



PZMedical Technology Co., Ltd.
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

August 23, 2021

Re: K212105

Trade/Device Name: 6543Z, 4386Z, 4343Z, 4343ZF, 3543Z, 3543ZF, 3030Z, 3025Z, 3025ZF
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: July 1, 2021
Received: July 6, 2021

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K212105

Device Name

6543Z, 4386Z, 4343Z, 4343ZF, 3543Z, 3543ZF, 3030Z, 3025Z, 3025ZF;

Indications for Use (Describe)

Solid State X-ray Imager (Flat Panel/Digital Imager) Indicated for use in generating radiographic images of human anatomy. Intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures, excluding dental, fluoroscopic, angiographic, and mammographic 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.

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510(k) Summary K212105



**PZMEDICAL TECHNOLOGY CO., LTD.
5F, Building 13
No. 2 Suide Road
Putuo District Shanghai, CN 200331**

1. Administrative Information

Submitter: PZMEDICAL TECHNOLOGY CO., LTD.
Submission contact person: Thomas Gourgon tgourgon@pzimaging.com
Contact telephone: 310-381-3800
Date prepared: July 23, 2021

2. Identification: 6543Z, 4386Z, 4343Z, 4343ZF, 3543Z, 3543ZF, 3030Z, 3025Z, 3025ZF
Classification Name: Stationary X-Ray System
Classification Panel: Radiology
Classification Regulation: 21 CFR §892.1680
Device Class: Class II
Product Code: MQB

3. Substantially equivalent device:

Manufacturer: PZMEDICAL TECHNOLOGY CO., LTD.
Trade Name: Models 3543A, 4343A, 2929A and A843B
510(k) Number: K170480
Classification Name: Stationary X-Ray System
Classification Panel: Radiology
Classification Regulation: 21 CFR §892.1680
Device Class: Class II
Product Code: MQB

4. Device description:

The PZMEDICAL devices are used in medical x-ray imaging systems. The product can only be used by trained personnel of medical facilities. The product is only used for diagnostic x-ray image acquisition applications. The flat panel detector consists of a CsI scintillator screen and thin-film transistors. The scintillator screen converts the x-rays into visible light. Thin-film transistors convert the visible light to an electrical charge. The flat panel detector can then obtain a digital image by analog to digital conversion and associated circuits. These panels can be used to acquire diagnostic x-ray images as an upgrade to traditional film systems. They can be used wired (Ethernet) or wirelessly (Wi-Fi) and are powered either by AC Line or by rechargeable batteries. The various models are constructed similarly to our previous models cleared in K170480. The suffix "ZF" means FINE pixel size, 99 µm Z means standard pixel size, 139 µm. All models have a battery life indicator. The supporting software PZDR is functionally the same as provided with the predicate. The software performs acquisition of the RAW image and converts it to DICOM format and performs operations as described in the comparison table below. It is functionally unchanged from the predicate software.

This software consists of following modules which provides a work flow of patient study:
 --Patient Management: including patient registration, work list, study management.
 --Study operation: including body part selection, study items selection, image acquisition.
 --Image preview: including display, layout and processing of image. Also tool options for advanced operation.
 --Configuration: including configuration of system, study and user management, especially the configuration for work list and storage.

5. **Indications for Use:** Solid State X-ray Imagers (Flat Panel/Digital Imager) Indicated for use in generating radiographic images of human anatomy. Intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures, excluding dental, fluoroscopic, angiographic, and mammographic applications.

6. **Technological characteristics:** Comparison Table

Comparable Properties	K170480 Models 3543A, 4343A, 2929A and A843B	6543Z, 4386Z, 4343Z, 4343ZF, 3543Z, 3543ZF, 3030Z, 3025Z, 3025ZF	Comparison Results
Indications for use	Solid State X-ray Imagers (Flat Panel/Digital Imager) are indicated for use in generating radiographic images of human anatomy. They are intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures, excluding dental, fluoroscopic, angiographic, and mammographic applications.	Solid State X-ray Imagers (Flat Panel/Digital Imager) Indicated for use in generating radiographic images of human anatomy. Intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures, excluding dental, fluoroscopic, angiographic, and mammographic applications.	SAME
Digital X-Ray Detectors	Models 3543A, 4343A, 2929A and A843B	6543Z, 4386Z, 4343Z, 4343ZF, 3543Z, 3543ZF, 3030Z, 3025Z, 3025ZF	New Models
Detector Sizes (Inches)	12 x 12 inch 14 x 17 inch 17 x 17 inch 42 x 17, inch	12x10 inch 12x12 inch 14 x 17 inch 17 x 17 inch 26x17 inch 34x 14 inch	The 42 inch size remains available but three new sizes are added.

