Nanjing Jusha Display Technology Co., Ltd.
℅ Donny Lee
Certification Engineer
8A, Block 1. No. 301, Hanzhongmen Street
Nanjing, Jiangsu 210036
CHINA

March 25, 2022

Re: K212231
Trade/Device Name: C1210G LCD Monitor, JUSHA-C1210G LCD Monitor, C1210 LCD Monitor, JUSHA-C1210 LCD Monitor
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: PGY
Dated: January 24, 2022
Received: January 24, 2022

Dear Donny Lee:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb, Ph.D.
Assistant Director
Mammography Ultrasound and Imaging
Software Branch
Division of Radiological Health
OHT7: Office of in vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K212231

Device Name
C1210G/JUSHA-C1210G/C1210/JUSHA-C1210 LCD Monitor

Indications for Use *(Describe)*
JUSHA-C1210G/JUSHA-C1210/C1210G/C1210 LCD Monitor is intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis, and diagnosis by trained medical practitioners. It is specially designed for displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis, and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications.

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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*"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."*

K212231

# 510(k) Summary

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

| | |
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| Date: | May 26, 2021 |
| Submitter: | Nanjing Jusha Display Technology Co., Ltd<br><br>Add: 301, 8F Block A, No.1, Nanjing International Service Outsourcing Mansion, Hanzhongmen Street,Nanjing, 210036 China |
| Contact Person: | Dongdong Li<br><br>Certification Manager<br><br>Nanjing Jusha Display Technology Co., Ltd<br><br>Tel: +86-25- 83305050<br><br>Fax: +86-25- 58783273 |
| Device Trade Name: | JUSHA-C1210G LCD Monitor, JUSHA-C1210 LCD Monitor,<br><br>C1210G LCD Monitor, C1210 LCD Monitor |
| Common/Usual Name: | 12MP Color LCD Monitor |
| Classification Name:<br><br>Product Code: | System, image processing, Radiological 21CFR 892.2050<br>PGY |
| Predicate Device(s): | JUSHA JUSHA-M550G; K190848 |
| Device Description: | JUSHA-C1210G/JUSHA-C1210/C1210G/C1210 LCD Monitor is the display system with the high resolution (4200×2800), high luminance (800 cd/m$^2$), and 16-bit grayscale (65536 level), built-in DICOM standard LUT. In particular, JUSHA- C1210G has ambient brightness adapt inside. In particular, JUSHA- C1210G has ambient brightness adapting, real-time DICOM automatic calibration, full-screen brightness equalization and presence induction system, with these this display can automatic adjustment according to different requirements in order to achieve the best results.<br><br>The product is consisted of the following components:<br><br>- 31" Color-TFT LCD Panel<br><br>- DMF2604AR0/main board/REV1.0<br><br>- JUSHA-C1210G LCD Monitor software<br><br>- Power Adapter |

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| | - Data Cable.<br><br>The LCD Monitor is designed, tested, and will be manufactured in accordance with both mandatory and voluntary standards:<br><br>1. IEC 60601-1:2012, EN 60601-1:2013, ANSI/AAMI ES60601-1:2005+A1:2012+C1:2009+A2:2010, CAN/CSA C22.2 NO.60601-1:14, Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance.<br>2. IEC 60601-1-2 Edition 4:2014, EN 60601-1-2:2015, CFR 47 FCC Part15 subpart B: 2017, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests. |
| Intended Use: | JUSHA-C1210G/JUSHA-C1210/C1210G/C1210 LCD Monitor is intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis, and diagnosis by trained medical practitioners. It is specially designed for displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis, and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications. |
| Technology: | JUSHA-C1210G/JUSHA-C1210/C1210G/C1210 LCD Monitor is the display system with the high resolution (4200×2800), high luminance (800 cd/$m^2$), and 16-bit grayscale (65536 level), built-in DICOM standard LUT. In particular, JUSHA- C1210G has ambient brightness adapt inside. In particular, JUSHA- C1210G has ambient brightness adapting, real-time DICOM automatic calibration, full-screen brightness equalization 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><br><br>The LCD Monitor complies with voluntary standards as following:<br><br>1 IEC 60601-1:2012, EN 60601-1:2013, ANSI/AAMI ES60601-1:2005+A1:2012+C1:2009+A2:2010, CAN/CSA C22.2 NO.60601-1:14, Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance. |

