DEC 16 2005 K052120

EXHIBIT 2

510(k) Summary

Heeyoung Co., Ltd

1048-8, Shingil-dong, Danwon-gu, Ansan-city, Kyunggi-do,

425-839, Korea

Tel: 82-31-491-5585

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Contact: Youngho Ro, Vice-President

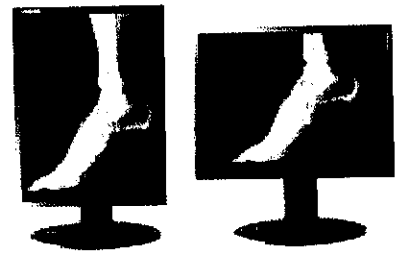
Date: December 14, 2005

1. Identification of the Device:
   Proprietary-Trade Name: "Lumimed Monochrome LCD Monitor" (Models: MM 20, MM 30, MM50)
   Classification Name: System, Image Processing, Radiological, Product Code 90 LLZ
   Common/Usual Name: Radiological Image Processing System, LCD Monitor

2. Equivalent legally marketed devices: RadiForce G51, 5 Megapixel Monochrome LCD Monitor (K042755, EIZO NANAO Corp.)

3. Indications for Use (intended use): Monochrome LCD Monitors intended to be used in various kinds of medical image applications (excluding digital mammography) for which the device complies with the performance specified by the manufacturer of the system.

4. Description of the device: Monochrome LCD Monitors (MM 20, MM 30 and MM 50) are used to display images such as X-ray, or MRI images. These models have resolutions of: 2560 X 2048, 2048 X 1536 and 1600 X 1200. These models have USB functions and an optional photo sensor GFU12-SEQ01 made by Gretagmacbeth. These models are certified to the EN 60601-1 medical safety standard. The monitors use universal switching power supplies compatible with AC100V-120V/200V-240V,50/60Hz. The graphics card needed for the personal computer is the VREngine MD/SMD Series. The monitors may be deployed in the portrait or the landscape position.



5. Safety and Effectiveness, comparison to predicate device:

Items	RadiForce G51	New		
		Lumimed MM20	Lumimed MM30	Lumimed MM50
510(k) Number	K042755	New	New	New
Manufacturer	Eizo Nano Corporation	Heeyoung Co., Ltd	Heeyoung Co., Ltd	Heeyoung Co., Ltd
Panel Size and Type	21.3" TFT monochrome LCD display	21.3" TFT monochrome LCD display	21.3" TFT monochrome LCD display	20.1" TFT monochrome LCD display
Pixel Pitch	0.165mm x 0.165mm	0.270mm x 0.270mm	0.2115mm x 0.2115	0.156mm x 0.156mm
Available Cabinet Colors	Black	Black	Black	Black
Native Resolutions	2048x2560(portrait) 2560x2048(landscape)	1200x1600(portrait) 1600x1200(landscape)	1536x2048(portrait) 2048x1536(landscape)	2048x2560(portrait) 2560x2048(landscape)
Brightness	700cd/m2	1000cd/m2	900cd/m2	850cd/m2
Contrast Ratio	600:1	700:1	700:1	600:1
Dot Clock	152MHz	125MHz	130MHz	162MHz
Serial Ports	Mini DIN 4pin(Remote In) Mini DIN 8pin (Remote Out)	Mini DIN 4pin(Remote In) Mini DIN 8pin (Remote Out)	Mini DIN 4pin(Remote In) Mini DIN 8pin (Remote Out)	Mini DIN 4pin(Remote In) Mini DIN 8pin (Remote Out)
Active Display Size(HxV)	337.9 x 422.4mm	432(H) x 324(V)	432(H) x 324(V)	399(H) x 319(V)
Dimensions(WxHxD	388 x 572 x 83.5mm	472 x 495 x92	472 x 495 x92	438 x 458 x 98
Luminance Calibration	Software(Optional) Photo-sensor (Optional)	Software(Optional) Photo-sensor (Optional)	Software(Optional) Photo-sensor (Optional)	Software(Optional) Photo-sensor (Optional)
Power	AC100V-120V/200V-240V, 50/60Hz	AC100V-120V/200V-240V, 50/60Hz	AC100V-120V/200V-240V, 50/60Hz	AC100V-120V/200V-240V, 50/60Hz

Testing information and Conclusion

In all material respects, the Lumimed monitors are substantially equivalent to the predicate device. Testing was performed according to internal company procedures and the monitors were safety certified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2005

Heeyoung Co., Ltd.
% Mr. Daniel Kamm
Regulatory Engineer
P.O. Box 7007
DEERFIELD IL 60015

Re: K052120
Trade/Device Name: Lumimed Monochrome LCD Monitor
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 9, 2005
Received: November 29, 2005

Dear Mr. Kamm:

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

Indications for Use

510(k) Number (if known): K052120

Device Name: "Lumimed Monochrome LCD Monitor"
(Models: MM 20, MM 30, MM50).

Monochrome LCD Monitors intended to be used in various kinds of medical image applications (excluding digital mammography) for which the device complies with the performance requirements specified by the manufacturer of the system.

Prescription Use X 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052120