K052942

DEC 2 7 2005

E1

·Section E – 510(k) Summary

E-1. 510(k) Application Date

July 28, 2005

E-2. Manufacturer

Submitter Name : NEC Display Solutions, Ltd.

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

E-3. Contact Person

Name : Shuichi Kino (Mr.)

Manager

Engineering Administration Section, Planning and Administration Department

R&D and Product Supply Division

Address : 686-1, Nishioi, Oi-machi, Ashigarakami-gun, Kanagawa, 258-8533 Japan

Tel : +81-465-85-2376

Fax : +81-465-85-2378

E-4. Device

Device Name : 21.3inch Monochrome LCD Monitor

Model : NEC MD21GS-3MP-CB

NEC MD21GS-3MP-BB

MITSUBISHI MD211GS3P-CB

MITSUBISHI MD211GS3P-BB

These are identical each other, except for model designation..

E-5. Common Name

Monochrome LCD Monitor

E-6. Registration Number

Manufacturer:

NEC Display Solutions, Ltd.

Registration Number: 3003623028

Factory:

NPG DISPLAY (DONG GUAN) CO., LTD.

Registration Number: 3002808782

E-7. Factory

Name : NPG DISPLAY (DONG GUAN) Co., LTD.

Address : Jin Xing Industrial Zone, Qing Xi Zhen, Dong Guan,
Guang Dong Sheng 511746, P.R. China

E-8. Classification

Device Class : Class Ⅱ

Classification Name : System, image processing, Radiological

Regulation Number : 21 CFR Part 892 Radiology Devices
Subpart B Section 892.2050

Device Description : Picture Archiving and Communications System

Product code : 90 LLZ

E-9. Reason for Submission

First time submission to market this LCD Monitor as Medical Device in the USA.

E-10. Description of Marketed Device

Device Name : Barco Coronis 3MP Medical Flat Panel Display System

510(k) number : K013922

Intended use :

The Barco Coronis 3MP Medical Flat Panel Display System is intended to be used in displaying and viewing digital images for review by trained medical practitioners.

Device description :

The monitor combines a TFT(thin film transistor) liquid crystal display panel structure and a built-in backlight with inverter for a better picture quality.

The monitor can be used in portrait or landscape version, simply by turning the panel.

The tilt and swivel foot allows ideal positioning of the panel, in height and viewing angle.

The image brightness can be adjusted by means of a control wheel on the monitor.

The 21.3inch Monochrome LCD Monitor has the same intended use, technical characteristics and performance as the legally marketed device (K013922) and thus Substantial Equivalence is given.

E-11. Substantial Equivalence Comparison

Device Description :

The LCD panel adopts Super Advanced-Super Fine TFT(SA-SFT) for the MD21GS-3MP-CB, BB and MD211GS3P-CB, BB.

Additionally, a low reflection overcoat is applied on top of the bead layer, which yields a low, uniform reflection over the surface of the glass.

This process also provides for a truer representation of black and a higher contrast ratio.

The MD21GS-3MP-CB, BB and MD211GS3P-CB, BB can select the use of the landscape or the portrait only by rotating the LCD panel.

The tilt and swivel foot allows ideal positioning of the panel, in height and viewing angle.

In addition, because our device has the height adjustment function of the stand, a more ideal positioning can be offered.

Please refer to "Table E-11".

Intended Use :

The MD21GS-3MP-CB, BB and MD211GS3P-CB, BB are intended to be used for displaying and viewing of digital images for diagnosis by trained physicians.

These gray scale display must not be used for primary diagnostic in mammography.

Barco Coronis 3MP is intended to be used in displaying and viewing digital images for review by trained medical practitioners.

It is intended to be used to support the diagnosis to either device.

Technical Characteristics and performance :

The MD21GS-3MP-CB, BB and MD211GS3P-CB, BB can select the use of 2048*1536 of the landscape modes or the portrait modes of 1536*2048 only by rotating the panel equally to the legally marketed device.

Barco Coronis 3MP has the viewing angle of 170°.

The MD21GS-3MP-CB, BB and MD211GS3P-CB, BB greatly decreases the shift of the Gamma characteristic by the view corner by the wide viewing angle of 176° by the adoption of the latest SA-SFT panel.

The MD21GS-3MP-CB, BB and MD211GS3P-CB, BB provides support for improved diagnostic accuracy with simultaneous reproduction of up to 1024 from a palette of 3061 possible grayscales.

The 10-bit gamma correction ensures precise and smooth grayscale tuning and better representation of just noticeable difference.

Up to 1024 grayscales can be depicted at the same time for film-less diagnosis.

The MD21GS-3MP-CB, BB and MD211GS3P-CB, BB are different in the following points compared with the legally marketed device.

Barco Coronis 3MP in difference of built-in circuit of power supply instead of AC adapter.

In Barco Coronis 3MP, the AC voltage converts into the DC voltage with the AC adaptor and is supplied to the device.

In The MD21GS-3MP-CB, BB and MD211GS3P-CB, BB, the AC voltage converts into the DC voltage in the device.

Therefore, the monitor is operated by the dc voltage, and is substantial equivalent to the legally marketed device.

The Barco Coronis 3MP has the insulation structure which meets the standard of UL60950.

However, The MD21GS-3MP-CB, BB and MD211GS3P-CB, BB has the insulation structure which meets the standard of UL60601.

The MD21GS-3MP-CB, BB and MD211GS3P-CB, BB are applied a severer safety standard compared with the legally marketed device.

Therefore, our monitor safety is more excellent than the legally marketed device.

Therefore, The MD21GS-3MP-CB, BB and MD211GS3P-CB, BB are device with higher safety compared with the legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 7 2005

NEC-Mitsubishi Electric Visual Systems Corp.
c/o Tamas Borsai
TŰV Rheinland of North America
12 Commerce RD.
NEWTON, CT 06470

Re: K052942
Trade/Device Name: 21.3inch Monochrome LCD Monitor (Models: NEC MD21GS-3MP-CB, NEC MD21GS-3MP-BB, MITSUBISHI MD211GS-3MP-CB, and MITSUBISHI MD211GS-3MP-BB)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: December 13, 2005
Received: December 15, 2005

Dear Mr. Borsai:

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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

·Section D – Indications for use

D-1. Indications for use

INDICATIONS FOR USE

510(K)Number : Not Known

Device Name : 21.3inch Monochrome LCD Monitor

Model : NEC MD21GS-3MP-CB

NEC MD21GS-3MP-BB

MITSUBISHI MD211GS3P-CB

MITSUBISHI MD211GS3P-BB

Indications for Use :

The 21.3inch Monochrome LCD Monitor is intended to be used for displaying and viewing of digital images for diagnosis by trained physicians.

The 21.3inch Monochrome LCD Monitor must not be used for primary diagnostic in mammography.

Prescription Use ✓ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052942