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|---|---|
| | 2 IEC 60601-1-2 Edition 4:2014, EN 60601-1-2:2015, CFR 47 FCC Part15 subpart B: 2017, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests<br><br>JUSHA-C1210G is substantially equivalent to JUSHA JUSHA-M550G. JUSHA-C1210G employs the maximum resolution values larger than that of JUSHA-M550G. Comparison table of the principal characteristics of 2 devices is shown in the Product Comparison.<br><br>The following quality assurance measures were applied to the development of the system:<br><br>• Risk Analysis<br>• Requirements Reviews<br>• Design Reviews<br>• Raw materials verification<br>• Testing on unit level (Module verification)<br>• Integration testing (System verification)<br>• Final acceptance testing (Validation)<br>• Performance testing (Verification)<br>• Safety testing (Verification)<br><br><u>Summary of Clinical Tests:</u><br><br>The subject of this premarket submission, LCD Monitor, did not require clinical studies to support substantial equivalence.<br><br>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-C1210G LCD Monitor to be as safe, as effective, and performance is substantially equivalent to the predicate device(s). |

12.1 Product Comparison

This comparison identifies the similarities and differences of the proposed JUSHA-C1210G LCD Monitor device to the legally marketed predicate JUSHA JUSHA-M550G LCD Monitor device to which substantial equivalency is claimed.

| Attributes | Predicate Device | Proposed Device | Discussion of Differences |
|---|---|---|---|
| Product | JUSHA JUSHA-M550G | JUSHA-C1210G LCD Monitor | |
| 510(k) Number | K190848 | / | |
| Display Performance/Specifications | | | |
| Screen technology | 21.3inches, Mono-TFT LCD Panel | 31inches, Color-TFT LCD Panel | C1210G is larger than M550G |
| Viewing angle （H，V） | Horizontal 170°,Vertical 170° | Horizontal 178°,Vertical 178° | C1210G is better than M550G |
| Resolution | 2560×2048/2048×2560 | 4200×2800 | C1210G is larger than M550G |
| Display area | 422.4(H)×377.92(V) mm | 676.9(H)×459.7(V) mm | C1210G is larger than M550G |
| Contrast Ratio | 1700:1 | 1500:1 | C1210G is smaller than M550G，but the difference does not make difference to the diagnosis. |
| Supplied CURVE | DICOM\CIE\GAMMA2.2\GAMMA2.4 | DICOM\CIE\GAMMA2.2\GAMMA2.4 | Same |
| DICOM calibrated luminance | 1000cd/$m^2$ | 800cd/$m^2$ | C1210G is smaller than M550G，and both of them meet the requirements of AAPM regarding breast diagnosis. |
| Pixel Pitch | 0.165×0.165 mm | 0.1554×0.1554mm | C1210G is better than M550G |
| Backlight | LED | LED | Same. |
| DICOM LUT | 16-bit:65536 | 16-bit:65536 | Same. |

