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

April 14, 2021

Re: K210493
Trade/Device Name: CX30N (CX30PQX)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: PGY
Dated: January 11, 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

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)*
K210493

Device Name
CX30N(CX30PQX)

Indications for Use *(Describe)*

The CX30N(CX30PQX) LCD Monitor System is intended to be used in displaying and viewing digital medical images for review and analysis by trained medical practitioners. The display is not intended for mammography.

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

K210493

[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)]

03/16/2021

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:	CX30N(CX30PQX)
Common Name:	TFT LCD Medical Monitor System
Classification Name:	Display, Diagnostic Radiology
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:	K153354
Applicant:	EIZO CORPORATION
Model Name:	3MP Color LCD Monitor, RadiForce RX350
Common Name:	TFT LCD Medical Monitor System
Classification Name:	Display, Diagnostic Radiology
Regulation Number:	21 CFR 892.2050
Product Code:	PGY
Device Class:	2

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

CX30N(CX30PQX) 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.
CX30N(CX30PQX) is being provided with the calibration software EzCal v.2 (developed by Qubyx Inc.) when requested by the customer.
CX30N is basic model and CX30PQX is identical to CX30N, except model name.

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

CX30N(CX30PQX) is intended to be used to display and view digital medical images for review and analysis by trained medical practitioners. The display is not intended for mammography.

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

The device is an image display system which consists of computer software and components. The device does not contact the patient, nor does it control any life sustaining devices. A physician or trained medical practitioner provides ample opportunity for competent human intervention to interpret images and information being displayed.

8. Substantial Equivalence [21 CFR 807.92(b) (1) and 807.92]

Attributes	Predicate Device	Subject Device	Discussion of Differences
Product	RadiForce RX340	CX30N(CX30PQX)	
Screen technology	IPS TFT Color LCD Panel	Dual domain IPS TFT Color LCD Panel	-
Viewing angle (H, V)	H: 170°, V: 170°	H: 178°, V: 178°	Provided by the panel manufacturers.
Active screen size	323.7 mm x 431.6 mm	324.86 mm x 433.15 mm	Provided by the panel manufacturers.
Resolution	3MP (1,536 x 2,048)	3MP (1,536 x 2,048)	-
Aspect ratio	3 : 4	3 : 4	-
Pixel pitch	0.21075 mm x 0.21075 mm	0.2115 mm x 0.2115 mm	Provided by the panel manufacturers.
Maximum luminance	1,000 cd/m^2	1,000 cd/m^2	-
DICOM calibrated luminance	400 cd/m^2	450 cd/m^2	Differences by manufacturers.
Contrast ratio	1400 : 1	1500 : 1	Provided by the panel manufacturers.
Backlighting	LED	LED	-
Display Colors	From a palette of 68 billion colors: - 10-bit input (DisplayPort): 1.07	From a palette of 68 billion colors: - 10-bit input (DisplayPort): 1.07	-

	billion colors (maximum) - 8-bit input: 16.77 million colors	billion colors (maximum) - 8-bit input: 16.77 million colors	
Luminance non-uniformity compensation	Digital Uniformity Equalizer	Luminance Uniformity Control	It is only a difference in terms of each manufacturer, but the functions are similar.
Input video signals	DVI-D (dual link) x 1, DisplayPort x 1	DVI-D (dual link) x 1, DisplayPort x 1	-
Scanning Frequency (H, V)	31 - 127 kHz, 29 - 61 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 29.5 - 30.5 Hz, 59 - 61 Hz	96KHz, 60Hz	Differences by manufacturers.
Power Requirements	AC 100 - 120 V, 200 - 240 V: 50 / 60 Hz	AC 100~240 V: 50 / 60 Hz DC +24V, 2.4A	Differences by manufacturers.
Power Consumption / Save Mode	125 W / Less than 3 W	75 W / Less than 2 W	Differences by manufacturers.
Power Management	DVI DMPM, DisplayPort 1.1a	DVI DMPM, DisplayPort 1.1a	-
QC software	RadiCS	EzCal	It is only a difference in terms of each manufacturer, but the functions are similar.
Sensors	Backlight Sensor, Presence Sensor, Integrated Front Sensor, Ambient Light Sensor	Backlight Sensor, IQ Sensor, Ambient Light Sensor	It is only a difference in terms of each manufacturer, but the functions are similar. but Integrated Front Sensor is not used.
USB Ports / Standard	1 upstream, 2 downstream / Rev. 2.0	1 upstream, 3 downstream / Rev. 3.0	Differences by manufacturers.
Dimensions w/o stand (W x H x D)	376 x 505 x 98 mm	366 x 476 x 65.5 mm	Different housing design due to the different panel size

CX30N(CX30PQX) 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

CX30N(CX30PQX) 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 CX30N(CX30PQX) 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

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, 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 CX30N(CX30PQX) 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.