WIDE Corporation
% Josh Baker
Consultant
OT Consulting Inc.
33781 Bayside Lane
DANA POINT CA 92629

Re: K222717 October 31, 2022
Trade/Device Name: CL24N
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: PGY
Dated: September 8, 2022
Received: September 8, 2022

Dear Josh Baker:

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
Imaging Software Team
DHT8B: Division of Imaging Devices
and Electronic Products
OHT8: Office of 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)*
K222717

Device Name
CL24N

Indications for Use *(Describe)*

The CL24N LCD Monitor System is intended to be used in displaying and viewing digital medical images for review by trained medical practitioners. It does not support the display of mammography images for diagnosis.

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.

510(k) Summary

[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)]

06/13/2022

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
510(k) Contact Person	Josh Baker – Consultant, OT Consulting Inc. 33781 Bayside Lane, Dana Point, California 92629 USA Tel: 714-788-8152 Email: josh@otconsulting.tech

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

Model Name:	CL24N
Common Name:	2.1MP Color LCD Monitor
Classification Name:	Medical Image management and Processing 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:	K143261
Applicant:	EIZO CORPORATION
Model Name:	RadiForce MX242W
Common Name:	2.3MP Color LCD Monitor
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)]

CL24N is intended to display 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 and reviewing of medical images.
EzCal is a software solution which enables the user to modify display output to meet DICOM Part 14 GSDF and other key industry standards.
EzCal is packed with the display.
While using the CL24N product, use the EzCal S/W provided as a bundle to periodically check whether the product meets the intended use.
If the product does not meet the intended use, the product must be returned to the manufacturer or an authorized service center to be calibrated to a product that can be used normally.

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

CL24N LCD Monitor is intended to be used to display and view digital medical images for review by trained medical practitioners. It does not support the display of mammography images for diagnosis.

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 MX242W	CL24N	
Screen technology	IPS TFT Color LCD Panel	AAS TFT Color LCD Panel	Provided by the panel manufacturers.
Viewing angle (H, V)	H: 178°, V: 178°	H: 178°, V: 178°	-
Active screen size	518.4 mm x 324.0 mm	527.04 mm x 296.48 mm	Provided by the panel manufacturers.
Resolution	2.3MP (1,920 x 1,200)	2.1MP (1920 x 1080)	Differences by manufacturers.
Aspect ratio	16 : 10	16 : 9	Provided by the panel manufacturers.
Pixel pitch	0.270 mm x 0.270 mm	0.2745 mm x 0.2745 mm	Provided by the panel manufacturers.
Maximum luminance	350 cd/m^2	400 cd/m^2	Provided by the panel manufacturers.

DICOM calibrated luminance	180 cd/m^2	150 cd/m^2	Differences by manufacturers.
Contrast ratio	1000 : 1	1000 : 1	-
Backlighting	LED	LED	-
Display Colors	From a palette of 68 billion colors: - 10-bit input (DisplayPort): 1.07 billion colors (maximum) - 8-bit input: 16.77 million colors	From a palette of 1.07 billion colors: - 8-bit input: 16.77 million colors	Tone between the predicate device and our subject devices are different. But It pass the exams in AAPM-TG18 4.3 " Luminance response". Therefore, they are equivalent to the predicate device.
Luminance non-uniformity compensation	Digital Uniformity Equalizer	-	Differences by manufacturers.
Input video signals	DVI-I x 1, DisplayPort x 1	Mini HDMI x 1, Mini DisplayPort x 1	It is only a difference connector types, but the functions are similar.
Scanning Frequency (H, V)	Digital: 31 - 76 kHz / 59 -61 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 59 - 61 Hz Analog: 26 - 76 kHz / 49 - 71 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 59 - 61 Hz	67.5KHz, 60Hz	Differences by manufacturers.
Power Requirements	AC 100 - 240 V, 50 / 60 Hz	AC 100~240 V: 50 / 60 Hz DC +12V, 3A	Differences by manufacturers.
Power Consumption / Save Mode	68 W / Less than 0.5 W	30 W / Less than 5 W	Differences by manufacturers.
Power Management	Digital : DVI DMPM, DisplayPort 1.1a Analog : VESA DPM	DVI DMPM, DisplayPort 1.1a	Differences by manufacturers.
QC software	RadiCS	EzCal	It is only a difference in terms of each manufacturer, but the functions are similar.
Sensors	Backlight Sensor	IQ Sensor, Ambient Light Sensor, Human Sensor	Differences by manufacturers
USB Ports / Standard	1 upstream, 2 downstream / Rev. 2.0	-	Differences by manufacturers.
Dimensions w/o stand (W x H x D)	575 x 398 x 71 mm	538.52 x 326.22 x 35.1 mm	Different housing design.

CL24N 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

CL24N comply with the following international and FDA-recognized consensus standards:

ANSI/AAMI ES60601-1:	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 CL24N 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, Veiling Glare, Color Uniformity, Luminance Response, Luminance at 30° and 45° in horizontal, and vertical directions, Luminance Stability test, Color Tracking, Gray Tracking, MTF

The tests showed that the device has similar characteristics compared to the predicated device.

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 ANSI/AAMI ES 60601-1 and IEC 60601-1-2. The effectiveness of the device was validated through bench tests.

The results of these tests demonstrate that CL24N 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.