| Attributes | Predicate Device | Proposed Device | Discussion of Differences |
|---|---|---|---|
| Product | JUSHA JUSHA-M550G | JUSHA-C1210G LCD Monitor | |
| 510(k) Number | K190848 | / | |
| Luminance calibration | Built in calibration sensor provided | Built in calibration sensor provided | Same |
| Video Signal Input | | | |
| Input signals | DVI standard 1.0,<br><br>DisplayPort 1.2a | DisplayPort 1.2a | The difference only shows that they have different input,has nothing to do with the display function. |
| Input terminational | DVI-D×1,<br><br>DisplayPort×1 | DisplayPort×2 | The difference only shows that they have different input,has nothing to do with the display function. |
| Output signals | DisplayPort 1.2a | HDMI 2.0 | The difference only shows that they have different output, has nothing to do with the display function. |
| Output<br><br>Terminational | DisplayPort×1 | HDMI×1 | The difference only shows that they have different output, has nothing to do with the display function. |
| Display controller | Off the shelf | Off the shelf | Same |
| Power Related Specification | | | |
| Power Requirement | AC 100~240V 50~60Hz | AC 100~240V 50~60Hz | Same |

| Attributes | Predicate Device | Proposed Device | Discussion of Differences |
|---|---|---|---|
| Product | JUSHA JUSHA-M550G | JUSHA-C1210G LCD Monitor | |
| 510(k) Number | K190848 | / | |
| Power Consumption/Save Mode | 55W/less than 0.5W | 150W/less than 0.5W | The differences caused by components used in the LCD Monitor. This only shows the power consumption is different, nothing to do with the display function |
| Power Management | DVI DMPM<br><br>DisplayPort 1.2a | DisplayPort 1.2a | The difference only shows that they have different power Management, has nothing to do with the display function. |
| Miscellaneous Features/Specifications | | | |
| USB Ports/standard | 1 upstream (endpoint),<br><br>2 downstream/ Rev. 2.0 | 1 upstream (endpoint),<br><br>2 downstream/ Rev. 3.0 | C1210G is better than M550G. |
| Dimensions w/o stand<br><br>(W×H×D) | Without stand:<br><br>363mm×475mm×66mm<br><br>With stand:<br><br>363mm×635mm×238mm | Without stand:<br>701.3 mm× 500 mm× 86.8mm<br><br>With stand:<br>701.3 mm× 589 mm× 245mm | Different housing design due to the different panel size. |

| Attributes | Predicate Device | Proposed Device | Discussion of Differences |
|---|---|---|---|
| Product | JUSHA JUSHA-M550G | JUSHA-C1210G LCD Monitor | |
| 510(k) Number | K190848 | / | |
| Indication for use | JUSHA-M550G/JUSHA-M550/M550G/M550 LCD Monitor is intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis, and diagnosis by trained medical practitioners. It is specially de displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis, and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications. | JUSHA-C1210G/JUSHA-C1210/ C1210G/ C1210 LCD Monitor is intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis, and diagnosis by trained medical practitioners. It is specially de displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis, and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications. | Same |

| Attributes | Predicate Device | Proposed Device | Discussion of Differences |
|---|---|---|---|
| Product | JUSHA JUSHA-M550G | JUSHA-C1210G LCD Monitor | |
| 510(k) Number | K190848 | / | |
| Applicable standard | 1 IEC 60601-1:2012, EN 60601-1:2013, ANSI/AAMI ES60601-1:2005+A1:2012+C1:2009+A2:2010, CAN/CSA C22.2 NO.60601-1:14, Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance.<br><br>2 IEC 60601-1-2 Edition 4:2014, EN 60601-1-2:2015, CFR 47 FCC Part15 subpart B: 2017, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests | 1 IEC 60601-1:2012, EN 60601-1:2013, ANSI/AAMI ES60601-1:2005+A1:2012+C1:2009+A2:2010, CAN/CSA C22.2 NO.60601-1:14, Medical equipment medical electrical equipment - Part 1: General requirements for basic safety and essential performance.<br><br>2 IEC 60601-1-2 Edition 4:2014, EN 60601-1-2:2015, CFR 47 FCC Part15 subpart B: 2017, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests | Same |

**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-C1210G 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 TG18 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-C1210G 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-C1210G, does not require animal or clinical studies to support substantial equivalence.

## CONCLUSIONS

JUSHA-C1210G 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-C1210G Medical Display does not raise any new issues of safety or effectiveness.