K111237

JUN 15 2011

510(K) Summary of Safety and Effectiveness

As required by 807.92

1. DEVICE ESTABLISHMENT AND CONTACT PERSON

Mr. Shuichi Kino

Manager

NEC Display Solutions Ltd.

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2. COMPANY REISTRATION NUMBER

3003623028

3. DATE SUMMARY PREPARED

09 February 2011

4. DEVICE NAME

Trade Name:	MD301C4 29.8" Diagnostic Imaging LCD monitor
Model Name:	L309TY
Common Name:	Color LCD Monitor, Color Diagnostic Display, etc.
Classification Name:	System, Image Processing, Radiological (CLASS II CFR 892.2050)

4. PREDICATE DEVICE

MD304MC 29.8" 4MP Color LCD Monitor by NEC Display Solutions Ltd. (K083916).

Trade Name:	MD304MC 29.8" Diagnostic Imaging LCD monitor
Model Name:	L307TD

5. DEVICE DESCRIPTION

Medical Display, MD301C4 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. MD301C4 conforms with DICOM.

6. INDICATION OF USE

MD301C4 is intended to be used for displaying and viewing of digital images for diagnosis by trained physicians.

Caution: MD301C4 cannot be used for a life-support system.

This unit is designed as component of a final system which is compliance to IEC60601-1-1 requirements.

MD301C4 must not be used in digital mammography.

7. CONCLUSION

Device with trade name MD301C4 (model name is L309TY) and predicate device with trade name MD304MC (model name is L307TD) 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 (UL60601-1) and human factors. It uses similar material, and has same compatibility with environment and other devices. The differences between the two devices are display colors (MD304MC can display more colors), input signals, input terminals, and USB input, power consumes in power save mode (MD301C4 consumes less power in power save mode), power consumption (MD301C4 consumes more power), however these do not effect the safety and effectiveness of the MD301C4 to be substantially equivalent to the predicate device. These two devices also have the same intended use; Therefore we concluded that it is substantially equivalent to MD304MC by NEC Display Solutions Ltd. (K083916).

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

NEC Display Solutions Ltd.
% Mr. Marc Mouser
Engineering Leader/ FDA Office Coordinator
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
CAMAS WA 98607-8542

JUN 15 2011

Re: K111237
Trade/Device Name: Medical Display, MD301C4
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 25, 2011
Received: June 3, 2011

Dear Mr. Mouser:

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,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Medical Display, MD301C4

Indications For Use: MD301C4 is intended to be used for displaying and viewing of digital images for diagnosis by trained physicians.

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

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

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

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111237