DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 19, 2016

EIZO Corporation
% Mr. Hiroaki Hashimoto
Manager
153 Shimokashiwano
Hakusan, Ishikawa 924-8566
JAPAN

Re: K162497
Trade/Device Name: 5MP Monochrome LCD Monitor, Radiforce GX550, GX550-AR
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: September 2, 2016
Received: September 7, 2016

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. 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,

For

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162497

Device Name
5MP Monochrome LCD Monitor, RadiForce GX550, GX550-AR

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

EIZO Corporation, 153 Shimokashiwano, Hakusan, Ishikawa
924-8566 Japan

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Name Hiroaki Hashimoto
Department Medical System Standards

Telephone +81 (76) 274-2468
Fax +81 (76) 274-2484
E-Mail hiroaki.hashimoto@eizo.com

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

1. Company

EIZO Corporation
153 Shimokashiwano, Hakusan
Ishikawa 924-8566 Japan
Tel: +81 (76) 274-2468
Fax: +81 (76) 274-2484

2. Contact Person

Hiroaki Hashimoto

3. Date of Summary

September 2nd, 2016

4. Device Information

- Trade Name/Model: RadiForce GX550, GX550-AR
- Common Name: 5MP Monochrome LCD Monitor
- Classification Name: Display, Diagnostic Radiology
- Regulation Number: 21 CFR 892.2050, Product Code PGY

5. Predicate Device

- 5MP Monochrome LCD Monitor, RadiForce GX540 (K151883)

6. Device Description

RadiForce GX550 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, GX550 and GX550-AR. The difference of the two variations is the surface treatment of the display screens; the surface treatment of the GX550 is Anti-Glare (AG) treatment and that of the GX550-AR is Anti-Reflection (AR) coating.

RadiCS is application software to be installed in each workstation offering worry-free quality control of the diagnostic monitors including the RadiForce GX550 based on the QC standards and guidelines and is capable of quantitative tests and visual tests defined by them. The RadiCS and its subset, RadiCS LE, are included in this 510(k) submission as an accessory to the RadiForce GX550.

7. Indications for 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 different technological characteristics are discussed in it:

Attributes	RadiForce GX550	RadiForce GX540	Explanation of Differences
Display Performance/Specifications			
Screen technology	TFT Monochrome LCD Panel (IPS)	TFT Monochrome LCD Panel (IPS)	-
Viewing angle (H, V)	H: 178°, V: 178°	H: 176°, V: 176°	-
Resolution	5MP (2,048 x 2,560)	5MP (2,048 x 2,560)	-
Aspect ratio	4 : 5	4 : 5	
Active screen size	337.9 mm x 422.4 mm	337.9 mm x 422.4 mm	
Pixel pitch	0.165 mm x 0.165 mm	0.165 mm x 0.165 mm	-
Maximum luminance	2,000 cd/m^2	1,200 cd/m^2	-
DICOM calibrated luminance	600 cd/m^2	500 cd/m^2	
Contrast ratio	1500 : 1	1200:1	-
Response Time (typical)	25 ms (On/Off)	25 ms (On/Off)	-
Backlighting	LED	LED	-
Grayscale Tones	10-bit (DisplayPort): 1,024 from a palette of 16,369 tones 8-bit: 256 from a palette of 16,369 tones	10-bit (DisplayPort): 1,024 from a palette of 16,369 tones 8-bit: 256 from a palette of 16,369 tones	-
Luminance non-uniformity compensation	Digital Uniformity Equalizer	Digital Uniformity Equalizer	-
Video Signals			
Input video signals	DVI-D (dual link) x 1, DisplayPort x 1	DVI-D (dual link) x 1, DisplayPort x 1	-
Output video signals	DisplayPort x 1 (daisy chain)	-	-
Scanning Frequency (H, V)	31 - 135 kHz / 23 - 61 Hz Frame synchronous mode: 23.5 - 25.5 Hz, 47 - 51 Hz	31 - 135 kHz / 24 - 61 Hz Frame synchronous mode: 24.5 - 25.5 Hz, 49 - 51 Hz	-

Power Related Specifications			
Power Requirements	AC 100 - 240 V: 50 / 60 Hz	AC 100 - 120 V, 200 - 240 V: 50 / 60 Hz	-
Power Consumption / Save Mode	95 W / Less than 1 W	108 W / Less than 0.7 W	Compared with the predicate device, the proposed device consumes less power in the operating mode and more power in the power saving mode.
Power Management	DVI DMPM, DisplayPort 1.2a	DVI DMPM, DisplayPort 1.1a	-
Miscellaneous Features/Specifications			
QC software	RadiCS	RadiCS	-
Sensors	Backlight Sensor, Integrated Front Sensor, Presence Sensor, Ambient Light Sensor	Backlight Sensor, Integrated Front Sensor, Presence Sensor, Ambient Light Sensor	-
USB Ports / Standard	1 upstream, 2 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	-
Dimensions w/o stand (W x H x D)	367 x 452 x 78 mm	388 x 496 x 99 mm	Different housing design.

It is clear that the technological characteristics differences discussed above do not affect the safety and the effectiveness of the GX550.

9. Performance Testing

The bench tests below were performed on the RadiForce GX550 following the 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

The test results showed that the RadiForce GX550 has display characteristics equivalent to those of the predicate device, RadiForce GX540.

Besides, the display characteristics of the RadiForce GX550 meet the pre-defined criteria when criteria are set.

No animal or clinical testing was performed on the RadiForce GX550.

10. Conclusion

The RadiForce GX550 was determined to be substantially equivalent to the predicate device due to the following reasons:

- The stated intended use is completely the same as that of the predicate device.
- It was confirmed that the technological characteristics differences from those of the predicate device do not affect the safety or the effectiveness.

The bench tests demonstrated that the display characteristics are equivalent to those of the predicate device.