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

February 4, 2019

Re: K183499
Trade/Device Name: JUSHA-M350G/JUSHA-M350/M350G/M350 LCD Monitor
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications System
Regulatory Class: Class II
Product Code: PGY
Dated: December 20, 2018
Received: December 20, 2018

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

Robert Ochs, 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)*
K183499

Device Name
JUSHA-M350G/JUSHA-M350/M350G/M350 LCD Monitor

Indications for Use *(Describe)*
JUSHA-M350G/JUSHA-M350/M350G/M350 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)*

X 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
K183499

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-M350G/JUSHA-M350/M350G/M350 LCD Monitor
Common/Usual Name:	3MP Monochrome LCD Monitor
Classification Name: Product Code:	Display, Diagnostic Radiology 21CFR 892.2050 PGY
Predicate Device(s):	JUSHA-M33C; K141690
Device Description:	JUSHA-M350G/JUSHA-M350/M350G/M350 LCD Monitor is the display system with the high resolution (2048*1536), high luminance (1000 cd/m^2), and 16-bit grayscale (65536 level), built-in DICOM standard LUT. In particular, JUSHA-M350G has ambient brightness adapting, real-time DICOM automatic calibration, full-screen brightness equalization, presence induction and focusview 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: - 21.3" Mono-TFT LCD Panel - DMX0704AR0/main board/REV1.1 - JUSHA-M350G 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-M350G/JUSHA-M350/M350G/M350 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-M350G/JUSHA-M350/M350G/M350 LCD Monitor is the display system with the high resolution (2048*1536), high luminance (1000 cd/m^2), and 16-bit grayscale (65536 level), built-in DICOM standard LUT. In particular, JUSHA-M350G has ambient brightness adapting, real-time DICOM automatic calibration, full-screen brightness equalization, presence induction and focusview 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-M350G/JUSHA-M350/M350G/M350 is substantially equivalent to JUSHA-M33C. JUSHA-M350G/JUSHA-M350/M350G/M350 employs the maximum resolution values same as that of JUSHA-M33C. 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-M350G 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 JUSHA-M350G LCD Monitor device to the legally marketed predicate JUSHA-M33C LCD Monitor device to which substantial equivalency is claimed.

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-M33C	JUSHA-M350G/JUSHA-M350/M350G/M350	
510(k) Number	K141684	/	
Display Performance/Specifications			
Screen technology	21.3" Color TFT LCD Panel	21.3" Color TFT LCD Panel	Same
Viewing angle （H，V）	Horizontal 176 °,Vertical 176 °	Horizontal 178 °,Vertical 178 °	-
Resolution	2048 x 1536/1536x 2048	2048 x1536/1536x 2048	Same
Display area	324.864(H) x 433.152 (V) mm	323.942(H) x 431.923 (V) mm	-
Contrast Ratio	1400:1	1400:1	same
Scanning frequency (H; V)	96.7kHz;60Hz	37.9~95.4kHz;60Hz	This difference between the two device is caused by the different no display area defined by different manufacturers , nothing to do with the display function
Recommended Luminance	400cd/m^2	450cd/m^2	-
Pixel Pitch	0.2115 x 0.2115 mm	0.2109x0.2109 mm	-
Backlight	LED	LED	Same.

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-M33C	JUSHA-M350G/JUSHA-M350/M350G/M350	
510(k) Number	K141684	/	
Display Colors	12-bit ,68.7 billion colors	16-bit , 281.47 Trillion colors	The JUSHA-M350G LCD Monitor uses a color bit expansion technology to improve image display quality, the image clarity is better than the image displayed on the predicate device.
Luminance calibration	Built in calibration sensor provided	Built in calibration sensor provided	Same
Video Signal Input			
Input signals	DVI-D (dual link) x 1, DisplayPort x 1	DVI-D (dual link) x 1, DisplayPort x 1	-
Output Signal	-	DisplayPort x1	-
Display controller	Off the shelf	Off the shelf	Same
Power Related Specification			
Power Requirement	AC 100~240V 50~60Hz	DC 24V	-

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-M33C	JUSHA-M350G/JUSHA-M350/M350G/M350	
510(k) Number	K141684	/	
Power Consumption/Save Mode	65W/less than 3W	80W/less than 0.5W	The differences caused by different adapter and components used in the LCD Monitor, the JUSHA-M350G has more power consumption and lower save mode power consumption. This only shows the power consumption is different, nothing to do with the display function
Power Management	DVI DMPM DisplayPort 1.1a	DVI DMPM DisplayPort 1.2a	-
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: 376mmx505mmx98 mm With stand: 376mmx599mmx245.5mm	Without stand: 356mm x476mm x85mm With stand: 356mm x525mm x238mm	Different housing design due to the different panel size.

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-M33C	JUSHA-M350G/JUSHA-M350/M350G/M350	
510(k) Number	K141684	/	
Indication for use	JUSHA-M33C 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-M350G/JUSHA-M350/M350G/M350 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 60601-1Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance 2005+CORR.1(2006)+CORR.2(2007) 2 IEC 60601-1-2 Edition 3:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.	1 IEC 60601-1:2012, Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance. 2 IEC 60601-1-2 Edition 4:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests.	-

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-M350G 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 JUSHA-M350G 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-M350G, does not require animal or clinical studies to support substantial equivalence.

CONCLUSIONS

JUSHA-M350G/JUSHA-M350/M350G/M350 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 JUSHA-M350G/JUSHA-M350/M350G/M350 LCD Monitor does not raise any new issues of safety or effectiveness.