



Wide Corporation  
% Mr. Yeojin Yun  
RA Manager  
15F, The First Tower III, 602, Dongtangiheung-Ro  
Hwaseong-Si, Gyeonggi-Do 18469  
REPUBLIC OF KOREA

April 8, 2021

Re: K210491  
Trade/Device Name: CW120N  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: Class II  
Product Code: PGY  
Dated: January 27, 2021  
Received: February 19, 2021

Dear Mr. Yun:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



Michael D. O'Hara For

Thalia T. Mills, Ph.D.  
Director  
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

## Indications for Use

510(k) Number (if known)  
K210491

Device Name  
CW120N

### Indications for Use (Describe)

CW120N LCD Monitor System is intended to be used in displaying and viewing digital medical images for review and analysis by trained medical practitioners. It is specifically designed for digital mammography applications and digital 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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"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

K210491

[As required by 21 CFR 807.92]

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR 807.92

## 1. Date Prepared [21 CFR 807.92(a) (1)]

01/27/2021

## 2. Submitter's Information [21 CFR 807.92(a) (1)]

Name of Sponsor: WIDE Corporation.  
Address: 15F, The First Tower III, 602, Dongtangiheung-Ro,  
Hwaseong-Si, Gyeonggi-Do 18469, Republic of Korea  
Contact Name: YeoJin Yun  
Telephone #: +82-31-218-1675  
Fax #: +82-31-376-9600  
Email: yyjin@widecorp.com  
Registration Number: 3004082357  
Name of Manufacturer: Same as Sponsor

## 3. Trade Name, Common Name, Classification [21 CFR 807.92(a) (2)]

Model Name: CW120N  
Common Name: TFT LCD Medical Monitor System  
Classification Name: Picture archiving and communications system  
Regulation Number: 21 CFR 892.2050  
Product Code: PGY  
Device Class: 2  
Review Panel: Radiology

## 4. Identification of Predicate Device(s) [21 CFR 807.92(a) (3)]

510(k) Number: K200485  
Applicant: EIZO CORPORATION  
Model Name: RadiForce RX1270, RadiForce RX1270-AR  
Common Name: 78.4 cm (30.9 inch) class Color LCD Monitor  
Classification Name: Picture archiving and communications system  
Regulation Number: 21 CFR 892.2050  
Product Code: PGY  
Device Class: 2

**5. Description of the Device [21 CFR 807.92(a) (4)]**

CW120N LCD Monitor is intended to provide high resolution color and grayscale medical imaging for PACS and Radiology system. This Medical Monitor is intended to be used by trained medical practitioners for displaying, reviewing, and analysis of medical images.

EzCal ver.2 is a software solution which enables the user to modify display output to meet DICOM Part 14 GSDF and other key industry standards.

CW120N is being provided with the calibration software EzCal v.2 (developed by Qubyx Inc.) when requested by the customer.

**6. Intended Use [21 CFR 807.92(a) (5)]**

CW120N LCD Monitor System is intended to be used in displaying and viewing digital medical images for review and analysis by trained medical practitioners. It is specifically designed for digital mammography applications and digital breast tomosynthesis applications.

**7. Technological Characteristics [21 CFR 807.92(a) (6)]**

The table below presents comparisons between the subject device (CW120N) and the predicate device (K200485):

<b>Attributes</b>	<b>Predicate Device</b>	<b>Subject Device</b>	<b>Discussion of Differences</b>
Product	RadiForce RX1270, RadiForce RX1270-AR	CW120N	
Screen technology	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)	-
Screen size	78.4cm / 30.9"	78.4cm / 30.9"	-
Resolution	4200 x 2800 (3:2 aspect ratio)	4200 x 2800 (3:2 aspect ratio)	-
Pixel pitch	0.1554 mm x 0.1554 mm	0.1554 mm x 0.1554 mm	-
Backlight type	LED	LED	-
Maximum luminance	1,200 cd/m <sup>2</sup>	1,200 cd/m <sup>2</sup>	-
DICOM calibrated luminance	500 cd/m <sup>2</sup>	500 cd/m <sup>2</sup>	-
Contrast ratio(typical)	1500 : 1	1500 : 1	-
Response Time(typical)	12ms (black-white-black)	14ms (gray-to-gray)	Provided by the panel manufacturers.
Digital Scanning Frequency (H / V)	HDMI: 31 - 160 kHz / 59 - 61 Hz (VGA Text: 69 - 71 Hz) DisplayPort: 31 - 175 kHz / 29 - 61 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 29.5 - 30.5 Hz, 59 - 61 Hz	DisplayPort : 170.4KHz, 60Hz	Differences by manufacturers.

Analog Scanning Frequency (H / V)	HDMI: 31 - 160 kHz / 59 - 61 Hz (VGA Text: 69 - 71 Hz) DisplayPort: 31 - 175 kHz / 29 - 61 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 29.5 - 30.5 Hz, 59 - 61 Hz	-	Differences by manufacturers.
Input video signals	DisplayPort x 2, HDMI x 1	DisplayPort x 1	Differences by manufacturers.
Ambient Light Sensor	Yes	Yes	-
Luminance calibration tools	Integrated optical sensor External optical sensor Calibration software: RadiCS	IQ Sensor, Calibration software: EzCal	It is only a difference in terms of each manufacturer, but the functions are similar.
Quality-control procedures	RadiCS	EzCal	It is only a difference in terms of each manufacturer, but the functions are similar.

CW120N Device is substantially equivalent to the currently marketed and predicate devices in terms of design features, indications for use, and safety and effectiveness.

## 9. Summary of Non-Clinical Data

CW120N comply with the following international and FDA-recognized consensus standards:

- IEC 60601-1: Medical Electrical Equipment -- Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests

The bench tests below were performed on the CW120N following the instructions in 'Display Devices for Diagnostic Radiology – Guidance for Industry and Food and Drug Administration Staff, issued on October 2, 2017.

- Test Item

Pixel Defects, Artifacts, Luminance, Reflection, Luminance Uniformity, Resolution, Noise, Veiling Glare, Color Uniformity, Luminance Response, Luminance at 30° and 45° in diagonal, horizontal, and vertical directions, Temporal Performance Test, Color Tracking, Gray Tracking, MTF

## **10. Summary of Clinical Data**

No clinical studies were considered necessary and performed.

## **11. Conclusion [21 CFR 807.92(b) (3)]**

Subject Device is substantially equivalent to the currently marketed and predicate devices in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Additionally, the safety of the subject device was validated through tests including IEC60601-1 and IEC 60601-1-2. The effectiveness of the device was validated through bench tests.

The results of these tests demonstrate that CW120N meets the acceptance criteria and is adequate for this intended use. The comparison of technological characteristics, non-clinical performance data, safety testing demonstrates that the device is as safe and effective as the predicate device and performs as well as the predicate device.