DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Nanjing Jusha Display Technology Co., Ltd.
% Mr. Ma Jing
Certifical Engineer
301 Hanzhongmen Street, 8F Block A, No. 1
Nanjing International Service Outsourcing
Mansion, Nanjing, 210036
CHINA

June 12, 2015

Re: K151238
Trade/Device Name: JUSHA-M23C LCD Monitor
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: March 16, 2015
Received: May 11, 2015

Dear Ma Jing:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151238

Device Name
JUSHA-M23C LCD monitor

Indications for Use *(Describe)*
JUSHA-M23C LCD Monitor is intended to be used in displaying and viewing digital images by trained medical practitioners. JUSHA-M23C LCD Monitor does not support the display of mammography images for diagnosis.

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.

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"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

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

Date:	May 6, 2015
Submitter:	Nanjing Jusha Display Technology Co., Ltd Add: 8A, Block 1. Nanjing International Service Outsourcing Mansion, No. 301, Hanzhongmen street, Nanjing, China.
Contact Person:	Ma Jing Certification Engineer Nanjing Jusha Display Technology Co., Ltd Tel: +86-25- 83305050 Fax: +86-25- 58783271
Device Trade Name:	JUSHA-M23C LCD Monitor
Common/Usual Name:	2MP Monochrome LCD Monitor
Classification Name: Product Code:	System, image processing 21CFR 892.2050 PGY
Predicate Device(s):	RADIFORCE GX240; K120407
Device Description:	JUSHA-M23C LCD Monitor is the display system with the high resolution (1600*1200), high luminance (1000cd/m^2), and 1024 simultaneous shades of gray out of a palette of 4096, 10 DICOM look up table and 3 GAMMA look up table inside. JUSHA-M23C has ambient brightness adapting 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: - 21.3inches, Mono-TFT LCD Panel - JUSHA- SMS_19inch motherboard/FR-4/REV:0.1 - JUSHA-M23C 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 60601-1Medical 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.
Intended Use:	JUSHA-M23C LCD Monitor is intended to be used in displaying and viewing digital images by trained medical practitioners. JUSHA-M23C LCD Monitor does not support the display of mammography images for diagnosis.
Technology:	JUSHA-M23C LCD Monitor is the display system with the high resolution monitor (2 megapixels) with electronic capabilities for evaluation of high resolution medical images, high luminance (1000 cd/m^2) and 1024 simultaneous shades of gray out of a palette of 4096, 10 DICOM look up table and 3 GAMMA look up table inside. JUSHA-M23C has ambient brightness adapting 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 60601-1Medical 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. JUSHA-M23C is substantially equivalent to RADIFORCE GX240. JUSHA-M23C employs the maximum resolution values same as that of RADIFORCE GX240. 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-M23C LCD Monitor to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

This comparison identifies the similarities and differences of the proposed JUSHA-M23C LCD Monitor device to the legally marketed predicate EIZO RADIFORCE GX240 LCD Monitor device to which substantial equivalency is claimed.

Attributes	Predicate Device	Proposed Device
Product	RADIFORCE GX240	JUSHA-M23C LCD Monitor
510(k) Number	K120407	/
Display Performance/Specifications		
Screen technology	21.3" Monochrome TFT LCD Panel	21.3" Monochrome TFT LCD Panel
Viewing angle （H，V）	Horizontal 176 °,Vertical 176 °	Horizontal 176 °,Vertical 176 °
Resolution	1600 x 1200/1200 x 1600	1600 x 1200/1200 x 1600
Display area	432.0 (H) x 324.0(V) mm	432.0 (H) x 324.0(V) mm
Contrast Ratio	1400:1	1400:1
Scanning frequency (H; V)	31~100 kHz;59~61Hz	52~76 kHz;59~61Hz
Recommended Luminance	500cd/m^2	500cd/m^2
Pixel Pitch	0.27x0.27 mm	0.27x0.27 mm
Backlight	LED	LED
DICOM LUT	10-bit (Display Port) : 1024 8-bit: 256	12-bit:4096
Luminance calibration	Built in calibration sensor provided	Built in calibration sensor provided
Input signals	DVI standard 1.0, DisplayPort 1.1a	DVI standard 1.0, DisplayPort 1.1a
Input terminational	DVI-D (dual link) x 1, DisplayPort x 1	DVI-D (dual link) x 1, DisplayPort x 1
Display controller	Off the shelf	Off the shelf
Power Requirement	AC 100~240V 50~60Hz	AC 100~240V 50~60Hz

Attributes	Predicate Device	Proposed Device
Product	RADIFORCE GX240	JUSHA-M23C LCD Monitor
510(k) Number	K120407	/
Power Consumption/Save Mode	36W/less than1.6W	45W/less than 3W
Power Management	DVI DMPM DisplayPort 1.1a	DVI DMPM DisplayPort 1.1a
USB Ports/standard	1 upstream (endpoint), 2 downstream/ Rev. 2.0	1 upstream (endpoint), 2 downstream/ Rev. 2.0
Dimensions w/o stand (W x H x D)	Without stand: 376mmx505mmx98mm With stand: 376mmx599mmx245.5 mm	Without stand: 382mm x490mm x75mm With stand: 382mm x533mm x238mm
Indication for use	RADIFORCE GX240 is intended to be used in displaying and viewing digital images by trained medical practitioners. RADIFORCE GX240 Monitor does not support the display of mammography images for diagnosis.	JUSHA-M23C LCD Monitor is intended to be used in displaying and viewing digital images by trained medical practitioners. JUSHA-M23C LCD Monitor does not support the display of mammography images for diagnosis.

Attributes	Predicate Device	Proposed Device
Product	RADIFORCE GX240	JUSHA-M23C LCD Monitor
510(k) Number	K120407	/
Applicable standard	1 IEC 60601-1Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance 2005+CORR.1(2006)+COR R.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 60601-1Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance 2005+CORR.1(2006)+COR R.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.

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-M23C 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-M23C. 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-M23C, does not require animal or clinical studies to support substantial equivalence.

CONCLUSIONS

JUSHA-M23C 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-M23C Medical Display does not raise any new issues of safety or effectiveness.