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

May 8, 2023

Re: K222716
Trade/Device Name: MX50N
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: PGY
Dated: March 17, 2023
Received: March 20, 2023

Dear Mr. 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 Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality

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)*
K222716

Device Name
MX50N

Indications for Use *(Describe)*

MX50N 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.

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510(k) Summary

Submission number: K222716

[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:	MX50N
Common Name:	TFT LCD Medical Monitor System
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:	K170781
Applicant:	WIDE Corporation
Model Name:	MX50N(MX50YQS)

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

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

MX50N 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.
MX50N 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)]

MX50N 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 (MX50N) and the predicate device (K170781):

Attributes	Predicate Device	Subject Device	Discussion of Differences
Product	MX50N(MX50YQS)	MX50N	
Intended Use	The MX50N (MX50YQS) 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.	MX50N 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.	-
Response Time (typical)	25ms (On/Off)	25ms (On/Off)	-
LCD Panel size	21.3”	21.3”	-
Resolution	2560 x 2048	2560 x 2048	-
Pixel pitch	0.165 mm x 0.165mm	0.165 mm x 0.165mm	-
Maximum luminance	1,200 cd/m^2	3,000 cd/m^2	Provided by the panel manufacturers.

Contrast Ratio	1000 : 1	2000 : 1	Provided by the panel manufacturers.
Input signal	DVI-I, DisplayPort	DVI-I, DisplayPort	-
Power Supply	100~240 VAC, 50/60Hz	100~240 VAC, 50/60Hz	-
Color/Monochrome	Monochrome	Monochrome	-
Firmware	Version: N1220_221229	Version: N1220_221229	No change of the firmware.
QC software	Lumical Advanced	EzCal	It is only a difference in terms of each QC software, but the functions are similar.
Luminance Non-uniformity compensation	Luminance Uniformity Correction	Luminance Uniformity Correction	-
Sensors	Backlight Sensor, IQ Sensor, Ambient Light Sensor	Backlight Sensor, IQ Sensor, Ambient Light Sensor	-
USB Ports / Standard	1 upstream, 3 downstream / Rev. 3.0	1 upstream, 3 downstream / Rev. 3.0	-
Dimensions (w stand) (W x H x D)	390.3 x 520.1 x 248.8 mm	390.3 x 520.1 x 248.8 mm	-

The subject monitor model MX50N device is an improved version of the predicate MX50N (MX50YQS) for the max luminance (from 1,200cd/m^2 to 3,000cd/m^2) and the contrast ratio (from 1,000:1 to 2,000:1). The rest of design features, usability, safety and effectiveness are same.

8. Summary of Non-Clinical Data

MX50N 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 MX50N 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, Temporal Performance Test, Color Tracking, Gray Tracking, MTF

9. Summary of Clinical Data

No clinical studies were considered necessary and performed.

10. 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 MX50N 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.