DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

NEC Display Solutions Ltd.
% Mr. David Cheng
Vice Director
Top Victory Electronics (Taiwan) Co., Ltd.
10F, No. 230, Liancheng Road, Zhonghe Dist.
New Taipei City, 23559
TAIWAN

May 13, 2016

Re: K161057
Trade/Device Name: Diagnostic Imaging Color LCD Monitor, Model MDC212C2
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: April 11, 2016
Received: April 14, 2016

Dear Mr. Cheng:

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)*

K161057

Device Name

Diagnostic Imaging Color LCD monitor, Model MDC212C2

Indications for Use *(Describe)*

The MDC212C2 Color displays are 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 in conjunction with NEC approved display controllers.

MDC212C2 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 IEC 60601-1-1 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared

April 12, 2016

2. Submitter's Information

Name of Sponsor:	NEC Display Solutions Ltd.
Address:	4-28, Mita 1-chome, Minato-ku, Tokyo, Japan.
Contact:	Mr. Satoru Kotani
Telephone No.:	+81-465-85-2384
Fax No.:	+81-465-85-2393

3. Trade Name, Common Name, Classification

Trade Name:	Diagnostic Imaging Color LCD Monitor, Model MDC212C2
Common Name:	Color LCD Monitor, Color Diagnostic Display, etc.
Classification Name:	System, Image Processing, Radiological
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892.2050
Product Code:	PGY
Device Class:	II

4. Identification of Predicate Device(s)

The identified predicates within this submission are as follows:

510(k) Number	K142951
Applicant	NEC Display Solutions Ltd.
Device Name	MD210C3 21.3" Diagnostic Imaging LCD monitor

5. Description of the Device

Diagnostic Imaging Color LCD Monitor, Model MDC212C2 is a 21.3" Color LCD monitor that displays image for medical use. It provides 1600*1200p resolution with adjustable gamma gray scale for more precise diagnose use in CT, MRI, HIS, and PACS.

6. Intended Use

The MDC212C2 Color displays are 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 in conjunction with NEC approved display controllers. MDC212C2 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 IEC 60601-1-1 certified equipment.

7. Technological Characteristics

MDC212C2 is a LCD display system for medical viewing, with high resolution 1600 x 1200, self-calibration, Gamma adjust, front sensor, ambient sensor calibration. There are no significant differences between subject device and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, operational principles and intended use.

Item	MDC212C2
Name of device	MDC212C2
Classifications/ code	Class II/ PGY
Panel Size and Type	21.3” TFT Color LCD Monitor
Pixel Pitch	0.270 mm x 0.270mm
Display Color	1,073,741,824
Viewing Angles (°)	H:89, V:89
Scanning Frequency (H, V)	31.5-94.0 kHz , 50-85 Hz
Brightness	440 cd/m2 calibrated, 180 cd/m2 Max.
Contrast Ratio	1500 : 1 (typical)
Input Signals	DVI-D (applicable to HDCP) Display Port (applicable to HDCP) 15pin Mini D-sub
Input Terminals	DVI-D, Display port, VGA
USB (option) / Standard	USB Specification Revision 3.0
Active Display Size (H x V)	Landscape: 432mm X 324 mm Portrait: 324 X 432 mm
Viewable Image Size	540 mm
Luminance Calibration	Software

Default Gamma	1.8,2.0,2.2 DICOM part 14
Power	AC100-240V, 50/60Hz
Input Rating	1.0 - 0.6 A

8. Substantial Equivalence

The subject device has same intended use, technology, operation principle and technical characteristics with the predicate device(s). Design Verification activities were performed on subject device and all tests were verified to meet the required acceptance criteria. The verification tests demonstrate that the differences in the device do not affect the intended use of the device or raise any unsolved issues. There are no significant differences between subject device and the predicate device(s) that would adversely affect the use of the product. We conclude that MDC212C2 is substantially equivalent to predicate devices. Comparative data is shown in Table 1.

9. Summary of Non-clinical Tests

The subject device conforms to the following 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 disturbances - Requirements and tests
- AAPM TG 18. Assessment of Display Performance for Medical Imaging Systems

10. Clinical Tests

The submission does not contain clinical data.

11. Conclusion

Diagnostic Imaging Color LCD Monitor, Model MDC212C2 has same intended use, technology, operation principle and technical characteristics with the predicate device(s). Based on the information and non- clinical tests provided in this premarket notification, we conclude that Diagnostic Imaging LCD monitor, Model MDC212C2 is substantially equivalent to predicate devices.

Table 1. Comparative Data

Item	Predicate Device K142951	Subject device
Name of device	MD210C3	MDC212C2
Classifications/ code	Class II/ PGY	Class II/ PGY
Panel Size and Type	21.3” TFT Color LCD Monitor	21.3” TFT Color LCD Monitor
Pixel Pitch	0.212 mm x 0.212mm	0.270 mm x 0.270mm
Display Color	1,073,741,824	1,073,741,824
Viewing Angles (°)	H:176, V:176	H:89, V:89
Scanning Frequency (H, V)	31.5-94.8, 126.3kHz, 50-85 Hz	31.5-94.0 kHz , 50-85 Hz
Native Resolutions	2048 x 1536	1600 x 1200
Brightness	400 cd/m2 calibrated, 800 cd/m2 Max.	440 cd/m2 calibrated, 180 cd/m2 Max.
Contrast Ratio	1400 : 1 (typical)	1500 : 1 (typical)
DOT Clock	214.3 MHz	214.3 MHz
Input Signals	DVI-D Display Port	DVI-D (applicable to HDCP) Display Port (applicable to HDCP) 15pin Mini D-sub
Input Terminals	DVI-D, Display port	DVI-D, Display port, VGA
USB (option) / Standard	No	USB Specification Revision 3.0
Active Display Size (H x V)	Landscape: 433mm x325mm Portrait: 325X433mm	Landscape: 432mm x 324 mm Portrait: 324 X 432 mm
Viewable Image Size	540 mm	540 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
Input Rating	1.1-0.44A	1.0 - 0.6 A
Dimensions (W x H x D)	W: Landscape: 467.8mm Portrait:361.6 mm H: Landscape:434.3.6-584.3mm Portrait:487.4-637.4mm D: 306 mm	W: Landscape: 466.4 mm Portrait: 359.0 mm H: Landscape: 374.6 - 524.6 mm Portrait: 484.0 - 580.0 mm D: 227.6 mm
NET Weight	11.8 kg	8.0 kg
Intended of use	The MD210C3 color display is	The MDC212C2 Color displays

	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 in conjunction with NEC approved display controllers. MD210C3 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.	are 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 in conjunction with NEC approved display controllers. MDC212C2 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 IEC 60601-1-1 certified equipment.