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

May 18, 2023

Re: K230723
Trade/Device Name: C510G/JUSHA-C510G/C510/JUSHA- C510 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

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)*
K230723

Device Name
C510G/JUSHA-C510G/C510/JUSHA-C510

Indications for Use *(Describe)*
C510G/JUSHA-C510G/C510/JUSHA-C510 LCD Monitor is intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for view, analysis, and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications.

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

（K230723）

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

Date:	March 16, 2023
Submitter:	Nanjing Jusha Display Technology Co., Ltd Add: 301, 8F Block A, No.1, Nanjing International Service Outsourcing Mansion, Hanzhongmen Street, Nanjing, 210036 China
Contact Person:	Donny Lee Certification Manager Nanjing Jusha Display Technology Co., Ltd Tel: +86-25- 83305050 Fax: +86-25- 58783273 lidongdong@jusha.com.cn
Device Trade Name:	C510G/JUSHA-C510G/C510/JUSHA- C510 LCD Monitor
Common/Usual Name:	5MP Color LCD Monitor
Classification Name: Product Code:	Medical image management and processing system 21CFR 892.2050 PGY
Predicate Device(s):	JUSHA-M550G; K190848
Device Description:	C510G/JUSHA-C510G/JUSHA-C510/C510 LCD Monitor is the display system with the high resolution (2560*2048), high luminance (1150 cd/m2), and 16-bit (65536 level), built-in DICOM standard LUT. In particular, C510G has ambient brightness adapting, real-time DICOM automatic calibration, full-screen brightness equalization and presence induction system, with these this display can automatic adjustment according to different requirements in order to achieve the best results. The product is consisted of the following components: - 21.3" Color-TFT LCD Panel - DMX0704AR1/Main Board/REV：1.2 - C510G 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, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests.
Intended Use:	C510G/JUSHA-C510G/JUSHA-C510/C510 LCD Monitor is intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for view, analysis, and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications.
Technology:	C510G/JUSHA-C510G/JUSHA-C510/C510 LCD Monitor is the display system with the high resolution (2560*2048), high luminance (1150 cd/m2), and 16-bit grayscale (65536 level), built-in DICOM standard LUT. In particular, C510G has ambient brightness adapting, real-time DICOM automatic calibration, full-screen brightness equalization and presence induction system, with these this display can automatic adjustment according to different requirements in order to achieve the best results.
Determination of Substantial Equivalence:	<u>Summary of Non-Clinical Tests:</u> 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

	C510G is substantially equivalent to JUSHA-M550G. C510G employs the maximum resolution values same as that of JUSHA-M550G. 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) <u>Summary of Clinical Tests:</u> 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 C510G LCD Monitor to be as safe, as effective, and performance is substantially equivalent to the predicate device JUSHA-M550G.

Product Comparison

This comparison identifies the similarities and differences of the proposed C510G LCD Monitor device to the legally marketed predicate JUSHA-M550G LCD Monitor device to which substantial equivalency is claimed.

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-M550G LCD Monitor	C510G LCD Monitor	
510(k) Number	K190848	K230723	
Display Performance/Specifications			
Screen technology	21.3inches, Mono-TFT LCD Panel	21.3inches, Color-TFT LCD Panel	Same
Viewing angle （H，V）	Horizontal 178°, Vertical 178°	Horizontal 178°, Vertical 178°	Same
Resolution	2560 x 2048/2048x 2560	2560 x2048/2048x 2560	Same
Display area	422.4(H) x 377.9 (V) mm	422.4(H) x337.9 (V) mm	The two monitors have different front frame style while the M550G employ a Slim Bezel design so that the display area is different.
Contrast Ratio	1700:1	2000:1	C510G has better contrast ratio for the panel, while the difference does not make difference to the diagnosis.
DICOM calibrated luminance	1000cd/m2	500cd/m2	The two models have different panels with different brightness but they have the same resolution for 5MP for Mammo image diagnosis.
Pixel Pitch	0.165x0.165 mm	0.165x0.165 mm	Same
Backlight	LED	LED	Same.

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-M550G LCD Monitor	C510G LCD Monitor	
510(k) Number	K190848	K230723	
DICOM LUT	16-bit: 65536	16-bit: 65536	Same
Luminance calibration	Built in calibration sensor provided	Built in calibration sensor provided	Same
Video Signal Input			
Input signals	DVI standard 1.0, DisplayPort 1.2a	DVI standard 1.0, DisplayPort 1.2a	Same
Input terminational	DVI-D x 1, DisplayPort x 1	DVI-D x 1, DisplayPort x 1	Same
Output signals	DisplayPort 1.2a	DisplayPort 1.2a	Same
Output Terminational	DisplayPort x 1	DisplayPort x 1	Same
Display controller	Off the shelf	Off the shelf	Same
Power Related Specification			
Power Requirement	DC 24V	DC 24V	Same
Power Consumption/Save Mode	55W/less than 0.5W	55W/less than 0.5W	Same
Power Management	DVI DMPM DisplayPort 1.2a	DVI DMPM 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	Same

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-M550G LCD Monitor	C510G LCD Monitor	
510(k) Number	K190848	K230723	
Dimensions w/o stand (W x H x D)	Without stand: 363mm x475mm x66mm With stand: 363mm x522mm x238mm	Without stand: 399mm x491mm x74mm With stand: 399mm x530mm x238mm	Different Dimensions design due to the different structure size.
Indication for use	JUSHA-M550G/JUSHA-M550/M550G/M550 LCD Monitor is intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for view, analysis, and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications.	C510G/JUSHA-C510G/C510/JUSHA-C510 LCD Monitor is intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for view, analysis, and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications.	Same

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-M550G LCD Monitor	C510G LCD Monitor	
510(k) Number	K190848	K230723	
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

PERFORMANCE DATA:

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

Bench testing:

Bench testing was conducted to demonstrate the C510G 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 C510G 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, C510G, does not require animal or clinical studies to support substantial equivalence.

CONCLUSIONS

C510G 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 C510G Medical Display does not raise any new issues of safety or effectiveness.