Nanjing Jusha Display Technology Co., Ltd.
% Zilong Liang
Certification Manager
Suite A, 8/F, Bldg 1, No. 301, Hanzhongmen St.,
Nanjing, Jiangsu 210036
CHINA

March 13, 2019

Re: K183492
Trade/Device Name: JUSHA-C620G LCD Monitor, JUSHA-C620 LCD Monitor, C620G LCD Monitor, C620 LCD Monitor
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: PGY
Dated: January 11, 2019
Received: January 11, 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,

Michael D. O'Hara For

Thalia Mills, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K183492

Device Name
JUSHA-C620G LCD Monitor, JUSHA-C620 LDC Monitor, C620G LCD Monitor, C620 LCD Monitor

Indications for Use *(Describe)*
JUSHA-C620G LCD/JUSHA-C620/C620G/C620 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.

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K183492

510(k) Summary

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

Date:	December 6, 2018
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:	Zilong Liang Certification Manager Nanjing Jusha Display Technology Co., Ltd Tel: +86-25- 83305050 Fax: +86-25- 58783273
Device Trade Name:	JUSHA-C620G LCD Monitor, JUSHA-C620 LCD Monitor, C620G LCD Monitor, C620 LCD Monitor
Common/Usual Name:	6MP Color LCD Monitor
Classification Name: Product Code:	Display, Diagnostic Radiology 21CFR 892.2050 PGY
Predicate Device(s):	JUSHA-C61; K141679
Device Description:	JUSHA-C620G LCD/JUSHA-C620/C620G/C620 LCD Monitor is the display system with the high resolution (3280*2048), high luminance (500 cd/m^2), and 281.47 trillion colors, built-in DICOM standard LUT. In particular, JUSHA-C620G LCD Monitor contains CGA function, it is specially made by JUSHA, it can automatic identify gray and color signals, then gray area calls DICOM LUT and color area calls GAMMA2.2 LUT. In addition, JUSHA-C620G has ambient brightness adapting, 3D LUT color calibration, real-time DICOM automatic calibration, Full-screen brightness equalization, presence induction, focusview and text mode function, 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: - 30” Color TFT LCD Panel - C44&C62 Mother board/FR-6/V1.2 - JUSHA-C620G 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-C620G LCD/JUSHA-C620/C620G/C620 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-C620G LCD/JUSHA-C620/C620G/C620 LCD Monitor is the display system with the high resolution (3280*2048), high luminance (500 cd/m2), and 281.47 trillion colors, built-in DICOM standard LUT. In particular, JUSHA-C620G LCD Monitor contains CGA function, it is specially made by JUSHA, it can automatic identify gray and color signals, then gray area calls DICOM LUT and color area calls GAMMA2.2 LUT. In addition, JUSHA-C620G has ambient brightness adapting, 3D LUT color calibration, real-time DICOM automatic calibration, Full-screen brightness equalization, presence induction, focusview and text mode function, 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, 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-C620G LCD/JUSHA-C620/C620G/C620 LCD Monitor is substantially equivalent to JUSHA-C61. JUSHA-C620G LCD/JUSHA-C620/C620G/C620 LCD Monitor employs the maximum resolution values same as that of JUSHA-C61. Comparison table of the principal characteristics of 2 devices is shown in the Attachment 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) <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 JUSHA-C620G LCD Monitor to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).