SEP 0 6 2013

K131389
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510(k) Summary

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

Date:	April 21,2013
Submitter:	Nanjing Jusha Display Technology Co., Ltd Add: 301, Hanzhongmen Street, 8F Block A, No.1, Nanjing International Service Outsourcing Mansion, Nanjing, 210036 China
Primary Contact Person:	Mike Gu Regulatory Manager Guangzhou Osmunda Medical Device Consulting Co., Ltd Tel: +86-20-62321333 Fax: +86-20-86330253
Secondary Contact Person:	Zhu chengshun Quality Manager Nanjing Jusha Display Technology Co., Ltd Tel: +86-25- 83305050 Fax: +86-25- 58783271
Device Trade Name:	JUSHA-C31 Medical Display
Common/Usual Name:	Image display system, medical image workstation, image monitor/display, and others
Classification Name: Product Code:	System, image processing 90LLZ
Predicate Device(s):	RADIFORCE R31;K052344
Device Description:	JUSHA-C31 Medical Display is 53cm(20.8") color medical display with the high resolution(2048 x 1536), the product is consisted of the following components: - 20.8 inch, Color Active Matrix TFT Liquid Crystal Display - Motherboard HDVI-3M V1.0 - JUSHA-C31 Medical Display software - Power Adapter - Data Cable. The Medical Display 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 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.
Intended Use:	JUSHA-C31 Medical Display is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The device is not specified for digital mammography system.
Technology:	JUSHA-C31 Medical Display is the display system with the high resolution monitor (3 megapixels) with electronic capabilities for evaluation of high resolution medical images, high luminance (450 cd/m^2 max) and 16.7M(8-bits data per R,G,B each)display color, 3 DICOM look up table inside
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The Medical Display complies with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. 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) Summary of Clinical Tests: The subject of this premarket submission, Medical Display, 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-C31 Medical Display to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

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

September 6, 2013

Nanjing Jusha Display Technology Co., Ltd.
% Mr. Mike Gu
Regulatory Manager
Guangzhou Osmunda Medical Device Consulting Co., Ltd.
7th Floor, 982 Congyun Road, Baiyun District
Guangzhou, Guangdong 510420
CHINA

Re: K131389
Trade/Device Name: Jusha-C31 Medical Display
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 23, 2013
Received: August 27, 2013

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for

Janine M. Morris
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): K131389

Device Name: JUSHA-C31 Medical Display

Indications for Use:

JUSHA-C31 Medical Display is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The device must not be used for digital mammography system.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) ___K131389___