



K112354

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U.S. Food and Drug Administration
Center for Devices and Radiological Health
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Date August 11th, 2011

Traditional 510(k) Summary (in accordance with 21 CFR 807.92)

1. Date of Summary

August 11th, 2011

2. Company

EIZO NANA O CORPORATION
153 Shimokashiwano, Hakusan
Ishikawa 924-8566 Japan

3. Authorized Contact Person

Hiroaki Hashimoto

4. Device Information

- Trade Name/Model: RadiForce GX530
- Common Name: 5MP Monochrome LCD Monitor
- Classification Name: System, Image Processing, Radiological
- Classification Number: 21 CFR 892.2050, Product Code LLZ

5. Predicate Device

5MP Monochrome LCD Monitor, RadiForce GS510 (K062054)

6. Device Description

The RadiForce GX530 is a 5MP monochrome LCD monitor for viewing medical images including those of digital mammography. The monochrome panel employs in-plane switching (IPS) technology allowing wide viewing angles. The matrix size (or resolution) of the panel is 2560 x 2048 pixels and the pixel pitch is 0.165 mm, both of which are the same as those of displays approved so far for digital mammography including the predicate device, RadiForce GS510. Since factory calibrated display modes, each of which is characterized by a specific tone curve (including DICOM GSDF) and a specific luminance range, are stored in lookup tables within the monitor, the tone curve is e.g. DICOM compliant regardless of the display controller used.

RadiCS is application software to be installed in each workstation offering worry-free quality control of the diagnostic monitors including GX530 based on several QC guidelines. The RadiCS and its subset, RadiCS LE are included in this 510(k) submission as an accessory to the RadiForce GX530.



7. Intended Use

The RadiForce GX530 is intended to be used in displaying and viewing digital images including those of digital mammography for review and analysis by trained medical practitioners.

8. Technological Characteristics

RadiForce GX530 can be said to have at least the same display performance as those of the predicate device by default due to the following reasons:

- The matrix sizes (2048 x 2560) and the active area sizes (337.9 mm x 422.4 mm) of the LCD panels used by the both devices are the same though they are from different manufacturers.
- The both devices display images in accordance with DICOM GSDF by default utilizing the factory calibrated display mode stored in one of the lookup tables inside of them.
- As for input video signal, in addition to the Digital Visual Interface (DVI) also supported by the predicate device, RadiForce GX530 supports DisplayPort, another type of digital video interface based on an industrial standard. As far as the both the DVI and the DisplayPort are digital, their differences do not affect the image quality.

As for the maintenance, the same QC software is used for the both devices and the implementation of the Backlight Sensor (BS) stabilizing the backlight is also the same.

As for built-in sensors, in addition to BS common to the both devices, GX530 has three kinds of sensors. However, only the Built-in Front Sensor (IFS) has something to do with the maintenance or the calibration; the Presence Sensor detects the absence of the user to trigger the power saving mode of the monitor and the Ambient Light Sensor is used to measure the ambient light by lx. The IFS enables automatic grayscale calibration by measuring the luminance at the screen surface. Without IFS, the grayscale calibration process requires human intervention and the use of an external sensor. The precision data of the calibration with an external sensor and with the IFS is provided as one of the validation data.

The overall design of the RadiForce GX530 was validated in accordance with internationally recognized safety and EMC standards by independent testing facilities and in-house ones. Besides, EIZO NANA O CORPORATION performed a range of system and performance tests to ensure that the RadiForce GX530 performs in accordance with its specifications. None of the tests revealed behaviors inconsistent with the expected performance.

9. Conclusion

5MP Monochrome LCD Monitor, RadiForce GX530 is substantially equivalent to the predicate device with respect to technical characteristics, application and intended use. The specifications of the primary components are the same and those that are different have been independently validated. Any differences between the devices do not affect safety or effectiveness.

The 510(k) Premarket Notification for the RadiForce GX530 contains sufficient information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Mr. Hiroaki Hashimoto
Manager
EIZO NANA CORPORATION
153 Shimokashiwano
924-8566 HAKUSAN ISHIKAWA
JAPAN

NOV 3 0 2011

Re: K112354
Trade/Device Name: 5 MP Monochrome LCD Monitor, RadiForce GX530
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 11, 2011
Received: August 16, 2011

Dear Mr. Hashimoto:

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.

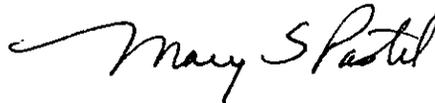
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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:

5 MP Monochrome LCD Monitor, RadiForce GX530

Indications For Use:

The RadiForce GX530 is intended to be used in displaying and viewing digital images including those of digital mammography for review and analysis by trained medical practitioners.

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 IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K112354