



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

EIZO Corporation  
% Hiroaki Hashimoto  
Manager  
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JAPAN

July 30, 2015

Re: K151883  
Trade/Device Name: 5MP Monochrome LCD Monitor, RadiForce GX540  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: PGY  
Dated: July 3, 2015  
Received: July 9, 2015

Dear Hiroaki 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); 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 Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. A faint, large "FDA" watermark is visible in the background behind the signature.

Robert Ochs, Ph.D.  
Acting Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151883

Device Name

5MP Monochrome LCD Monitor, RadiForce GX540

Indications for Use (Describe)

This product is intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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

### 1. Company

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Fax: +81 (76) 274-2484

### 2. Contact Person

Hiroaki Hashimoto

### 3. Date of Summary

July 3rd, 2015

### 4. Device Information

- Trade Name/Model: RadiForce GX540
- Common Name: 5MP Monochrome LCD Monitor
- Classification Name: Display, Diagnostic Radiology
- Regulation Number: 21 CFR 892.2050, Product Code PGY
- 510(k) Number: K130336 (for digital mammography)

### 5. Predicate Device

- Trade/Device Name: Barco Mammo Tomosynthesis (MDMG-5221)
- 510(k) Number: K103792

## **6. Device Description**

RadiForce GX540 is a monochrome LCD monitor for viewing medical images including those of mammography. The monochrome panel employs in-plane switching (IPS) technology allowing wide viewing angles and the matrix size (or resolution) is 2,048 x 2,560 pixels (5MP) with a pixel pitch of 0.165 mm.

Since factory calibrated display modes, each of which is characterized by a specific tone curve (including DICOM GSDF), a specific luminance range and a specific color temperature, are stored in lookup tables within the monitor, the tone curve is e.g. DICOM compliant regardless of the display controller used.

There are two model variations, GX540-CL and GX540-CLAR (GX540 without any suffix does not exist). The difference of the two variations is the surface treatment of the display screens; the surface treatment of the GX540-CL is Anti-Glare (AG) treatment and that of the GX540-CLAR is Anti-Reflection (AR) coating. The suffix common to the both variations, “-CL”, means that the tint of the backlight is Clear Base (vs. Blue Base, another popular tint slightly bluish).

RadiCS is application software to be installed in each workstation offering worry-free quality control of the diagnostic monitors including the RadiForce GX540 based on the QC standards and guidelines and is capable of quantitative tests and visual tests defined by them. The RadiCS is included in this 510(k) submission as an accessory to the RadiForce GX540.

## **7. Intended Use**

This product is intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications.

## 8. Comparison of Technological Characteristics

The comparison table below enumerates information derived from the product brochure of the each device and other differences are discussed:

Attributes	EIZO RadiForce GX540	Barco MDMG-5221	Explanation of Differences
<b>Display Performance/Specifications</b>			
<b>Response Time (typical)</b>	<b>25 ms (On/Off)</b>	<b>15 ms (Tr + Tf)</b>	<b>EIZO uses typical data provided by the panel manufacturer. See main text for further explanation.</b>
Resolution or Matrix Size	5MP (2,048 x 2,560)	5MP (2,048 x 2,560)	-
Screen Technology	TFT Monochrome LCD Panel (IPS)	TFT (Monochrome) AMLCD Dual Domain IPS WideView	-
<i>Backlighting</i>	<i>LED</i>	<i>CCFL</i>	See main text for further explanation.
<i>Maximum Luminance</i>	<i>1,200 cd/m<sup>2</sup></i>	<i>2,100 cd/m<sup>2</sup></i>	<i>The luminance ratio (max/min) between 250 and 650 generally recommended taking account of the contrast sensitivity of human eyes is available in the proposed devices. EIZO does not see merits of the extremely high luminance offering contrast beyond what the eyes can see.</i>
<i>DICOM Calibrated Luminance</i>	<i>500 cd/m<sup>2</sup></i>	<i>1,000 cd/m<sup>2</sup></i>	
Viewing Angle (H, V)	H: 176°, V: 176°	176°	-
Active Screen Size	337.9 mm x 422.4 mm	337.9 mm x 422.4 mm	-
Aspect Ratio	4:5	4:5	-
Pixel Pitch	0.165 mm x 0.165 mm	0.165 mm x 0.165 mm	-
Contrast Ratio	1200:1	950:1	-
Grayscale Tones	10-bit (DisplayPort): 1,024 from a palette of 16,369 tones 8-bit: 256 from a palette of 16,369 tones	Number of grayscales (LUT in/LUT out): 1024 gray levels (10/12)	-

