DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 4, 2017

WIDE Corporation
% YeoJin Yun
RA Manager
12 Wongomae-Ro, Giheung-Gu
Yongin-Si, Gyeonggi-Do 17086
REPUBLIC OF KOREA

Re: K170781
Trade/Device Name: MX50N(MX50YQS)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: March 10, 2017
Received: March 17, 2017

Dear YeoJin 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170781

Device Name
MX50N(MX50YQS)

Indications for Use *(Describe)*
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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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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)]

03/10//2017

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

Name of Sponsor:	WIDE Corporation.
Address:	12 Wongomae-Ro, Giheung-Gu, Yongin-Si, Gyeonggi-Do 17086, Republic of Korea
Contact Name:	YeoJin Yun Telephone #: +82-31-218-1675 Fax #: +82-31-218-7400 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:	MX50N(MX50YQS)
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:	K160326
Applicant:	JVC KENWOOD Corporation
Model Name:	5MP Monochrome LCD Monitor MS55i2 (ML21055, MD211G5)
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)]

MX50N(MX50YQS) is a flat panel hi-resolution LCD monitor system for displaying digital medical images. The system consists of a state-of-the-art LCD monitor and a high-resolution graphic control board that connects to a PACS workstation for grayscale image display. The WIDE controller board is installed into the PACS workstation computer or other computer system to display PACS medical images.

Subject of this new 510(k) premarket notification is an addition to the indications for use for the MX50N(MX50YQS). The device was cleared via premarket notification K160353. There is no any change of configuration/components and functionality of the subject device as compared with cleared device (K160353).

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

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.

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]

Parameter	Subject Device	Predicate Device
510(k) Number	Unknown	K160326
Model Name	MX50N(MX50YQS)	5MP Monochrome LCD Monitor MS55i2 (ML21055, MD211G5)
Manufacturer	WIDE Corporation.	JVC KENWOOD Corporation
Common Name	TFT LCD Medical Monitor System	
Classification Name	Display, Diagnostic Radiology	
Classification Panel	Radiology	
Classification Regulation	21 CFR 892.2050	
Product Code	PGY	
Device Class	Class II	
Intended Use	The MX50N(MX50YQS) LCD Monitor System is intended to be used in displaying and viewing	5MP Monochrome LCD Monitor MS55i2 (ML21055, MD211G5) are intended to be

Parameter	Subject Device	Predicate Device
	digital medical images for review and analysis by trained medical practitioners. It is specifically designed for digital mammography applications and digital breast tomosynthesis applications.	used in displaying and viewing medical images for diagnosis by trained medical practitioners. They are to be used in digital mammography PACS, modalities including FFDM, and breast tomosynthensis.
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	0.165mm x 0.165mm	0.165mm x 0.165mm
Brightness	1200cd/m²	1200cd/m²
Contrast Ratio	1000 : 1	1200 : 1
Input Signal	DVI-I, DisplayPort	DVI-I
Power Supply	100~240 VAC, 50/60Hz	100~240 VAC, 50/60Hz
Color/Monochrome	Monochrome	Monochrome

When compared to the predicate devices (K160326), the MX50N(MX50YQS) presented in this submission has the same of the followings:

- Intended Use
- Technological characteristics
- Response Time
- LCD Panel Size
- Resolution
- Pixel pitch
- Brightness

The two devices share the similar performance as the following:

- Contrast Ratio

There is no significant difference between the MX50N(MX50YQS) and the predicate device that would adversely affect the use of the product. The subject device is substantially equivalent to the predicate device in intended use, technological characteristics, panel size, resolution, pixel pitch, Brightness and contrast ratio.

9. Summary of Non-Clinical Data

MX50N(MX50YQS) 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 tests conducted for resolution, luminance, contrast and noise all met the acceptance criteria specified in the standards.

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. Even though the predicate device and the subject device differ in the brightness, the difference is not a critical in the effectiveness because subject device covers brightness range of predicate device.

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 tests for resolution, luminance, contrast and noise.

The results of these tests demonstrate that MX50N(MX50YQS) 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.