



Nanjing Jusha Display Technology Co., Ltd.  
% Donny Lee  
Certification Engineer  
8A, Block 1. Nanjing International Service Outsourcing  
Mansion, No. 301, Hanzhongmen street  
Nanjing, Jiangsu 210036  
CHINA

June 7, 2023

Re: K231170

Trade/Device Name: C350/C350G LCD Monitor; M550/M550G LCD Monitor

Regulation Number: 21 CFR 892.2050

Regulation Name: Medical image management and processing system

Regulatory Class: Class II

Product Code: PGY

Dated: April 25, 2023

Received: April 25, 2023

Dear Donny Lee:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



Jessica Lamb, PhD.  
Assistant Director  
Imaging Software Team  
DHT8B: Division of Radiological Imaging Devices  
and Electronic Products  
OHT8: Office of Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K231170

Device Name  
C350/C350G LCD Monitor  
M550/M550G LCD Monitor

Indications for Use (Describe)

C350G/C350/JUSHA-C350G/JUSHA-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 is not specified for digital mammography system.

M550G/ M550 /JUSHA-M550G/JUSHA-M550 LCD Monitor is intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis, and diagnosis by trained medical practitioners. It is specially de displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis, and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications.

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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## 510(k) Summary

(K231170)

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

Date:	Apr 16, 2023
Submitter:	Nanjing Jusha Display Technology Co., Ltd  Add: 8A, Block 1. Nanjing International Service Outsourcing Mansion, No. 301, Hanzhongmen street, Nanjing City, Jiangsu Province, 210036 China.
Contact Person:	Donny Lee  Certification Engineer  Nanjing Jusha Display Technology Co., Ltd  Tel: +86-25- 83305050  Fax: +86-25- 58783273
Device Trade Name:	C350G LCD Monitor, C350 LCD Monitor, JUSHA-C350G LCD Monitor, JUSHA-C350 LCD Monitor (There is no difference between C350G LCD Monitor, C350 LCD Monitor, JUSHA-C350G LCD Monitor and JUSHA-C350 LCD Monitor except for labeling as they are marketed in different areas. It does not affect their safety or effectiveness in any terms. )  M550G LCD Monitor, M550 LCD Monitor, JUSHA-M550G LCD Monitor, JUSHA-M550 LCD Monitor (There is no difference between M550G LCD Monitor, M550 LCD Monitor, JUSHA-M550G LCD Monitor and JUSHA-M550 LCD Monitor except for labeling as they are marketed in different areas. It does not affect their safety or effectiveness in any terms. )
Common/Usual Name:	3MP LCD Monitor and 5MP LCD Monitor
Classification Name:	Medical Image Management and Processing System, 21 CFR 892.2050
Product Code:	PGY
Device Class:	Class II

<p>Predicate Device(s):</p> <p>Classification Name:</p> <p>Product Code:</p> <p>Device Class:</p>	<p>C270G;K183498</p> <p>BARCO MDMG-5221; K161229</p> <p>Medical Image Management and Processing System, 21 CFR 892.2050</p> <p>PGY</p> <p>Class II</p>
<p>Device Description:</p>	<p>C350G LCD Monitor is the display system with the high resolution (2048*1536), high luminance (800 cd/m<sup>2</sup>), and 281.47 trillion colors, built-in DICOM standard LUT. In particular, C350G has ambient brightness adapting, real-time DICOM automatic calibration and presence induction system, with these this display can automatic adjustment according to different requirements in order to achieve the best results.</p> <p>The product is consisted of the following components:</p> <ul style="list-style-type: none"> <li>- 21.3" Color TFT LCD Panel</li> <li>- DMX3304AR2/main board</li> <li>- C350G LCD Monitor software</li> <li>- a graphic card</li> <li>- a graphic card driver CD</li> <li>- a CGA software CD</li> <li>- an AC power cord</li> <li>- an external power supply</li> <li>- a DVI cable</li> <li>- a DP cable</li> <li>- a USB cable</li> </ul> <p>M550G LCD Monitor is the display system with the high resolution (2560*2048), high luminance (1000 cd/m<sup>2</sup>), and 16-bit grayscale (65536 level), built-in DICOM standard LUT. In particular, M550G</p>

has ambient brightness adapt inside. In particular, M550G has ambient brightness adapting, real-time DICOM automatic calibration, full-screen brightness equalization and presence induction 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
- DMX3304AR2/main board
- M550G LCD Monitor software
- a graphic card
- a graphic card driver CD
- an AC power cord
- an external power supply
- a DVI cable
- a DP cable
- a USB cable

In accordance with the May 11, 2005 Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, the software level of concern for the C350G and M550G LCD Monitor was determined to be Moderate on account of a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider. The software doesn't include any functions of image manipulation.

The LCD Monitors are 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.

