Nanjing Jusha Display Technology Co., Ltd.
Donny Lee
Certification Engineer
8A, Block 1, 301 Hanzhongmen Street
Nanjing, Jiangsu 210036
China

September 19, 2022

Re: K222121
Trade/Device Name: C630G LCD monitor, JUSHA-C630G LCD monitor, C630 LCD monitor, JUSHA-C630 LCD monitor
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: PGY
Dated: July 18, 2022
Received: July 18, 2022

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)*

K222121

Device Name

C630G/JUSHA-C630G/C630/JUSHA-C630 LCD Monitor

Indications for Use *(Describe)*

JUSHA-C630G/JUSHA-C630G/C630/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.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Date:	July 12, 2022
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:	JUSHA-C630G LCD Monitor, JUSHA-C630 LCD Monitor, C630G LCD Monitor, C630 LCD Monitor
Common/Usual Name:	6MP Color LCD Monitor
Classification Name: Product Code:	Display, Diagnostic Radiology 21CFR 892.2050 PGY
Predicate Device(s):	JUSHA-C620G; K183492
Device Description:	JUSHA-C630G/JUSHA-C630/C630G/C630 LCD Monitor is the display system with the high resolution (3280×2048), high luminance (1050 cd/m^2), and 281.47 trillion colors, built-in DICOM standard LUT. In particular, C630G contains GAMMA2.2/GAMMA2.4 LUT. In addition, C630G has ambient brightness adaptation inside, 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: - 30” Color TFT LCD Panel - DMX0704AR0/main board/REV:1.1 - JUSHA-C630G LCD Monitor software - Power Adapter - Data Cable. 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, 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.
Intended 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.
Technology:	JUSHA-C630G/JUSHA-C630/C630G/C630 LCD Monitor is the display system with the high resolution (3280×2048), high luminance (1050 cd/m^2), and 281.47 trillion colors, built-in DICOM standard LUT. In particular, C630G contains GAMMA2.2/GAMMA2.4 LUT. In addition, C630G has ambient brightness adaptation inside, 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:	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, 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. JUSHA-C630G/ JUSHA-C630/ C630G/ C630 LCD Monitor is substantially equivalent to JUSHA-C620G. Comparison table of the principal characteristics of two devices is shown in the Attachment 1.

	1. Attachment 1 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 C630G LCD Monitor to be safe and effective, and its performance is substantially equivalent to the predicate device(s).

12.1 Product Comparison

This comparison identifies the similarities and differences of the proposed JUSHA-C630G LCD Monitor device to the legally marketed predicate JUSHA-C620G LCD Monitor device to which substantial equivalency is claimed.

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-C620G	JUSHA-C630G/JUSHA-C630/C630G/C630 LCD Monitor	
510(k) Number	K183492	K222121	
Display Performance/Specifications			
Screen technology	30” Color TFT LCD Panel	30” Color TFT LCD Panel	Same
Viewing angle （H，V）	Horizontal 170°, Vertical 170°	Horizontal 170°, Vertical 170°	Same
Resolution	3280 x 2048	3280 x 2048	Same
Display area	645.5 (H) x403.0 (V) mm	645.5(H)×403.0(V)mm	Same
Contrast Ratio	1000:1	1000:1	Same
Recommended Luminance	500cd/m^2	500cd/m^2	Same
Pixel Pitch	0.197x0.197 mm	0.197×0.197mm	Same
Backlight	LED	LED	Same.
Display Colors	16-bit, 281.47 trillion colors	16-bit, 281.47 trillion colors	Same
Luminance calibration	Built in calibration sensor provided	Built in calibration sensor provided	Same
Video Signal Output			
Output signals	DisplayPort x 1	DisplayPort x 1	Same
Display controller	Off the shelf	Off the shelf	Same
Power Related Specification			

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-C620G	JUSHA-C630G/JUSHA-C630/C630G/C630 LCD Monitor	
510(k) Number	K183492	K222121	
Power Requirement	AC 100~240V 50~60Hz	24V DC	The differences caused by components used in the LCD Monitor. This only shows the power requirement is different, not raising different questions of its safety and effectiveness.
Power Consumption/Save Mode	150W/less than 0.5W	150W/less than 0.5W	Same
Power Management	DVI DMPM DisplayPort 1.1a	DVI DMPM DisplayPort 1.2	Same
Miscellaneous Features/Specifications			
USB Ports/standard	1 upstream (endpoint), 2 downstream/ Rev. 2.0	1 upstream (endpoint), 2 downstream/ Rev. 2.0	Same
Dimensions w/o stand (W x H x D)	Without stand: 721.5mm×493.5mm×110mm With stand: 721.5mm×585mm×262mm	Without stand: 705mm×477mm×77mm With stand: 705mm×567mm×262mm	Different housing design which has nothing to do with the display function.

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-C620G	JUSHA-C630G/JUSHA-C630/C630G/C630 LCD Monitor	
510(k) Number	K183492	K222121	
Indication for use	JUSHA-C620G 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.	JUSHA-C630G 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, 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.	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 JUSHA-C630G 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 TG18 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 JUSHA-C630G 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, JUSHA-C630G, does not require animal or clinical studies to support substantial equivalence.

CONCLUSIONS

JUSHA-C630G/JUSHA-C630/C630G/C630 LCD Monitor.

or 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 JUSHA-C630G Medical Display does not raise any new issues of safety or effectiveness.