



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Nanjing Jusha Display Technology Co., LTD  
% Mr. Ma Jing  
Certification Engineer  
301 Hanzhongmen Street, 8F Block A, No.1  
Nanjing International Service Outsourcing  
MANSION, NANJING 210036  
CHINA

April 14, 2015

Re: K150746  
Trade/Device Name: JUSHA-M52C Medical Display  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: PGY  
Dated: March 16, 2015  
Received: March 23, 2015

Dear Mr. 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,

A handwritten signature in cursive script that reads "Robert A. Ochs". The signature is written in black ink and is positioned above a large, faint, light-colored watermark of the letters "FDA".

Robert Ochs, PhD.  
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)

K150746

Device Name

JUSHA-M52C Medical Display

Indications for Use (Describe)

JUSHA-M52C Medical Display is intended to be used for review and analysis by trained medical practitioners in displaying and viewing various kinds of medical images including digital mammography system.

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:                                 | July 21,2013   |
| Submitter:                            | Nanjing Jusha Display Technology Co., Ltd<br>Add: 301, Hanzhongmen Street, 8F Block A, No.1, Nanjing International Service Outsourcing Mansion, Nanjing, 210036 China  |
| Contact Person:                       | Ma Jing<br>Certification engineer<br>301, Hanzhongmen Street, 8F Block A, No.1, Nanjing International Service Outsourcing Mansion, Nanjing, 210036 China<br>Tel: +86-25-83305050,<br>fax +86-25-58783271   |
| Device Trade Name:                    | JUSHA-M52C Medical Display   |
| Common/Usual Name:                    | Image display system, medical image workstation, image monitor/display, and others   |
| Classification Name:<br>Product Code: | System, image processing 21CFR 892.2050<br>90LLZ   |
| Predicate Device(s):                  | JUSHA-M52C;K131390   |
| Device Description:                   | <p>JUSHA-M52C Medical Display is the display system with the high resolution(2048 x 2560), high luminance(700 cd/m<sup>2</sup> ), and 256 simultaneous shades of gray out of a palette of 4096, 8 DICOM look up table inside, the product is consisted of the following components:</p> <ul style="list-style-type: none"> <li>- 21.3 inch, mono-TFT Liquid Crystal Display</li> <li>- Motherboard HDVI-3M V1.0</li> <li>- JUSHA-M52C Medical Display software</li> <li>- Power Adapter</li> <li>- Data Cable.</li> </ul> <p>The Medical Display is designed, tested, and will be manufactured in accordance with both mandatory and voluntary standards:</p> <ol style="list-style-type: none"> <li>1. IEC 60601-1Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance</li> </ol> <p style="text-align: center;">IEC 60601-1:2005 + CORR. 1 (2006) +CORR. 2 (2007)/</p> |

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|---|---|
|   | <p>EN 60601-1: 2006/AC: 2010</p> <p>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>  |
| Intended Use:                             | JUSHA-M52C Medical Display is intended to be used for review and analysis by trained medical practitioners in displaying and viewing various kinds of medical images including digital mammography system.  |
| Technology:                               | JUSHA-M52C Medical Display is the display system with the high resolution monitor (5 megapixels) with electronic capabilities for evaluation of high resolution medical images, high luminance (700 cd/m <sup>2</sup> ) and 256 simultaneous shades of gray out of a palette of 4096, 8 DICOM look up table inside  |
| Determination of Substantial Equivalence: | <p><u>Summary of Non-Clinical Tests:</u></p> <p>The Medical Display complies with voluntary standards as following:</p> <p>1 IEC 60601-1 Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance</p> <p>IEC 60601-1:2005 + CORR. 1 (2006) +CORR. 2 (2007)/</p> <p>EN 60601-1: 2006/AC: 2010</p> <p>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>JUSHA-M52C is substantially equivalent to RadiForce G51. G51. M52C employs the maximum resolution values same as that of RadiForce G51. Comparison table of the principal Characteristics of 2 devices is shown in the Attachment 1 .</p> <p>Attachment 1</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> </ul> |

|                    |   |
|--------------------|---|
|                    | <ul style="list-style-type: none"> <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, Medical Display, did not require clinical studies to support substantial equivalence.</p> <p>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.</p> |
| <p>Conclusion:</p> | <p>Nanjing Jusha Display Technology Co., Ltd Considers the JUSHA-M52C Medical Display to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).</p>  |