DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Nanjing Jusha Display Technology Co., Ltd.
% Ma Jing
Certification Engineer
301 Hnazhongmen Street, 8F Block A, No. 1
Nanjing International Service Outsourcing
Mansion, Nanjing Jiangsu 210036
CHINA

September 10, 2015

Re: K151972
Trade/Device Name: JUSHA-C43 LCD Monitor
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: June 16, 2015
Received: July 16, 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 Ochs, Ph.D.
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)*
K151972

Device Name
JUSHA-C43 LCD Monitor

Indications for Use *(Describe)*
JUSHA-C43 LCD Monitor is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. It 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.

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510(k) Summary

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

Date:	Jun,15,2015
Submitter:	Nanjing Jusha Display Technology Co., Ltd Add: 301, Hanzhongmen Street, 8F Block A, No.1, Nanjing International Service Outsourcing Mansion, Nanjing, 210036 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-C43 LCD Monitor
Common/Usual Name:	4MP Color LCD Monitor
Classification Name: Product Code:	System, image processing ,Radiology PGY
Predicate Device(s):	RADIFORCE RX440;K130070
Device Description:	JUSHA-C43 LCD Monitoris the display system with the high resolution(2560 x 1600), high luminance(350cd/m^2) and 1024 simultaneous shades of gray out of a palette of 4096, 4 DICOM look up table inside, the product is consisted of the following components: - 30inch, Color Active Matrix Liquid Crystal Display - FR4-v0.4

	- JUSHA-C43 LCD Monitor software - Power Adapter - Data Cable. The LCD Monitoris 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-C43 LCD Monitoris intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. It does not support the display of mammography images for diagnosis.
Technology:	JUSHA-C43 LCD Monitor is the display system with the high resolution monitor (4 megapixels) with electronic capabilities for evaluation of high resolution medical images, high luminance(350cd/m^2) and 1024 simultaneous shades of gray out of a palette of 4096, 4 DICOM look up table inside
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-C43 is substantially equivalent to EZIO RADIFORCE RX440. JUSHA-C43 employs the maximum resolution values same as that of EZIO RADIFORCE RX440. Comparison table of the principal characteristics of two 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-C43 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-C43 LCD Monitor device to the legally marketed predicate EIZO RADIFORCE RX440 LCD Monitor device to which substantial equivalency is claimed.

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	RADIFORCE RX440	JUSHA-C43 LCD Monitor	
510(k) Number	K130070	/	
Display Performance/Specifications			
Screen technology	29.8” Color TFT LCD Panel	30”, Color Active Matrix TFT LCD Panel	The panel of JUSHA-C43 is larger than the predicate device, it can display more information
Viewing angle （H，V）	Horizontal 176°,Vertical 176°	Horizontal 178°,Vertical 178°(CR > 10)	The viewing angle of JUSHA-C43 is wider than the predicate device, it can get greater field of view
Resolution	2560 x1600/1280 x1600 x2	2560 x 1600/1280 x 1600 x2	Same
Display area	641.2(H) x 400.8 (V) mm	641.28 (H) x 400.8 (V) mm	Same
Recommended Luminance	300cd/m^2	300cd/m^2	Same

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	RADIFORCE RX440	JUSHA-C43 LCD Monitor	
510(k) Number	K130070	/	
Contrast Ratio	1100:1	1200:1	The contrast ratio of JUSHA-C43 is higher than the predicate device, it can display image more clarity
Scanning frequency (H; V)	31 - 159 kHz / 29 - 61 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 59 - 61 Hz, 29.5 - 30.5 Hz	103.8kHz;50Hz	The two differences between the two device is caused by the different no display area defined by different manufacturers, but the display area is same(2048*2560),so the same picture displayed on the two devices has the same effect
Dot clock	152MHz	148MHz	
Pixel Pitch	0.2505 x 0.2505 mm	0.2505 x 0.2505 mm	Same
Backlighting	LED	LED	Same

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	RADIFORCE RX440	JUSHA-C43 LCD Monitor	
510(k) Number	K130070	/	
Display Colors	10-bit，1.07 billion colors	12-bit ， 68.7billion colors	The JUSHA-C43 LCD Monitor uses a color extension technology to improve image display quality
Luminance calibration	Built in calibration sensor provided	Built in calibration sensor provided	Same
Video Signal Input			
Input signals	DVI standard 1.0	DVI standard 1.0	Same
Input terminational	DVI-D (dual link) x 1, DVI-D (single link) x 1, DisplayPort x 1	DVI-D (dual link) x 1, DVI-D (single link) x 1, DisplayPort x 1	Same
Display controller	Off the shelf	Off the shelf	Same
Power Related Specification			
Power Requirement	AC 100 - 120 V, 200 - 240 V: 50 / 60 Hz	AC 100~240V 50~60Hz	same

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	RADIFORCE RX440	JUSHA-C43 LCD Monitor	
510(k) Number	K130070	/	
Power Consumptions/Save Mode	84W/less than 0.7W	82W/less than1.5W	The differences caused by different adapter and components used in the LCD Monitor, the JUSHA-C43 has fewer power consumptions, this only shows the power consumption is different, nothing to do with the display function
Power Management	DVI DMPM, DisplayPort 1.1a	DVI DMPM, DisplayPort 1.1a	Same
Miscellaneous Features/Specifications			
USB Ports/standard	1 upstream , 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: 702x108x473 mm	With stand: 692x252x523mm Without stand: 692x87x453mm	Different housing design due to the different panel size.

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	RADIFORCE RX440	JUSHA-C43 LCD Monitor	
510(k) Number	K130070	/	
Indication for use	RADIFORCE RX440 is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. It does not support the display of mammography images for diagnosis.	JUSHA-C43 LCD Monitor is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. It does not support the display of mammography images for diagnosis.	Same

Attributes	Predicate Device	Proposed Device	Discussion of Differences
Product	RADIFORCE RX440	JUSHA-C43 LCD Monitor	
510(k) Number	K130070	/	
Applicable standard	1 IEC 60601-1Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance 1988+A1 : 1991 + A2:1995 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 IEC 60601-1:2005 + 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.	The JUSHA-C43 safety standard is edition 3.0, RADIFORCE RX440 safety standard is edition 2.0. nothing to do with the display function

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-C43 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-C43. 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-C43, does not require animal or clinical studies to support substantial equivalence.

CONCLUSIONS

JUSHA-C43 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-C43 Medical Display does not raise any new issues of safety or effectiveness.