Comparable Properties	K170480 Models 3543A, 4343A, 2929A and A843B	6543Z, 4386Z, 4343Z, 4343ZF, 3543Z, 3543ZF, 3030Z, 3025Z, 3025ZF	Comparison Results																				
Pixel Pitch	140 μm	<table border="1"> <thead> <tr> <th>Model</th> <th>Pixel Pitch (μm)</th> </tr> </thead> <tbody> <tr><td>3025Z</td><td>139</td></tr> <tr><td>3025ZF</td><td>77</td></tr> <tr><td>3030Z</td><td>139</td></tr> <tr><td>3543Z</td><td>139</td></tr> <tr><td>3543ZF</td><td>99</td></tr> <tr><td>4343Z</td><td>139</td></tr> <tr><td>4343ZF</td><td>99</td></tr> <tr><td>4386Z</td><td>139</td></tr> <tr><td>6543Z</td><td>139</td></tr> </tbody> </table>	Model	Pixel Pitch (μm)	3025Z	139	3025ZF	77	3030Z	139	3543Z	139	3543ZF	99	4343Z	139	4343ZF	99	4386Z	139	6543Z	139	Similar to or better than predicate
Model	Pixel Pitch (μm)																						
3025Z	139																						
3025ZF	77																						
3030Z	139																						
3543Z	139																						
3543ZF	99																						
4343Z	139																						
4343ZF	99																						
4386Z	139																						
6543Z	139																						
Limiting Resolution	3.6 lp/mm	<table border="1"> <thead> <tr> <th>Model</th> <th>(lp/mm)</th> </tr> </thead> <tbody> <tr><td>3025Z</td><td>3.6</td></tr> <tr><td>3025ZF</td><td>5.9</td></tr> <tr><td>3030Z</td><td>3.6</td></tr> <tr><td>3543Z</td><td>3.6</td></tr> <tr><td>3543ZF</td><td>4.9</td></tr> <tr><td>4343Z</td><td>3.6</td></tr> <tr><td>4343ZF</td><td>4.9</td></tr> <tr><td>4386Z</td><td>3.6</td></tr> <tr><td>6543Z</td><td>3.6</td></tr> </tbody> </table>	Model	(lp/mm)	3025Z	3.6	3025ZF	5.9	3030Z	3.6	3543Z	3.6	3543ZF	4.9	4343Z	3.6	4343ZF	4.9	4386Z	3.6	6543Z	3.6	Same as or better than predicate
Model	(lp/mm)																						
3025Z	3.6																						
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3543Z	3.6																						
3543ZF	4.9																						
4343Z	3.6																						
4343ZF	4.9																						
4386Z	3.6																						
6543Z	3.6																						
DQE	32% at 2 lp/mm (Csl) 15% at 2 lp/mm (GOS)	<p>The DQE values at 2 lp/mm are listed in the table below (only for Csl):</p> <table border="1"> <tbody> <tr> <td>3025ZF</td> <td>3543ZF 4343ZF</td> <td>6543Z; 4386Z; 4343Z; 3543Z; 3030Z; 3025Z</td> </tr> <tr> <td>36%</td> <td>37%</td> <td>35%</td> </tr> </tbody> </table>	3025ZF	3543ZF 4343ZF	6543Z; 4386Z; 4343Z; 3543Z; 3030Z; 3025Z	36%	37%	35%	Similar performance, Only CSI is offered in the new models														
3025ZF	3543ZF 4343ZF	6543Z; 4386Z; 4343Z; 3543Z; 3030Z; 3025Z																					
36%	37%	35%																					
MTF	33% at 2 lp/mm (Csl) 24% at 2 lp/mm (GOS)	<p>The MTF value at 2 lp/mm are listed in the table below (only for Csl):</p> <table border="1"> <tbody> <tr> <td>3025ZF</td> <td>3543ZF 4343ZF</td> <td>6543Z 4386Z 4343Z 3543Z 3030Z 3025Z</td> </tr> <tr> <td>43%</td> <td>42%</td> <td>39%</td> </tr> </tbody> </table>	3025ZF	3543ZF 4343ZF	6543Z 4386Z 4343Z 3543Z 3030Z 3025Z	43%	42%	39%	Similar or better performance														
3025ZF	3543ZF 4343ZF	6543Z 4386Z 4343Z 3543Z 3030Z 3025Z																					
43%	42%	39%																					
A/D Conversion	16 bit	16 bit	SAME																				

