



Food and Drug Administration
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Nanjing Jusha Display Technology Co., Ltd.
% Mr. Mike Gu
Regulatory Affairs Manager
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No. 982 Congyun Road, Baiyun District
Guangzhou, Guangdong 510420
CHINA

April 28, 2015

Re: K150842
Trade/Device Name: JUSHA-M53 Medical Display
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: March 27, 2015
Received: March 30, 2015

Dear Mr. Gu:

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,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. Behind the signature, there is a faint, large watermark of the letters "FDA" in a light blue color.

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

Indications for Use

510(k) Number (if known)

K150842

Device Name

JUSHA-M53 Medical Display

Indications for Use (Describe)

JUSHA-M53 Medical Display is intended to be used in displaying and viewing digital images including those of digital mammography for review and analysis by trained medical practitioners.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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:

I. SUBMITTER

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Certification Engineer

Nanjing Jusha Display Technology Co., Ltd

Date Prepared: March 23, 2015

II. DEVICE

Name of Device: JUSHA-M53 Medical Display

Common/Usual Name: Display, 5M Grayscale Flat panel Display

Classification Names: System, image processing (21 CFR 892.2050)

Regulation Class: II

Product Code: LLZ

III. PREDICATE DEVICE

Eizo Nanao Corporation's RadiForce GX540, K130336

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

JUSHA-M53 Medical Display is a display system with the high resolution (2560 x 2048), high luminance (1000 cd/m²), and 1024 simultaneous shades of gray out of a palette of 4096, 8 DICOM look up table with 12 bit inside. It is compliant with DICOM Part 14, and it has front sensor, presents induction system and ambient brightness adapting function. JUSHA-M53 employs energy efficient LED as backlight, it can achieve a high brightness and low power consumption at the same time. LED backlights deteriorate more slowly and thus the monitor offers a long service time. JUSHA-M53 with 10 bit (1024 tones) simultaneous grayscale display extends grayscale fidelity to the boundaries of human visual perception abilities and helps radiologists discern the finest nuances within an image.

The product is consisted of the following components:

- 21.3 inch, mono-TFT Liquid Crystal Display
- JUSHA-45T Motherboard/FR-4/REV1.0
- JUSHA-M53 Medical Display software
- Power Adapter
- Data Cable.

V. INDICATIONS FOR USE

JUSHA-M53 Medical Display is intended to be used in displaying and viewing digital images including those of digital mammography for review and analysis by trained medical practitioners.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

JUSHA-M53 Medical Display is the display system with the high resolution (2560 x 2048) monitor (5 megapixels) with electronic capabilities for evaluation of high resolution medical images. It uses a monochrome LCD panel with IPS (in-plane switching) technology, so that it can

Traditional 510(k) Submission_ JUSHA-M53 Medical Display

achieve wide viewing angles. JUSHA-M53 has a backlight sensor inside to stabilize the set luminance level automatically. JUSHA-M53 also has an integrated front sensor used for independent grayscale. With high luminance (1000 cd/m²) and 1024 simultaneous shades of gray out of a palette of 4096, 8 DICOM look up table with 12 bit, DSA, DSI and CT/MRI-JS curve which are calibrated in our factory are stored -inside the display.JUSHA-M53 has a ambient brightness sensor used to adjust the luminance and DICOM LUT along with the ambient brightness changing when the ambient function is enable. It has a brightening quickly button which can adjust the luminance and curve when press the button, this can be used to switch the using mode between high luminance and low luminance level, the is luminance used for diagnosis, the low luminance level is used for normal reading.JUSHA-M53 has an infrared sensor to detect whether there is a person in front of the display, it is working when there is a person, and it will be in power saving mode if there is no person in front of it. The JUSHA-M53 employs the same technology as its predicate devices K130336.

Items	Predicate Device	Proposed Device
Product	RADIFORCE GX540	JUSHA-M53 Medical Display
510(k) Number	K130336	/
Display Performance/Specifications		
Screen technology	21.3”TFT Monochrome LCD Panel	21.3”TFT Monochrome LCD Panel
Viewing angle (H,V)	Horizontal 176°,Vertical 176°	Horizontal 176°,Vertical 176°
Resolution	2048×2560	2048×2560
Display area	337.9× 422.4 mm	337.9 × 422.4mm
Aspect ratio	4:5	4:5
Contrast Ratio(typ)	1200:1	1200:1
Recommended brightness	500cd/m ²	500cd/m ²
Pixel Pitch	0.165×0.165 mm	0.165×0.165 mm
Backlighting	LED backlight	LED backlight
grayscale	1024	1024
Response time	25ms	25ms

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Sensor	Backlight sensor, Integrated front sensor, Presence sensor, Ambient light sensor	Backlight sensor, Integrated front sensor, Presence sensor, Ambient light sensor
Video Signal Input		
Input signals	DVI standard 1.0	DVI standard 1.0
Input terminational	1 DVI-D Dual Link 1 Display Port	1 DVI-D Dual Link 1 Display port
Display controller	Off the shelf	Off the shelf
Scanning Frequency (H,V)	31 - 135 kHz /24 -61 Hz Frame synchronous mode: 24.5 - 25.5 Hz, 49 -51 Hz	123KHz/60Hz
Power Related Specification		
Power Requirement	100 - 120 Vac \pm 10%, 50/60 Hz 1.1 - 0.9A 200 - 240 Vac \pm 10%, 50/60 Hz 0.6 - 0.5A	100 - 120 Vac \pm 10%, 50/60 Hz 1.1 - 0.9A 200 - 240 Vac \pm 10%, 50/60 Hz 0.6 - 0.5A
Power Consumptions/Save Mode	108W/less than 0.7W	48.9W/less than 1.5W
Power Management	DVI DMPM	DVI DMPM
Miscellaneous Features/Specifications		
USB Ports/standard	1 upstream (endpoint), 2 downstream	1 upstream (endpoint), 2 downstream

Traditional 510(k) Submission_ JUSHA-M53 Medical Display

<p>Dimensions w/o stand (W x H x D)</p>	<p>With stand: 338×512-595×245.5 Without stand: 688.5×496×99 mm</p>	<p>With stand: 395×238×530 Without stand: 395×74×491</p>
<p>Indication for use</p>	<p>RadiForce GX540 is intended to be used in displaying and viewing digital images, including those of digital mammography, for review and analysis by trained medical practitioners.</p>	<p>JUSHA-M53 Medical Display is intended to be used in displaying and viewing digital images, including those of digital mammography, for review and analysis by trained medical practitioners.</p>
<p>Applicable standard</p>	<p>1 IEC 60601-1 Medical 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.</p>	<p>1 IEC 60601-1 Medical 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.</p>

VII. 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-M53 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-M53. 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-M53, does not require animal or clinical studies to support substantial equivalence.

VIII. CONCLUSIONS

JUSHA-M53 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-M53 Medical Display does not raise any new issues of safety or effectiveness.