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## 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.

4-13-23 Shibaura, Minato-ku, Tokyo, 108-0023 Japan

Ph: +81-465-85-2376

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APR 15 2009

### 2. COMPANY REISTRATION NUMBER

3003623028

### 3. DATE SUMMARY PREPARED

15 December 2008

### 4. DEVICE NAME

Trade Name: MD213 MG 21.3" Diagnostic Imaging LCD monitor

Model Name: L218TL

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

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

### 4. PREDICATE DEVICE

MDM2130-3NC 21.3" 3MP Monochrome LCD Monitor by CHILIN Technology Co., Ltd.  
(K063266).

### 5. DEVICE DESCRIPTION

Medical Display, L218TL 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.

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**6. DEVICE OF INTENDRD USE**

The L218TL monochrome display is intended to be used for displaying and viewing of digital image diagnosis by trained physicians.

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

The L218TL cannot be used for a life-support system.

This device must not be used in digital mammography.

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

**7. 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 (UL60601-1) and human factors. 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 MDM2130-3NC by Chi Lin Technology Co., Ltd. (K063266).



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NEC Display Solutions, Ltd.  
c/o Mr. Morten Simon Christensen  
Asst. Manager, Program Reviewer  
UL Health Sciences  
Underwriters Laboratories, Inc.  
455 E. Trimble Road  
SAN JOSE CA 95131-1230

APR 15 2009

Re: K090215  
Trade/Device Name: Medical Display, L218TL  
Regulation Number: 21 CFR §892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: March 26, 2009  
Received: April 1, 2009

Dear Mr. Christensen:

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 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.

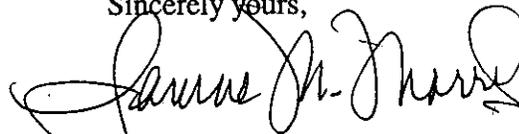
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K090215

Device Name: Medical Display, L218TL

**Indications For Use:** The L218TL Monochrome display is intended to be used for displaying and viewing of digital image diagnosis by trained physicians.

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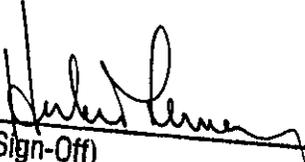
This unit is designed for exclusive interconnection with IEC60601-1 certified equipment.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal and  
Radiological Devices  
510(k) Number K090215