE DATA:

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

Bench testing:

Bench testing was conducted to demonstrate the E240AG meets all performance standards as follows:

Measurement of the luminance non-uniformity characteristics of the display screen

Measurement of the chromaticity non-uniformity characteristics of the display screen

Measurement of contrast ratio.

Performance data on luminance stability

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the E240AG The device complies with the IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC.

Animal and clinical study

The subject of this premarket submission, E240AG, does not require animal or clinical studies to support substantial equivalence.

CONCLUSIONS

E240AG, C230A, C230M, E240A, JUSHA-E240AG, JUSHA-C230A, JUSHA-C230M, JUJSHA-E240A LCD Monitor is substantially equivalent to the predicate device with respect to technical characteristics, performance, application and intended use. The non-clinical data support the safety of the device. The device should perform as intended in the specified use conditions. Nanjing Jusha Display Technology Co., Ltd considers the E240AG Medical Display does not raise any new issues of safety or effectiveness.