

510(K) Summary of Safety and Effectiveness

As required by 807.92

FEB 14 2014

1. DEVICE ESTABLISHMENT AND CONTACT PERSON

Mr. Naohiko Shimazu

Senior Manager

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2. COMPANY REISTRATION NUMBER

3003623028

3. DATE SUMMARY PREPARED

09 October 2013

4. DEVICE NAME

Trade Name: MD302C4 29.8" Diagnostic Imaging LCD monitor

Model Name: MD302C4

Common Name: Color LCD Monitor, Color Diagnostic Display, etc.

Classification Name: System, Image Processing, Radiological (CLASS II CFR
892.2050)

4. PREDICATE DEVICE

MD242C2 Color LCD Monitor by NEC Display Solutions Ltd. (K132587)

5. DEVICE DESCRIPTION

Medical Display, MD302C4 is a 29.8" Color LCD monitor that displays image for medical use. It provides 4 mega pixel (2560*1600) resolution with adjustable gamma gray scale for more precise diagnose use in CT, MRI, HIS, and PACS.

6. DEVICE OF INTENDED USE

The MD302C4 color display is intended to be used for displaying and viewing of digital images for diagnosis by trained physicians.

To guarantee the display performance as specified, it must only be used for in conjunction with NEC approved display controllers.

MD302C4 cannot be used for a life-support system.

This device must not be used in digital mammography.

This device is designed for exclusive interconnection with IEC60601-1-1 certified equipment.

7. SE Comparison Table:

Comparison tables between MD302C4 & MD242C2

Items	MD242C2	MD302C4
510(k) Number		
Panel Size and Type	24.1" TFT Color LCD Monitor	29.8" TFT Color LCD Monitor
Pixel Pitch	0.270 mm x 0.270mm	0.251mm x 0.251mm
Display Color	1,073,741,824	16,777,216
Viewing Angles (°)	H:178, V:178	H:178, V:178
Scanning Frequency (H, V)	31.5-93.8, 118.4kHz, 50-85 Hz	31.5-98.7 kHz, 50-85 Hz
Native Resolutions	1920X1200	2560X1600
Brightness	180 cd/m ² calibrated, 350 cd/m ² Max.	180 cd/m ² calibrated, 340 cd/m ² Max.
Contrast Ratio	1000 : 1 (typical)	1000 : 1 (typical)
DOT Clock	202.5 MHz (Max) (Analog) 162 MHz (Max) (Digital)	269 MHz (Max)
Input Signals	Three connectors: one DVI port, one Display port, one HDMI port.	Three connectors: one DVI port, one Display port, one HDMI port.

Input Terminals	DVI-D, Display port, HDMI port	DVI-D, Display port, HDMI port
USB (option) / Standard	No	No
Active Display Size (H x V)	Landscape: 518.4mmX324mm Portrait: 324X518.4mm	Landscape: 641mmX401mm Portrait: 401X641mm
Viewable Image Size	540 mm (diagonal)	756 mm
Luminance Calibration	Software	Software
Default Gamma	1.8,2.0,2.2 DICOM part 14	1.8,2.0,2.2 DICOM part 14
Power	AC100-240V, 50/60Hz	AC100-240V, 50/60Hz
Power Consumption	38.4W (Max)	87W (Max)
Power Save Mode	<2W	<2W
Dimensions (W x H x D)	W: Landscape: 556.8mm Portrait: 362.4 mm H: Landscape: 378 - 528mm Portrait: 572.4-625.2mm D: 227.6 mm	W: Landscape: 688mm Portrait: 446.8 mm H: Landscape: 466.4 – 616.4mm Portrait: 707.1-737.0mm D: 301.6 mm
NET Weight	10.2 kg	17 kg
Intended of use	Displaying and viewing of digital images for diagnosis by trained physicians This device can not use for a life support system. This device must not be use in digital mammography. This device is designed for exclusive interconnection with IEC60601-1-1 certified equipment	Displaying and viewing of digital images for diagnosis by trained physicians This device can not use for a life support system. This device must not be use in digital mammography. This device is designed for exclusive interconnection with IEC60601-1-1 certified equipment
Certifications & Standards	CE ITE/Medical Device Directive, UL/cUL (ANSI/AAMI ES 60601-1:2005), FCC Class B, EN60601-1-2, DIN V 6868-57, DICOM	CE ITE/Medical Device Directive, UL/cUL (ANSI/AAMI ES 60601-1:2005), FCC Class B, EN60601-1-2, DIN V 6868-57, DICOM

CONCLUSION

These two devices have the same target population of trained practitioner in hospital; it shares the same design, same performance and is the same in radiation safety (EN60601-1-2), mechanical safety, electrical safety (AAMI/ES 60601-1) human factors and DICOM conformance. It use similar material, and have same compatibility with environment and other device. Comparison table of the principal characteristics of two devices is shown in the Section 3, table 3.3. These two devices also have the same intended use; Therefore we concluded that it is substantially equivalent to MD242C2 by NEC Display Solutions Ltd. (K132587)



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 14, 2014

NEC Display Solutions, Ltd.
% Mr. Tony Hsu
Safety Engineer
Prodigy Technology Consultant Co., Ltd.
1F, No. 181, Sec. 2 Wunhua
1st Road, Linkou Township
NEW TAIPEI CITY 24457
TAIWAN

Re: K133708

Trade/Device Name: MD302C4 29.8" Diagnostic Imaging LCD Monitor
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 23, 2013
Received: December 23, 2013

Dear Mr. Hsu:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K133708

Device Name
MD302C4

Indications for Use (Describe)

The MD302C4 color display is intended to be used for displaying and viewing of digital images for diagnosis by trained physicians.

To guarantee the display performance as specified, it must only be used for in conjunction with NEC approved display controllers.

MD302C4 cannot be used for a life-support system.

This device must not be used in digital mammography.

This device is designed for exclusive interconnection with IEC60601-1-1 certified equipment.

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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