Attributes	EIZO RadiForce GX540	Barco MDMG-5221	Explanation of Differences
Non-Uniformity Compensation	Digital Uniformity Equalizer (DUE)	Per Pixel Uniformity	The both features are intended to improve uniformity of brightness and color.
<b>Video Signal Input</b>			
Input Video Signals	DVI-D (dual link) x 1, DisplayPort x 1	DVI, DisplayPort	-
Scanning Frequency (H, V)	31 - 135 kHz / 24 - 61 Hz Frame synchronous mode: 24.5 - 25.5 Hz, 49 - 51 Hz	30-150 kHz; 15-80 Hz	-
Dot Clock	290 MHz	280 MHz	-
<b>Power Related Specifications</b>			
Power Requirements	AC 100 - 120 V, 200 - 240 V: 50 / 60 Hz	100 - 240 V	-
Power Consumption	108 W / Less than 0.7 W	125 W (nominal)	-
Power Management	DVI DMPM, DisplayPort 1.1a	DVI-DMPM	-
<b>Miscellaneous Features/Specifications</b>			
QC Software	RadiCS	MediCal QAWeb	-
Sensors	Integrated Front Sensor (IFS)	I-Guard	The both sensors/technologies enable automatic grayscale check and calibration by measuring the luminance at the screen surface.
	Backlight Sensor (BS)	Backlight Output Stabilization (BLOS)?	BS enables backlight brightness stabilization by measuring the backlight brightness directly and the feature is very common to medical displays. The implementation of BLOS on the predicate device is not certain though the feature is mentioned in the overall products brochure.
	Ambient Light Sensor (ALS)	Hemispherical Ambient Light Sensor	-

Attributes	EIZO RadiForce GX540	Barco MDMG-5221	Explanation of Differences
	Presence Sensor (PS)	-	PS detects the absence of the user as a trigger of the power saving mode.
USB Ports / Standard	1 upstream, 2 downstream / Rev. 2.0	1 upstream + 1 endpoint, 2 downstream / Rev. 2.0	-
Dimensions w/o Stand (W x H x D)	388 x 496 x 99 mm	392 x 484 x 123 mm	Different housing design due to the different panel size.

For the substantial equivalence determination, only the difference of the response time needs further evidences by performance testing for the proposed additional usage, “multi-frame digital mammography” or “digital breast tomosynthesis”.

## **9. Performance Testing**

### **9.1. Bench Testing**

The following bench tests were performed on the RadiForce GX540 following instructions in *Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) Submissions*:

- Verification of the conformance to DICOM GSDF as specified in *Assessment of Display Performance for Medical Imaging Systems* by AAPM Task Group 18 (TG18 guideline)
- Measurement of the angular dependency of luminance response in horizontal, vertical and diagonal directions
- Measurement of the luminance non-uniformity characteristics of the display screen as specified in TG18 guideline
- Measurement of the chromaticity non-uniformity characteristics of the display screen as specified in TG18 guideline
- Measurement of the chromaticity at the center of the display screen at 5%, 50% and 95% of the maximum luminance
- Measurement of display reflections including specular, diffuse and haze components
- Measurement of small-spot contrast ratio
- Measurement of spatial resolution expressed as modulation transfer function (MTF)
- Measurement of noise expressed as noise power spectrum (NPS)
- Measurement of pixel aperture ratio
- Visual check of presence or absence of miscellaneous artifacts on the display screen as specified in TG18 guideline
- Measurement of temporal response
- Performance data on luminance stability
- The maximum number allowed for each type of pixel defects/faults agreed with the manufacturer from which EIZO buys the LCD panels for RadiForce GX540

The test results showed that the display characteristics of the RadiForce GX540 meet the pre-defined criteria when criteria are set.

The corresponding testing data of the predicate device, Barco Mammo Tomosynthesis (MDMG-5221), was not available because the device is from other manufacturer.

### **9.2. Clinical Testing**

The goal of the clinical testing was to assess the image quality of tomosynthesis images on the proposed device compared to that on the predicate device.

The results of the testing indicated that the proposed device is at least equivalent to the predicate device for viewing tomosynthesis images, especially lesions like masses, micro-calcifications and architectural distortions within the images.

### **9.3. Animal Testing**

No animal testing was performed on the RadiForce GX540.

### **10. Conclusion**

The RadiForce GX540 was determined to be substantially equivalent to the predicate device due to the following reasons:

- The stated intended use is substantially the same as that of the predicate device.
- It was confirmed that the technological characteristics different from those of the predicate device do not affect the safety and the effectiveness except one item, which was determined that it would not affect observer's performance based on the results of the clinical testing.