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

August 24th, 2018

Re: K181609
Trade/Device Name: RadiForce GX560, GX560-AR
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: June 15, 2018
Received: June 19, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181609

Device Name
RadiForce GX560, GX560-AR

Indications for Use *(Describe)*
This product is indicated for use in displaying radiological images (including full-field digital mammography and digital breast tomosynthesis) for review, analysis, and diagnosis by trained medical practitioners.

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.

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510(k) Summary

1. Submitter

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Contact Person: Hiroaki Hashimoto
Date of Prepared: June 15th, 2018

2. Device

- Name of Device: RadiForce GX560, GX560-AR
- Common or Usual Name: 54.1 cm (21.3 inch) class Monochrome LCD Monitor
- Classification Name: Picture archiving and communications system (21 CFR 892.2050)
- Regulatory Class: II
- Product Code: PGY

3. Predicate Device

EIZO Corporation
RadiForce GX550, GX550-AR (K162497)

4. Device Description

RadiForce GX560 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, GX560 and GX560-AR. The difference of the two variations is the surface treatment of the display screens; the surface treatment of the GX560 is Anti-Glare (AG) treatment and that of the GX560-AR is Anti-Reflection (AR) coating.

Two GX560 monitors mounted on a single stand configuration is available identified by with “MD” like GX560-MD and GX560-AR-MD.

RadiCS is application software to be installed in each workstation offering worry-free quality control of the diagnostic monitors including the RadiForce GX560 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 GX560.

5. Indications for use

This product is indicated for use in displaying radiological images (including full-field digital mammography and digital breast tomosynthesis) for review, analysis, and diagnosis by trained medical practitioners.

6. Comparison of Technological Characteristics with the predicate device

The comparison table below enumerates information derived from the product brochure and measured values of the each device and different technological characteristics are discussed in it:

Attributes	Proposed Device: RadiForce GX560	Predicate Device: RadiForce GX550
Display Technology		
	TFT Monochrome LCD Panel (IPS)	TFT Monochrome LCD Panel (IPS)
Screen size		
	54.1cm / 21.3" Aspect ratio: 4 : 5	54.1cm / 21.3" Aspect ratio: 4 : 5
Backlight type		
	LED	LED
Frame rate and refresh rate		
Digital Scanning Frequency (H / V)	31 - 135 kHz / 23 - 61 Hz Frame synchronous mode: 23.5 - 25.5 Hz, 47 - 51 Hz	31 - 135 kHz / 23 - 61 Hz Frame synchronous mode: 23.5 - 25.5 Hz, 47 - 51 Hz
Display Interface		
Input video signals	DVI-D (dual link) x 1, DisplayPort x 2	DVI-D (dual link) x 1, DisplayPort x 1
Output video signals	DisplayPort x 1 (daisy chain)	DisplayPort x 1 (daisy chain)
Video bandwidth		
	DVI : 290MHz DisplayPort : 290MHz	DVI : 290MHz DisplayPort : 290MHz
Ambient light sensing		
Ambient light sensor	Yes	Yes
Luminance calibration tools		
	Integrated optical sensor External optical sensor Calibration software: RadiCS	Integrated optical sensor External optical sensor Calibration software: RadiCS
Quality-control procedures		
	Software: RadiCS	Software: RadiCS

It is clear that the technological characteristics differences discussed above do not affect the safety and the effectiveness of the GX560.

7. Performance Testing

The bench tests below were performed on the RadiForce GX560 following the instructions in "*Guidance for Industry and FDA Staff: Display Devices for Diagnostic Radiology"* issued on October 2, 2017:

- Measurement of spatial resolution expressed as modulation transfer function (MTF)
- The maximum number allowed for each type of pixel defects/faults
- Visual check of presence or absence of miscellaneous artifacts on the display screen as specified in TG18 guideline
- Measurement of temporal response
- Measurement of Luminance
- 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
- Performance data on luminance stability
- Measurement of noise expressed as noise power spectrum (NPS)
- Measurement of display reflections including specular, diffuse and haze components
- Measurement of small-spot contrast ratio
- Measurement of pixel aperture ratio

The test results showed that the RadiForce GX560 has display characteristics equivalent to those of the predicate device, RadiForce GX550.

Besides, the display characteristics of the RadiForce GX560 meet the pre-defined criteria when criteria are set.

No animal or clinical testing was performed on the RadiForce GX560.

8. Conclusion

The RadiForce GX560 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 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.