May 14, 2019

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

Re: K190848
Trade/Device Name: JUSHA-M550G/ JUSHA-M550/M550G/M550 LCD Monitor
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: Class II
Product Code: PGY
Dated: April 10, 2019
Received: April 10, 2019

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,

For Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*
K190848

Device Name
JUSHA-M550G/JUSHA-M550/M550G/M550 LCD Monitor

Indications for Use *(Describe)*
JUSHA-M550G/JUSHA-M550/M550G/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 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K190848

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

Date:	February 26, 2019
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-M550G/JUSHA-M550/M550G/M550 LCD Monitor
Common/Usual Name:	5MP Color LCD Monitor
Classification Name: Product Code:	System, image processing, Radiological 21CFR 892.2050 PGY
Predicate Device(s):	BARCO MDMG-5221; K161229
Device Description:	JUSHA-M550G/JUSHA-M550/M550G/M550 LCD Monitor is the display system with the high resolution (2560*2048), high luminance (1000 cd/m2), and 16-bit grayscale (65536 level), built-in DICOM standard LUT. In particular, JUSHA-M550G has ambient brightness adapt inside. In particular, JUSHA-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 - DMX0704AR0/main board/REV1.1 - JUSHA-M550G 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-M550G/JUSHA-M550/M550G/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.
Technology:	JUSHA-M550G/JUSHA-M550/M550G/M550 LCD Monitor is the display system with the high resolution (2560*2048), high luminance (1000 cd/m2), and 16-bit grayscale (65536 level), built-in DICOM standard LUT. In particular, JUSHA-M550G has ambient brightness adapt inside. In particular, JUSHA-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
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-M550G is substantially equivalent to BARCO MDMG-5221. JUSHA-M550G employs the maximum resolution values same as that of BARCO MDMG-5221. 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-M550G 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-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	JUSHA-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
Viewing angle （H，V）	Horizontal 176°,Vertical 176°	Horizontal 170°,Vertical 170°	-
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	1700:1	-
DICOM calibrated luminance	1000cd/m2	1000cd/m2	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	JUSHA-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	AC 100~240V 50~60Hz	Same
Power Consumption/Save Mode	57W/less than 0.7W	55W/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	JUSHA-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: 363mm x475mm x66mm With stand: 363mm x635mm 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.	JUSHA-M550G/JUSHA-M550/M550G/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.	Same

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	BARCO MDMG-5221	JUSHA-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

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-M550G 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-M550G 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-M550G, does not require animal or clinical studies to support substantial equivalence.

CONCLUSIONS

JUSHA-M550G 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-M550G Medical Display does not raise any new issues of safety or effectiveness.