510(K) Summary of Safety and Effectiveness

As required by 807.92

OCT 5 2012

1. DEVICE ESTABLISHMENT AND CONTACT PERSON

Mr. Saohiko Shimazu

Manager

NEC Display Solutions Ltd.

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2. COMPANY REISTRATION NUMBER

3003623028

3. DATE SUMMARY PREPARED

21 June 2012

4. DEVICE NAME

Trade Name:	MD211G3 21.3" Diagnostic Imaging LCD monitor
Model Name:	MD211G3
Common Name:	Monochrome LCD Monitor, Monochrome Diagnostic Display, etc.
Classification Name:	System, Image Processing, Radiological (CLASS II CFR 892.2050)

4. PREDICATE DEVICE

L218TL 3MP Monochrome LCD Monitor by NEC Display Solutions Ltd. (K090215)

5. DEVICE DESCRIPTION

Medical Display, MD211G3 is a 21.3" Monochrome LCD monitor that displays image for medical use. It provides 3 mega pixel (2048*1536) resolution with adjustable gamma gray scale for more precise diagnose use in CT, MRI, HIS, and PACS.

6. DEVICE OF INTENDED USE

The MD211G3 gray scale display is intended to be use 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.

MD211G3 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 MD211G3 & L218TL

Items	**L218TL**	**MD211G3**
510(k) Number	K090215	
Panel Size and Type	21.3" TFT Monochrome LCD Monitor	21.3" TFT Monochrome LCD Monitor
Pixel Pitch	0.212 mm x 0.212mm	0.212 mm x 0.212mm
Display Monochromes	10-bit (1024 grey tones) with 3061 total colors	10-bit (1024 grey tones) with 3061 total colors
Viewing Angles (°)	H:176, V:176	H:176, V:176
Scanning Frequency (H, V)	31.5-95.4kHz , 30-85 Hz	31.5-95.4kHz , 30-85 Hz
Native Resolutions	2048X1536	2048X1536
Brightness	400 cd/m^2 calibrated, 1450 cd/m^2 Max.	400 cd/m^2 calibrated, 1450 cd/m^2 Max.
Contrast Ratio	900 : 1 (typical)	900 : 1 (typical)
DOT Clock	162 MHz	188 MHz
Input Signals	Three connectors: one D-sub analog VGA; and two DVI-D (VGA analog or digital)	Three connectors: one D-sub analog VGA; and two DVI-D (VGA analog or digital)
Input Terminals	DVI-D, D-sub	DVI-D, D-sub

USB (option) / Standard	No	No
Active Display Size (H x V)	Landscape: 433mmX325mm Portrait: 325X433mm	433 mm x 325 mm
Viewable Image Size	540 mm (diagonal)	540 mm (diagonal)
Luminance Calibration	Software	Software
Default Gamma	1.8,2.0,2.2 DICOM part 14 + off, user	1.8,2.0,2.2 DICOM part 14
Power	AC100-240V, 50/60Hz	AC100-240V, 50-60Hz
Power Consumption	98W (Max)	100W (Max)
Power Save Mode	<2W	<2W
Dimensions (W x H x D)	W: Landscape: 467.8mm Portrait:361.6 mm H: Landscape: 434.3-584.3mm Portrait: 487.4-637.4mm D: 306 mm	W: Landscape: 467.8mm Portrait:361.6 mm H: Landscape:377.6-527.6mm Portrait:483.4-580.7mm D: 227.6 mm
NET Weight	10.7 kg	10.7 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 IEC60601-1-1certified 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 IEC60601-1-1certified equipment
Certifications & Standards	CE ITE/Medical Device Directive, UL/cUL (UL60601-1, CSA C22.2 No.601-1), 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

8. PERFORMANCE TESTING

Test items according to "Assessment of Display Performance for Medical Imaging Systems" published by American Association of Physicists in Medicine (AAPM) Task Group 18 were performed to device MD211G3. The complete system configuration as well as the device verification and validation have also been assessed in-house. The results showed that all the testing items met the criteria. The predicate device – L218TL also has the above mentioned tests performed and has the same results and this demonstrates that MD211G3 and L218TL are equivalent in terms of performance.

9. 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 L218TL by NEC Display Solutions Ltd. (K090215)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

OCT 5 2012

NEC Display Solutions Ltd.
% Mr. Ned Devine
Senior Staff Engineer/FDA Office Coordinator
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

Re: K122843
Trade/Device Name: Medical Display, MD211G3
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 11, 2012
Received: September 17, 2012

Dear Mr. Devine:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely Yours,

Michael D O'Hara 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): K122843

Device Name: Medical Display, MD211G3

Indications For Use: The MD211G3 gray scale display is intended to be used for displaying and viewing of digital images for diagnosis by trained physicians.

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

Prescription Use ___V___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K122843

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