510(k) Summary

K183496

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

Date:	December 1, 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- 58783271
Device Trade Name:	JUSHA-C350G LCD Monitor , JUSHA-C350 LCD Monitor , C350G LCD Monitor , C350 LCD Monitor
Common/Usual Name:	3MP Color LCD Monitor
Classification Name: Product Code:	Display, Diagnostic Radiology 21CFR 892.2050 PGY
Predicate Device(s):	JUSHA-C33C; K141684
Device Description:	JUSHA-C350G LCD Monitor , JUSHA-C350 LCD Monitor , C350G LCD Monitor , C350 LCD Monitor is the display system with the high resolution monitor (3 megapixels) with electronic capabilities for evaluation of high resolution medical images, high luminance (800 cd/m^2) and 281.47 trillion colors, built-in DICOM standard LUT. JUSHA-C350G 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-C350G has ambient brightness adapting, 3D LUT color calibration, 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" Color TFT LCD Panel - DMX0704AR0/main board/REV1.1 - JUSHA-C350G 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, 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.
Intended Use:	JUSHA-C350G LCD Monitor , JUSHA-C350 LCD Monitor , C350G LCD Monitor , C350 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-C350G LCD Monitor , JUSHA-C350 LCD Monitor , C350G LCD Monitor , C350 LCD Monitor is the display system with the high resolution monitor (3 megapixels) with electronic capabilities for evaluation of high resolution medical images, high luminance (800 cd/m^2) and 281.47 trillion colors, built-in DICOM standard LUT. JUSHA-C350G 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-C350G has ambient brightness adapting, 3D LUT color calibration, 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, 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. JUSHA-C350G LCD Monitor , JUSHA-C350 LCD Monitor , C350G LCD Monitor , C350 LCD Monitor is substantially equivalent to JUSHA-C33C. JUSHA-C350G employs the maximum resolution values same as that of JUSHA-C33C. 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) 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 JUSHA-C350G LCD Monitor , JUSHA-C350 LCD Monitor , C350G LCD Monitor , C350 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-C350G LCD Monitor device to the legally marketed predicate JUSHA-C33C LCD Monitor device to which substantial equivalency is claimed.

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-C33C	JUSHA-C350G LCD Monitor	
510(k) Number	K141684	/	
Display Performance/Specifications			

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-C33C	JUSHA-C350G LCD Monitor	
510(k) Number	K141684	/	
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-C33C	JUSHA-C350G LCD Monitor	
510(k) Number	K141684	/	
Display Colors	12-bit ,68.7 billion colors	16-bit , 281.47 Trillion colors	The JUSHA-C350G 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-C33C	JUSHA-C350G LCD Monitor	
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-C350G 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-C33C	JUSHA-C350G LCD Monitor	
510(k) Number	K141684	/	
Indication for use	JUSHA-C33C 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-C350G 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-C350G 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-C350G 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-C350G, does not require animal or clinical studies to support substantial equivalence.

CONCLUSIONS

JUSHA-C350G/JUSHA-C350/C350G/C350 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-C350G Medical Display does not raise any new issues of safety or effectiveness.