Nanjing Jusha Display Technology Co., Ltd.
℅ Donny Lee
Certification Engineer
8A, Block 1. No. 301, Hanzhongmen Street
Nanjing, Jiangsu 210036
CHINA

May 1, 2023

Re: K230643
Trade/Device Name: CP620G LCD monitor, CP620 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 9, 2023
Received: March 9, 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, Ph.D.
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)*
K230643

Device Name
CP620G LCD Monitor / CP620 LCD Monitor

Indications for Use *(Describe)*
CP620G/CP620 LCD Monitor is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. It 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

（K230643）

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

Date:	Mar 3, 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
Device Trade Name:	CP620G LCD Monitor, CP620 LCD Monitor
Common/Usual Name:	6MP Color LCD Monitor
Classification Name: Product Code: Device Class	Medical Image Management and Processing System, 21 CFR 892.2050 PGY Class II
Predicate Device(s): Classification Name: Product Code: Device Class	JUSHA-CP610; K200742 Medical Image Management and Processing System ,21 CFR 892.2050 PGY Class II
Device Description:	CP620G/CP620 LCD Monitor is the display system with the high resolution (3000*2000), high luminance (500 cd/m2), and 4398 billion colors, built-in DICOM standard LUT. In particular, CP620G/CP620 LCD

	Monitor is portable and light, the 750g weight make it is easy to carry. With these this display can automatic adjustment according to different requirements in order to achieve the best results.(There is no difference between CP620G and CP620 except for labeling as they are marketed in different areas. CP620G is global sales, CP620 is domestic sales .It does not affect their safety or effectiveness in any terms.) The product is consisted of the following components: - 13.5" Color-TFT LCD Panel - DMS3400AR0/6 layers/214*150mm/1.0mm/REV:1.0 - CP620G LCD Monitor software - Power Adapter - Data Cable. In accordance with the May 11, 2005 Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, the software level of concern for the CP620G/CP620 LCD Monitor was determined to be Moderate on account of a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider. the software doesn't include any functions of image manipulation. The LCD Monitor is 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:	CP620G/CP620 LCD Monitor is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. It does not support the display of mammography images for diagnosis.
Technology:	CP620G/CP620 LCD Monitor is the display system with the high resolution (3000*2000), high luminance (500 cd/m²), and 4,398 billion

	colors, built-in DICOM standard LUT. In particular, CP620G/CP620 LCD Monitor is portable and light, the 750 g weight make it is easy to carry. With these this display can automatic adjustment according to different requirements in order to achieve the best results.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The LCD Monitor 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 CP620G LCD Monitor are substantially equivalent to JUSHA-CP610 LCD Monitor. They have equivalent characteristics and functions according to comparison table, please refer to ***2. 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 CP620G/CP620 LCD Monitor to be as safe, as effective, and performance

	is substantially equivalent to the predicate device(s).

2. Product Comparison

This comparison identifies the similarities and differences of the proposed CP620G LCD Monitor device to the legally marketed predicate JUSHA-CP610 LCD Monitor device to which substantial equivalency is claimed.

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-CP610	CP620G LCD Monitor	
510(k) Number	K200472	K230643	
Display Performance/Specifications			
Screen technology	13.5” Color TFT LCD Panel	13.5” Color TFT LCD Panel	Same
Viewing angle （H，V）	Horizontal 170°,Vertical 170°	Horizontal 170°,Vertical 170°	Same
Resolution	3000×2000	3000×2000	Same
Display area	285.3(V)×190.2(H)mm	285.3(V)×190.2(H)mm	Same
Contrast Ratio	1800:1	1800:1	Same
Scanning frequency (H; V)	94.94~123.84kHz; 60Hz	94.94~123.84kHz; 60Hz	Same
Recommended Luminance	300cd/m2	500cd/m^2	CP620G is better than CP610
Pixel Pitch	0.0951×0.0951mm	0.0951×0.0951mm	Same.
Backlight	LED	LED	Same.
Display Colors	14-bit, 4398 billion colors	14-bit, 4398 billion colors	Same.
Luminance calibration	General calibration sensor	General calibration sensor	Same
Video Signal Input			
Input signals	Type-C×1, Mini DP×1	Type-C×2 HDMI×1	The difference only shows that they have different input, has nothing to do with the display function.

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-CP610	CP620G LCD Monitor	
510(k) Number	K200472	K230643	
Output signals	-	-	
Display controller	Off the shelf	Off the shelf	Same
Power Related Specification			
Power Requirement	AC 100~240V 50~60Hz	AC 100~240V 50~60Hz	Same
Power Consumption/Save Mode	15W / N/A	20W/NA	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	NA	NA	Same
Miscellaneous Features/Specifications			
USB Ports/standard	upstream (endpoint)/Rev. 3.1	upstream (endpoint)/Rev. 3.1	
Dimensions w/o stand (W×H×D)	323mm×225×11.5mm	312.3mm×220mm×11.5mm	Different housing design due to the different glass size.
Indication for use	JUSHA-CP610 LCD Monitor is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. It does not support the display of mammography images for diagnosis.	CP620G/CP620 LCD Monitor is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. It does not support the display of mammography images for diagnosis.	CP620G/CP620 LCD Monitor is the display system with the high resolution (3000*2000), high luminance (500 cd/m²), and 4398 billion

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-CP610	CP620G LCD Monitor	
510(k) Number	K200472	K230643	
			colors, can be used in displaying and viewing digital images for diagnosis of X-ray, MRI and mammography, etc.
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, 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
New Features			
Bidirectional power supply function	/	When one USB-C is connected to the power supply, it can power the CP620 and reverse charge the connected phone or computer through the other USB-C port	This is a new feature of CP620G that makes using the product more convenient and has nothing to do with the display

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-CP610	CP620G LCD Monitor	
510(k) Number	K200472	K230643	
			function.
dual-screen display function	/	With two inputs connected, users can have a seamless experience like a traditional 6MP medical monitor, two independent 3MP window side by side.	This is a new feature of CP620G that makes using the product more convenient.
gravity sensing function	/	With build-in gravity sensor, windows will rotate automatically with the device orientation.	This is a new feature of CP620G that makes using the product more convenient and has nothing to do with the display function.
Adaptive environment brightness function	/	CP620G will monitor the ambient light in real time, and change brightness and DICOM compensation accordingly, making it more comfortable to do diagnosis in different lighting environment	This is a new feature of CP620G that makes using the product more convenient.
Screen touch function	/	The touch screen enables users directly interact with PACS and many more software with fingers. Easier and more intuitive	This is a new feature of CP620G that makes using the product more convenient and has nothing to do with the display function.

PERFORMANCE DATA:

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

determination.

Bench testing:

Bench testing was conducted to demonstrate the CP620/CP620G 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 .
- Measurement of the chromaticity non-uniformity characteristics of the display screen.
- 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 CP620G 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, CP620G, does not require animal or clinical studies to support substantial equivalence.

CONCLUSIONS

CP620G Medical Display 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 CP620G Medical Display does not raise any new issues of safety or effectiveness.