Nanjing Jusha Display Technology Co., Ltd
Donny Lee
Certification Engineer
8A, Block 1. Nanjing International Service Outsourcing
Mansion, No. 301. Hanzhongmen street
NANJING, JIANGSU 210036
CHINA

June 9, 2023

Re: K230728
Trade/Device Name: JUSHA-C810G/C810G LCD Monitor, JUSHA-C660/JUSHA-C660G/C660/C660G LCD Monitor
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: PGY
Dated: March 16, 2023
Received: March 16, 2023

Dear Donny 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 (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/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 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 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,
Assistant Director
Imaging Software 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230728

Device Name
JUSHA-C810G/C810G LCD Monitor, JUSHA-C660/JUSHA-C660G/C660/C660G LCD Monitor

Indications for Use *(Describe)*
C660G/C810G LCD Monitor is intended to be used in displaying and viewing digital images diagnosis of X-ray or MRI,etc.by trained medical practitioners. The device does not support the display of mammography images for diagnosis.

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

（K230728）

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

Date:	Mar 16, 2023
Submitter:	Nanjing Jusha Display Technology Co., Ltd Add: 8A, Block 1. Nanjing International Service Outsourcing Mansion, No. 301, Hanzhongmen street, Nanjing City, Jiangsu Province, 210036 China.
Contact Person:	Donny Lee Certification Engineer Nanjing Jusha Display Technology Co., Ltd Tel: +86-25- 83305050 Fax: +86-25- 58783273 lidongdong@jusha.com.cn
Device Trade Name:	JUSHA-C810G/C810G LCD Monitor, JUSHA-C660/JUSHA-C660G/C660/C660G LCD Monitor
Common/Usual Name:	6MP/8MP Color LCD Monitor
Classification Name: Product Code:	Medical Image Management and Processing System 21CFR 892.2050 PGY
Predicate Device(s):	C630G, K222121
Device Description:	JUSHA-C660G/JUSHA-C660/C660G/C660 LCD Monitor is the display system with high resolution (3280×2048), high luminance (800 cd/m2), and 16-bit grayscale (65536 level), built-in DICOM standard LUT. In particular, C660G has ambient brightness adaptation inside, on top of which C660G has real-time DICOM automatic calibration, full-screen brightness equalization and presence induction system, therefore this display automatically adjust according to different requirements to achieve the best results. The product is consisted of the following components: - the display with stand - a graphic card

	- agraphic card driver CD - an AC power cable - an external power supply - a Type-C cable - Three DP cables - a USB cable JUSHA-C810G/ C810G LCD Monitor is the display system with high resolution (3840×2160), high luminance (800 cd/m2), and 14-bit grayscale (16384 grayscale), built-in DICOM standard LUT. In particular, C810G has ambient brightness adaptation inside, on top of which C810G has real-time DICOM automatic calibration, full-screen brightness equalization and presence induction system, therefore this display automatically adjust according to different requirements to achieve the best results. The product is consisted of the following components: - the display with stand - a graphic card - agraphic card driver CD - an AC power cable - an external power supply - a DVI cable - two Mini DP switch to DP cable - a USB cable The LCD Monitors are designed, tested, and will be manufactured in accordance with both mandatory and voluntary standards:

