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-M260G/JUSHA-M260/M260G/M260 LCD Monitor
Common/Usual Name:	2MP monochrome LCD Monitor
Classification Name: Product Code:	Display, Diagnostic Radiology 21CFR 892.2050 PGY
Predicate Device(s):	JUSHA-M23C; K151238
Device Description:	JUSHA-M260G/JUSHA-M260/M260G/M260 LCD Monitor is the display system with the high resolution (1600*1200), high luminance (800 cd/m^2), and 14-bit grayscale (16384 level), built-in DICOM standard LUT. In particular, JUSHA-M260G has real-time DICOM automatic calibration 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" Mono-TFT LCD Panel - DMX0302CR0/main board/V1.2 - JUSHA-M260G 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-M260G 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-M260G LCD Monitor is the display system with the high resolution (1600*1200), high luminance (800 cd/m2), and 14-bit grayscale (16384 level), built-in DICOM standard LUT. In particular, JUSHA-M260G has real-time DICOM automatic calibration 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, 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-M260G is substantially equivalent to JUSHA-M23C. JUSHA-M260G employs the maximum resolution values same as that of JUSHA-M23C. 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-M260G 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-M260G LCD Monitor device to the legally marketed predicate JUSHA-M23C LCD Monitor device to which substantial equivalency is claimed.

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-M23C	JUSHA-M260G	
510(k) Number	K151238	/	
Display Performance/Specifications			
Screen technology	21.3" Mono-TFT LCD Panel	21.3" Mono-TFT LCD Panel	Same
Viewing angle （H，V）	Horizontal 176°,Vertical 176°	Horizontal 178°,Vertical 178°	-
Resolution	1600 x 1200/1200 x 1600	1600 x 1200/1200 x 1600	Same
Display area	432.0 (H) x 324.0(V) mm	432.0 (H) x 324.0(V) mm	Same
Contrast Ratio	1400:1	1400:1	Same
Scanning frequency (H; V)	52~76 kHz;59~61Hz	37.9~75kHz;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	500cd/m^2	400cd/m^2	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
Pixel Pitch	0.27x0.27 mm	0.27x0.27 mm	Same
Backlight	LED	LED	Same.

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-M23C	JUSHA-M260G	
510(k) Number	K151238	/	
DICOM LUT	12-bit:4096	14-bit:16384	The JUSHA-M260G 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 x 1, DisplayPort x 1	DVI-D x 1, DisplayPort x 1	Same
Display controller	Off the shelf	Off the shelf	Same
Power Related Specification			
Power Requirement	AC 100~240V 50~60Hz	DC 12V	-
Power Consumption/Save Mode	45W/less than 3W	50W/less than 0.5W	The differences caused by components used in the LCD Monitor. This only shows the power consumption is different, nothing to do with the display function

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-M23C	JUSHA-M260G	
510(k) Number	K151238	/	
Power Management	DVI DMPM DisplayPort 1.1a	DVI DMPM DisplayPort 1.1a	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: 382mm x490mm x75mm With stand: 382mm x533mm x238mm	Without stand: 382mm x490mm x77mm With stand: 382mm x635mm x238mm	Different housing design due to the different panel size.
Indication for use	JUSHA-M23C 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-M260G 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

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	JUSHA-M23C	JUSHA-M260G	
510(k) Number	K151238	/	
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, 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.	-

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-M260G 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-M260G 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-M260G, does not require animal or clinical studies to support substantial equivalence.

CONCLUSIONS

JUSHA-M260G 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 JUSHA-M260G Medical Display does not raise any new issues of safety or effectiveness.