	<p>2. IEC 60601-1-2 Edition 4:2014, 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.</p>
Intended Use:	<p>C350G/C350/JUSHA-C350G/JUSHA-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 is not specified for digital mammography system.</p> <p>M550G/M550/JUSHA-M550G/JUSHA-M550 LCD Monitor is intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis, and diagnosis by trained medical practitioners. It is specially designed for displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis, and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications.</p>
Technology:	<p>C350G LCD Monitor is the display system with the high resolution (2048*1536), high luminance (800 cd/m<sup>2</sup>), and 281.47 trillion colors, built-in DICOM standard LUT. In particular, C350G LCD Monitor has ambient brightness adapting, real-time DICOM automatic calibration and presence induction system, with these this display can automatic adjustment according to different requirements in order to achieve the best results.</p> <p>M550G LCD Monitor is the display system with the high resolution (2560*2048), high luminance (1000 cd/m<sup>2</sup>), and 16-bit grayscale (65536 level), built-in DICOM standard LUT. In particular, M550G/M550 LCD Monitor has ambient brightness adapt inside. In particular, M550G LCD Monitor has ambient brightness adapting, real-time DICOM automatic calibration, full-screen brightness equalization and presence induction system, with these this display can automatic adjustment according to different requirements in order to achieve the best results.</p>
Determination of Substantial Equivalence:	<p><u>Summary of Non-Clinical Tests:</u></p> <p>The LCD Monitor complies with voluntary standards as following:</p> <p>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.</p>

	<p>2 IEC 60601-1-2 Edition 4:2014, 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</p> <p>C350G LCD Monitor is substantially equivalent to C270G. M550G LCD Monitor is substantially equivalent to BARCO MDMG-5221. They have equivalent characteristics and functions according to comparison table, please refer to <b>2. Product Comparison</b></p> <p>The following quality assurance measures were applied to the development of the system:</p> <ul style="list-style-type: none"> <li>• Risk Analysis</li> <li>• Requirements Reviews</li> <li>• Design Reviews</li> <li>• Raw materials verification</li> <li>• Testing on unit level (Module verification)</li> <li>• Integration testing (System verification)</li> <li>• Final acceptance testing (Validation)</li> <li>• Performance testing (Verification)</li> <li>• Safety testing (Verification)</li> </ul> <p><u>Summary of Clinical Tests:</u></p> <p>The subject of this premarket submission, LCD Monitor, did not require clinical studies to support substantial equivalence.</p> <p>The proposed devices are Substantially Equivalent (SE) to the predicate devices which is US legally market device. Therefore, the subject devices are determined as safe and effectiveness.</p>
<p>Conclusion:</p>	<p>Nanjing Jusha Display Technology Co., Ltd Considers the C350G LCD Monitor and M550G LCD Monitor to be as safe, as effective, and performance are substantially equivalent to the predicate device(s).</p>

## 2. Product Comparison

### 2.1 C350G and its predicate device comparison

This comparison identifies the similarities and differences of the proposed C350G LCD monitor device to the legally marketed predicate C270G LCD Monitor device to which substantial equivalency is claimed.



Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	C270G LCD Monitor	C350G LCD Monitor	
510(k) Number	K183498	/	
Display Performance/Specifications			
Screen technology	21.3" Color TFT LCD Panel	21.3" Color TFT LCD Panel	Same
Viewing angle (H, V)	Horizontal 178 °,Vertical 178 °	Horizontal 178 °,Vertical 178 °	Same
Resolution	1600 x 1200/1200 x 1600	2048x 1536	C350G has a higher resolution than C270G  Image quality is better than the image displayed on the predicate device.
Display area	432.0 (H) x 324.0(V) mm	433.15(H) x324.86(V) mm	-
Contrast Ratio	1400:1	1500:1	C350G has a higher contrast ratio than C270G  Image quality is better than the image displayed on the predicate device.
DICOM calibrated luminance	350cd/m <sup>2</sup>	Max:800cd/m <sup>2</sup>  Recommend:500cd/m <sup>2</sup>	C350G has a higher calibrated luminance than C270G  Image quality is better than the image displayed on the predicate device.

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	C270G LCD Monitor	C350G LCD Monitor	
510(k) Number	K183498	/	
Pixel Pitch	0.27x0.27 mm	0.2115x0.2115 mm	C350G has a smaller pixel pitch than C270G
Backlight	LED	LED	Same.
DICOM LUT	16-bit:65536	16-bit:65536	same
Scanning frequency (H; V)	37.9~75kHz;60Hz	74.2~97.68kHz;60Hz	-
Luminance calibration	Built in calibration sensor provided	Built in calibration sensor provided	Same
Video Signal Input			
Input signals	DVI standard 1.0, DisplayPort 1.2a	DVI standard 1.0, DisplayPort 1.2a	Same
Input terminational	DVI-D x 1, DisplayPort x 1	DVI-D x 1, DisplayPort x 1	Same
Output signals	-	DisplayPort 1.2a	-
Output Terminational	-	DisplayPort x 1	-
Display controller	Off the shelf	Off the shelf	Same
Power Related Specification			
Power Requirement	DC 24V	DC 24V	Same