	1. IEC 60601-1:2012, EN 60601-1:2013, ANSI/AAMI ES60601-1:2005+A1:2012+C1:2009+A2:2010, CAN/CSA C22.2 NO.60601-1:14, Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance. 2. IEC 60601-1-2 Edition 4:2014, EN 60601-1-2:2015, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests.
Intended Use:	C660G/C810G LCD Monitor is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The device does not support the display of mammography images for diagnosis.
Technology:	JUSHA-C660G/JUSHA-C660/C660G/C660 LCD Monitor is the display system with high resolution (3280×2048), high luminance (800 cd/m2), and 16-bit grayscale (65536 level), built-in DICOM standard LUT. In particular, C660G has ambient brightness adaptation inside, on top of which C660G has real-time DICOM automatic calibration, full-screen brightness equalization and presence induction system, therefore this display automatically adjust according to different requirements to achieve the best results. JUSHA-C810G/ C810G LCD Monitor is the display system with high resolution (3840×2160), high luminance (800 cd/m2), and 14-bit grayscale (16384 grayscale), built-in DICOM standard LUT. In particular, C810G has ambient brightness adaptation inside, on top of which C810G has real-time DICOM automatic calibration, full-screen brightness equalization and presence induction system, therefore this display automatically adjust according to different requirements to achieve the best results.
Determination of Substantial Equivalence:	<u>Summary of Non-Clinical Tests:</u> The LCD Monitor(C660G,C810G) complies with voluntary standards as following: 1 IEC 60601-1:2012, EN 60601-1:2013, ANSI/AAMI ES60601-1:2005+A1:2012+C1:2009+A2:2010, CAN/CSA C22.2 NO.60601-1:14, Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

	2 IEC 60601-1-2 Edition 4:2014, EN 60601-1-2:2015, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests C660G/C810G LCD Monitor are substantially equivalent to C630 LCD Monitor. They have equivalent characteristics andfunctions according to comparison table, pleaserefer to *12. Product Comparison* The following quality assurance measures were applied to the development of the system: • Risk Analysis • Requirements Reviews • Design Reviews • Raw materials verification • Testing on unit level (Module verification) • Integration testing (System verification) • Final acceptance testing (Validation) • Performance testing (Verification) • Safety testing (Verification) Summary of Clinical Tests: The subject of this premarket submission, LCD Monitor, did not require clinical studies to support substantial equivalence. The proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device. Therefore, the subject device is determined as safe and effectiveness.
Conclusion:	Nanjing Jusha Display Technology Co., Ltd Considers the C660G/C810G LCD Monitor to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

12.1 Product Comparison

This comparison identifies the similarities and differences of the proposed C660G/C810G LCD Monitor device to the legally marketed predicate C630 LCD Monitor device to which substantial equivalency is claimed.

Attributes	Predicate Device	Proposed Device		Discussion of Differences
Product	C630G LCD Monitor	C660G LCD Monitor	C810G LCD Monitor	
510(k) Number	K222121	K230728		
Display Performance/Specifications				
Screen technology	30 inches, Color-TFT LCD Panel	30inches,Color-TFT LCD Panel	31.5inches, Color-TFT LCD Panel	C660G and C630G are same，C810G is larger than C630G.
Viewing angle （H，V）	Horizontal 178°,Vertical 178°	Horizontal 178°,Vertical 178°	Horizontal 178°,Vertical 178°	Same
Resolution	3280x2048	3280x2048	3840x2160	C660G and C630G are same，C810G is better than C630G.
Display area	645.5 (H) mm× 403 (V)mm	645.5 (H) mm× 409.3 (V)mm	697.31(H) mm× 392.23(V)mm	C660G and C630G are same，C810G is larger than C630G.
Contrast Ratio	1000:1	2000:1	1300:1	C660G and C810G are larger than C630G.
DICOM calibrated luminance	500cd/m^2	800 cd/m^2	1000cd/m^2	C660G and C810G are larger than C630G.
Pixel Pitch	0.197mm× 0.197mm	0.197mm× 0.197mm	0.1816mm× 0.1816mm	C660G and C630G are same，C810G is better than C630G.
Backlight	LED	LED	LED	Same.

