510(k) Summary

K183494

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

Date:	Dec 3, 2018
Submitter:	Nanjing Jusha Display Technology Co., Ltd Add: 8A, Block 1. Nanjing International Service Outsourcing Mansion, No. 301, Hanzhongmen street, Nanjing, China.
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Device Trade Name:	R190 LCD Monitor,R191 LCD Monitor
Common/Usual Name:	1MP Monochrome LCD Monitor
Classification Name: Product Code:	Display, Diagnostic Radiology 21CFR 892.2050 PGY
Predicate Device(s):	MDM 1900-1NR AND MDM 1900-1NR; K061303
Device Description:	R190/R191 LCD Monitor is the display system with the resolution (1280*1024), high luminance (800cd/m^2), and can present up to 1.07 billion colors(1024 grayscale), 1 DICOM look up table inside. R190/R191 uses luminance stabilization mechanism to ensure brightness stability in the product service time. The product is consisted of the following components: -19inches, Mono-TFT LCD Panel - M150M/P38 motherboard/FR-4 - R190/R191 LCD Monitor software - Power cable - 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 electrical equipment-Part 1:General requirements for basic safety and essential performance 2. IEC 60601-1-2:2014,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:	R190/R191 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:	R190/R191 LCD Monitor is the display system with the resolution monitor (1 megapixels) with electronic capabilities for evaluation of high resolution medical images,the resolution (1280*1024), high luminance (800cd/m^2), and can present up to 1.07 billion colors(1024 grayscale), 1 DICOM look up table inside. R190/R191 uses luminance stabilization mechanism to ensure brightness stability in the product service time.
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 electrical equipment-Part 1:General requirements for basic safety and essential performance 2. IEC 60601-1-2:2014,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 R190/R191 is substantially equivalent to MDM 1900-1NR. R190/R191 employs the maximum resolution values same as that of MDM 1900-1NR. 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 R190/R191 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 R190/R191 LCD Monitor device to the legally marketed predicate CHILIN MDM 1900-1NR LCD Monitor device to which substantial equivalency is claimed.

Attributes	Predicate Device	Proposed Device	Proposed Device	Discussion of Differences
Product	CHILIN MDM 1900-1NR	R190 LCD Monitor	R191 LCD Monitor	
510(k) Number	K061303	K183494	K183494	
Display Performance/Specifications				
Screen technology	19" Monochrome TFT LCD Panel	19" Monochrome TFT LCD Panel	19" Monochrome TFT LCD Panel	Same
Viewing angle（H，V）	Horizontal 170°,Vertical 17 0°	Horizontal 176°,Vertical 176°	Horizontal 176°,Vertical 176°	-

Attributes	Predicate Device	Proposed Device	Proposed Device	Discussion of Differences
Product	CHILIN MDM 1900-1NR	R190 LCD Monitor	R191 LCD Monitor	
510(k) Number	K061303	K183494	K183494	
Resolution	1024 x 1280	1280*1024	1280*1024	The difference between the two devices is due to the different viewing directions and does not affect performance.
Display area	376.32 (H) x 301.056(V) mm	374.7840 (H) x 299.8272(V) mm	374.7840 (H) x 299.8272(V) mm	Same
Contrast Ratio	800:1	1000:1	1000:1	-
Response Time	18ms	16ms	16ms	-
Scanning frequency (H; V)	75 kHz;63.4~79.78Hz	52~76 kHz;59~61Hz	52~76 kHz;59~61Hz	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	1000cd/m^2	800cd/m^2	800cd/m^2	This item is the maximum brightness of the LCD panel. After the curve is corrected, the difference is not large and does not affect the use.
Pixel Pitch	0.294x0.294 mm	0.2928x0.2928mm	0.2928x0.2928mm	-
Backlight	LED	LED	LED	Same.

Attributes	Predicate Device	Proposed Device	Proposed Device	Discussion of Differences
Product	CHILIN MDM 1900-1NR	R190 LCD Monitor	R191 LCD Monitor	
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DICOM LUT	12-bit : 4096	10-bit:1024	10-bit:1024	Both devices use grayscale extension technology, and the final display effect is not much different, which does not affect the use of the product.
Luminance calibration	Built in calibration sensor provided	Built in calibration sensor provided	Built in calibration sensor provided	Same
Video Signal Input				
Input signals	DVI standard D-Sub	DVI -D DisplayPort HDMI DVI-A	DVI -D DisplayPort HDMI SOG	-
Input terminational	DVI-D (dual link) x 1, D-Sub x 1	DVI-D (dual link) x 1, DisplayPort x 1 HDMI x1 DVI-A x 1	DVI-D (dual link) x 1, DisplayPort x 1 HDMI x1 SOG x 1	-
Display controller	Off the shelf	Off the shelf	Off the shelf	Same
Power Related Specification				
Power Requirement	AC 100~240V	AC 100~240V	AC 100~240V	Same
Power Consumption/Save Mode	47W/less than 0.5W	25W/less than 0.5W	25W/less than 0.5W	-

Attributes	Predicate Device	Proposed Device	Proposed Device	Discussion of Differences
Product	CHILIN MDM 1900-1NR	R190 LCD Monitor	R191 LCD Monitor	
510(k) Number	K061303	K183494	K183494	
Power Management	DVI DMPM DisplayPort	DVI DMPM DisplayPort	DVI DMPM DisplayPort	-
Miscellaneous Features/Specifications				
Service interface	RS232	USB	USB	This interface is only used to communicate with the host, does not affect the performance of the display.
Dimensions w/o stand (W x H x D)	Without stand: 344mmx418mmx82.5mm With stand: 344mmx433mmx227 mm	Without stand: 419mm x343mm x71mm With stand: 419mm x379mm x198mm	Without stand: 419mm x343mm x71mm With stand: 419mm x379mm x198mm	Different housing design due to the different panel size.

Attributes	Predicate Device	Proposed Device	Proposed Device	Discussion of Differences
Product	CHILIN MDM 1900-1NR	R190 LCD Monitor	R191 LCD Monitor	
510(k) Number	K061303	K183494	K183494	
Indication for use	MDM 1900-1NR 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.	R190 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.	R191 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	Proposed Device	Discussion of Differences
Product	CHILIN MDM 1900-1NR	R190 LCD Monitor	R191 LCD Monitor	
510(k) Number	K061303	K183494	K183494	
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 electrical equipment-Part 1:General requirements for basic safety and essential performance 2.IEC 60601-1-2:2014,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,Medical electrical equipment-Part 1:General requirements for basic safety and essential performance 2.IEC 60601-1-2:2014,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	-

PERFORMANCE DATA:

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

Bench testing:

Bench testing was conducted to demonstrate the R190/R191 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 R190/R191 The device complies with the IEC 60601-1:2012 standard for safety and the IEC 60601-1:2012 and EN 60601-1-2:2015 standard for EMC.

Animal and clinical study

The subject of this premarket submission,R190/R191, does not require animal or clinical studies to support substantial equivalence.

CONCLUSIONS

R190/R191 Medical 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 R190/R191 Medical Monitor does not raise any new issues of safety or effectiveness.