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	C270G LCD Monitor	C350G LCD Monitor	
510(k) Number	K183498	/	
Power Consumption/Save Mode	50W/less than 0.5W	90W/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
Power Management	DVI DMPM Display Port 1.1a	DVI DMPM Display Port 1.2a	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 x77mm With stand:  382mm x635mm x238mm	Without stand:  382mm x490mm x77mm With stand:  363mm x(530-635)mm x238mm	Different housing design due to the different panel size.
Indication for use	C270G 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.	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 is not specified for digital mammography system.	Same

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	C270G LCD Monitor	C350G LCD Monitor	
510(k) Number	K183498	/	
Applicable standard	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.  IEC 60601-1-2 Edition 4:2014, 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	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.  IEC 60601-1-2 Edition 4:2014, 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	Same

## 2.2 M550G and its predicate device comparison

This comparison identifies the similarities and differences of the proposed M550G LCD monitor device to the legally marketed predicate BARCO MDMG-5221 LCD Monitor device to which substantial equivalency is claimed.

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	BARCO MDMG-5221	M550G LCD Monitor	
510(k) Number	K161229	/	
Display Performance/Specifications			
Screen technology	21.3inches, Mono-TFT LCD Panel	21.3inches, Mono-TFT LCD Panel	Same

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	BARCO MDMG-5221	M550G LCD Monitor	
510(k) Number	K161229	/	
Viewing angle (H, V)	Horizontal 176 °,Vertical 176 °	Horizontal 178 °,Vertical 178 °	-
Resolution	2560 x 2048/2048x 2560	2560 x2048/2048x 2560	Same
Display area	422.4(H) x 377.9 (V) mm	422.4(H) x377.92(V) mm	-
Contrast Ratio	950:1	2000:1	M550G has a higher contrast ratio than MDMG5221  Image quality is better than the image displayed on the predicate device.
DICOM calibrated luminance	1000cd/m2	Max: 1000cd/m <sup>2</sup>  Recommended:500cd/m <sup>2</sup>	Same
Pixel Pitch	0.165x0.165 mm	0.165x0.165 mm	Same
Backlight	LED	LED	Same.
DICOM LUT	10-bit:1024	16-bit:65536	The JUSHA-M550G 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			

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	BARCO MDMG-5221	M550G LCD Monitor	
510(k) Number	K161229	/	
Input signals	DVI standard 1.0, DisplayPort 1.2a	DVI standard 1.0, DisplayPort 1.2a	Same
Input terminational	DVI-D x 1, DisplayPort x 1	DVI-D x 1, DisplayPort x 1	Same
Output signals	-	DisplayPort 1.2a	-
Output Terminational	-	DisplayPort x 1	-
Display controller	Off the shelf	Off the shelf	Same
Power Related Specification			
Power Requirement	AC 100~240V 50~60Hz	DC 24V	Different power supply, will not affect the performance
Power Consumption/Save Mode	57W/less than 0.7W	80W/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
Power Management	DVI DMPM DisplayPort 1.2a	DVI DMPM DisplayPort 1.2a	Same
Miscellaneous Features/Specifications			
USB Ports/standard	1 upstream (endpoint), 2 downstream/ Rev. 2.0	1 upstream (endpoint), 2 downstream/ Rev. 2.0	Same

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	BARCO MDMG-5221	M550G LCD Monitor	
510(k) Number	K161229	/	
Dimensions w/o stand  (W x H x D)	Without stand:  392mm x484mm x122mm With stand:  780mm x550mm x261mm	Without stand:  368mm x474mm x70mm With stand:  368mm x(521-631)mm x238mm	Different housing design due to the different panel size.
Indication for use	BARCO MDMG-5221 device intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis, and diagnosis by trained medical practitioners. It is specially de displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis, and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications.	M550G LCD Monitor is intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis, and diagnosis by trained medical practitioners. It is specially de displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis, and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications.	Same

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	BARCO MDMG-5221	M550G LCD Monitor	
510(k) Number	K161229	/	
Applicable standard	Electrical Safety test (IEC 60601-1)  EMC test (IEC 60601-1-2)	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	Same

### 2.3 PERFORMANCE DATA

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

#### 2.3.1 Bench testing:

Bench testing was conducted to demonstrate the C350G LCD Monitor and M550G LCD Monitor meet 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



### 2.3.2 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the C350G LCD Monitor and M550G LCD Monitor. The device complies with the IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC.

### 2.3.3 Animal and clinical study

The subject of this premarket submission, C350G LCD Monitor and M550G LCD Monitor, do not require animal or clinical studies to support substantial equivalence.

## **2.4 CONCLUSIONS**

C350G LCD Monitor and M550G LCD Monitor are substantially equivalent to the predicate devices 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 C350G LCD Monitor and M550G LCD Monitor do not raise any new issues of safety or effectiveness.