Attributes	Predicate Device	Proposed Device		Discussion of Differences
Product	C630G LCD Monitor	C660G LCD Monitor	C810G LCD Monitor	
510(k) Number	K222121	K230728		
DICOM LUT	16-bit:65536	16-bit:65536	14-bit:16384	This parameter is an output range.C810G is smaller than them, But the three products can only output 10bit images.
Luminance calibration	Built in calibration sensor provided	Built in calibration sensor provided	Built in calibration sensor provided	Same.
Video Signal Input				
Input signals	DisplayPort 1.2a DVI	DisplayPort 1.2a Type-C DVI	DisplayPort 1.2a DVI	The difference only shows that they have different input,has nothing to do with the display function.
Input terminational	DisplayPort×2 DVI×1	DisplayPort×2 Type-C DVI×1	DisplayPort×2 DVI×1	The difference only shows that they have different input,has nothing to do with the display function.
Output signals	DisplayPort 1.2a	DisplayPort 1.2a	NA	C660G and C630G are same，C810G has no output interface.
Output Terminational	DisplayPort×1	DisplayPort×1	NA	C660G and C630G are same，C810G has no output interface.
Display controller	Off the shelf	Off the shelf	Off the shelf	Same

Attributes	Predicate Device	Proposed Device		Discussion of Differences
Product	C630G LCD Monitor	C660G LCD Monitor	C810G LCD Monitor	
510(k) Number	K222121	K230728		
Power Related Specification				
Power Requirement	24VDC-9.2A	24VDC-6.25A	24V 5A	Same
Power Consumption/Save Mode	150W/less than 0.5W	150W/less than 0.5W	120W/less than 0.5W	The differences caused by components used in the LCD Monitor. This only shows the power consumption is different, nothing to do with the display function
Power Management	DisplayPort 1.2a	DisplayPort 1.2a	DisplayPort 1.2a	Same
Miscellaneous Features/Specifications				
USB Ports/standard	1 upstream (endpoint), 2 downstream/ Rev. 2.0	1 upstream (endpoint), 2 downstream/ Rev. 2.0	1 upstream (endpoint), 2 downstream/ Rev. 2.0	Same
Dimensions w/o stand (W×H×D)	Without stand: 701.3 mm× 500 mm× 86.8mm With stand: 701.3 mm× 589 mm× 245mm	Without stand: 721.5 mm× 493.5 mm× 110mm With stand: 721.5 mm× 585 mm× 262mm	Without stand: 756.7 mm× 464.2 mm× 70.2mm With stand: 756.7 mm× 556.7 mm× 262mm	Different housing design due to the different glass size.

Attributes	Predicate Device	Proposed Device		Discussion of Differences
Product	C630G LCD Monitor	C660G LCD Monitor	C810G LCD Monitor	
510(k) Number	K222121	K230728		
Indication for use	JUSHA-C630G/JUSHA-C630/C630G/C630 LCD Monitor is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The device does not support the display of mammography images for diagnosis.	C660G/C810G LCD Monitor is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The device does not support the display of mammography images for diagnosis.		Same

Applicable standard	1 IEC 60601-1:2012, EN 60601-1:2013, ANSI/AAMI ES60601-1:2005+A1:2012+C1:2009+A2:2010, CAN/CSA C22.2 NO.60601-1:14, Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance. 2 IEC 60601-1-2 Edition 4:2014, EN 60601-1-2:2015, CFR 47 FCC Part15 subpart B: 2017, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests	1 IEC 60601-1:2012, EN 60601-1:2013, ANSI/AAMI ES60601-1:2005+A1:2012+C1:2009+A2:2010, CAN/CSA C22.2 NO.60601-1:14, Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance. 2 IEC 60601-1-2 Edition 4:2014, EN 60601-1-2:2015, 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 C660G/C810G meets all performance standards as follows:

- Measurement of the angular dependency of luminance response in horizontal, vertical and diagonal directions
- Measurement of the luminance non-uniformity characteristics of the display screen as specified in TGI18 guideline.
- Measurement of the chromaticity non-uniformity characteristics of the display screen as specified in TG18 guideline.
- Measurement of small-spot contrast ratio.
- Measurement of temporal response
- Performance data on luminance stability

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the C660G/C810G 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, C660G/C810G, does not require animal or clinical studies to support substantial equivalence.

CONCLUSIONS

C660G/C810G 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 C660G/C810G Medical Display does not raise any new issues of safety or effectiveness.