Comparable Properties	K170480 Models 3543A, 4343A, 2929A and A843B	6543Z, 4386Z, 4343Z, 4343ZF, 3543Z, 3543ZF, 3030Z, 3025Z, 3025ZF	Comparison Results																				
Active Area	4343A: 430.08 x 430.08 mm or 16.9 x 16.9 inch 3543A: 350.00 x 427.28 mm or 13.8 x 16.8 inch 2929A: 286.72 x 286.72 mm or 11.3 x 11.3 inch A843B: 1075.2 x 430.08 mm or 42.3 x 16.9 inch	<table border="1"> <thead> <tr> <th>Model</th> <th>Active Area</th> </tr> </thead> <tbody> <tr> <td>3025Z</td> <td>290x250 mm or 11.4x9.8 inch</td> </tr> <tr> <td>3025ZF</td> <td>300x240 mm or 11.8x9.4 inch</td> </tr> <tr> <td>3030Z</td> <td>290x290 mm or 11.4x11.4 inch</td> </tr> <tr> <td>3543Z</td> <td>350x430 mm or 13.8 x 16.8 inch</td> </tr> <tr> <td>3543ZF</td> <td>350x430 mm or 13.8 x 16.8 inch</td> </tr> <tr> <td>4343Z</td> <td>430x430 mm or 16.9 x 16.9 inch</td> </tr> <tr> <td>4343ZF</td> <td>430x430 mm or 16.9 x 16.9 inch</td> </tr> <tr> <td>4386Z</td> <td>430x860 mm or 13.8x33.5 inch</td> </tr> <tr> <td>6543Z</td> <td>650x430 mm or 25.6x16.9 inch</td> </tr> </tbody> </table>	Model	Active Area	3025Z	290x250 mm or 11.4x9.8 inch	3025ZF	300x240 mm or 11.8x9.4 inch	3030Z	290x290 mm or 11.4x11.4 inch	3543Z	350x430 mm or 13.8 x 16.8 inch	3543ZF	350x430 mm or 13.8 x 16.8 inch	4343Z	430x430 mm or 16.9 x 16.9 inch	4343ZF	430x430 mm or 16.9 x 16.9 inch	4386Z	430x860 mm or 13.8x33.5 inch	6543Z	650x430 mm or 25.6x16.9 inch	Similar range of active areas
Model	Active Area																						
3025Z	290x250 mm or 11.4x9.8 inch																						
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4386Z	430x860 mm or 13.8x33.5 inch																						
6543Z	650x430 mm or 25.6x16.9 inch																						
Dimensions	4343A: 460 x 460 x 15 mm 3543A: 383 x 460 x 15 mm 2929A: 316 x 316 x 15 mm A843B: 1120 x 465 x 20 mm	<table border="1"> <thead> <tr> <th>Model</th> <th>Dimensions (W xL xH)</th> </tr> </thead> <tbody> <tr> <td>3025Z</td> <td>315x278x15 mm</td> </tr> <tr> <td>3025ZF</td> <td>328x268x15 mm</td> </tr> <tr> <td>3030Z</td> <td>315x315x15 mm</td> </tr> <tr> <td>3543Z</td> <td>460x383x15 mm</td> </tr> <tr> <td>3543ZF</td> <td>460x383x15 mm</td> </tr> <tr> <td>4343Z</td> <td>460x460x15 mm</td> </tr> <tr> <td>4343ZF</td> <td>460x460x15 mm</td> </tr> <tr> <td>4386Z</td> <td>891x383x15 mm</td> </tr> <tr> <td>6543Z</td> <td>460x676x15 mm</td> </tr> </tbody> </table>	Model	Dimensions (W xL xH)	3025Z	315x278x15 mm	3025ZF	328x268x15 mm	3030Z	315x315x15 mm	3543Z	460x383x15 mm	3543ZF	460x383x15 mm	4343Z	460x460x15 mm	4343ZF	460x460x15 mm	4386Z	891x383x15 mm	6543Z	460x676x15 mm	Similar range of dimensions
Model	Dimensions (W xL xH)																						
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Weights	4343A: 4.3 kg (wireless, w/ batteries) 4.3 kg (wired, w/o batteries) 3543A: 3.3 kg (wireless, w/ batteries) 2.9 kg (wired, w/o batteries) 2929A: 1.8 kg (wireless, w/ batteries) 1.5 kg (wired, w/o batteries) A843B: 11.6 kg (wireless, w/ batteries) 10.9 kg (wired, w/o batteries)	<table border="1"> <thead> <tr> <th>Model</th> <th>Weights</th> </tr> </thead> <tbody> <tr> <td>3025Z</td> <td>1.7kg(wireless, w/ batteries) 1.5 kg(wired, w/o batteries)</td> </tr> <tr> <td>3025ZF</td> <td>1.7kg(wireless, w/ batteries) 1.5 kg(wired, w/o batteries)</td> </tr> <tr> <td>3030Z</td> <td>2.1 kg(wireless, w/ batteries) 1.9 kg(wired, w/o batteries)</td> </tr> <tr> <td>3543Z</td> <td>3.1 kg (wireless, w/ batteries) 2.7 kg (wired, w/o batteries)</td> </tr> <tr> <td>3543ZF</td> <td>3.1 kg (wireless, w/ batteries) 2.7 kg (wired, w/o batteries)</td> </tr> <tr> <td>4343Z</td> <td>3.6 kg (wireless, w/ batteries) 3.2 kg (wired, w/o batteries)</td> </tr> <tr> <td>4343ZF</td> <td>3.6 kg (wireless, w/ batteries) 3.2 kg (wired, w/o batteries)</td> </tr> <tr> <td>4386Z</td> <td>3.7kg(wireless, w/ batteries) 3.4kg(wired, w/o batteries)</td> </tr> <tr> <td>6543Z</td> <td>7.5kg (wireless, w/ batteries) 7.0kg(wired, w/o batteries)</td> </tr> </tbody> </table>	Model	Weights	3025Z	1.7kg(wireless, w/ batteries) 1.5 kg(wired, w/o batteries)	3025ZF	1.7kg(wireless, w/ batteries) 1.5 kg(wired, w/o batteries)	3030Z	2.1 kg(wireless, w/ batteries) 1.9 kg(wired, w/o batteries)	3543Z	3.1 kg (wireless, w/ batteries) 2.7 kg (wired, w/o batteries)	3543ZF	3.1 kg (wireless, w/ batteries) 2.7 kg (wired, w/o batteries)	4343Z	3.6 kg (wireless, w/ batteries) 3.2 kg (wired, w/o batteries)	4343ZF	3.6 kg (wireless, w/ batteries) 3.2 kg (wired, w/o batteries)	4386Z	3.7kg(wireless, w/ batteries) 3.4kg(wired, w/o batteries)	6543Z	7.5kg (wireless, w/ batteries) 7.0kg(wired, w/o batteries)	Similar range
Model	Weights																						
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Comparable Properties	K170480 Models 3543A, 4343A, 2929A and A843B	6543Z, 4386Z, 4343Z, 4343ZF, 3543Z, 3543ZF, 3030Z, 3025Z, 3025ZF	Comparison Results																				
Pixels	3543A: 2500 x 3052 (7.6 Million) 4343A: 3072 x 3072 (9.4 Million) 2929A: 2048 x 2048 (4.2 Million) A843B: 7680 x 3072 (23.6 Million)	<table border="1"> <thead> <tr> <th>Model</th> <th>Pixels</th> </tr> </thead> <tbody> <tr> <td>3025Z</td> <td>2048x1792 (3.7 Million)</td> </tr> <tr> <td>3025ZF</td> <td>3108x3956 (12.3 Million)</td> </tr> <tr> <td>3030Z</td> <td>2048x2048 (4.2 Million)</td> </tr> <tr> <td>3543Z</td> <td>2500x3052 (7.6 Million)</td> </tr> <tr> <td>3543ZF</td> <td>3534x4302 (15.2 Million)</td> </tr> <tr> <td>4343Z</td> <td>3072x3072 (9.4 Million)</td> </tr> <tr> <td>4343ZF</td> <td>4302x4302 (18.5 Million)</td> </tr> <tr> <td>4386Z</td> <td>3072x6144 (18.9 Million)</td> </tr> <tr> <td>6543Z</td> <td>4608x3072 (14.2 Million)</td> </tr> </tbody> </table>	Model	Pixels	3025Z	2048x1792 (3.7 Million)	3025ZF	3108x3956 (12.3 Million)	3030Z	2048x2048 (4.2 Million)	3543Z	2500x3052 (7.6 Million)	3543ZF	3534x4302 (15.2 Million)	4343Z	3072x3072 (9.4 Million)	4343ZF	4302x4302 (18.5 Million)	4386Z	3072x6144 (18.9 Million)	6543Z	4608x3072 (14.2 Million)	Similar range
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6543Z	4608x3072 (14.2 Million)																						
Interface	Wired: Gigabit Ethernet (1000Base-T) Wireless: IEEE802.11ac, backward compatible	Wired: Gigabit Ethernet (1000Base-T) Wireless: IEEE802.11ac, backward compatible	SAME																				
Power Source	AC Line and/or Rechargeable Lithium Battery	AC Line and/or Rechargeable Lithium Battery	SAME																				
Electrical safety and EMC	Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2 as well as IEEE 802.11ac. Meets FCC requirements.	Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2 as well as IEEE 802.11ac. Meets FCC requirements.	SAME																				
Standards	Same as below	See below	SAME																				
Software Related																							
Software	Outputs a DICOM image	Outputs a DICOM image	SAME																				
SW Name	PZDR	PZDR	SAME																				
DICOM	Yes	Yes	SAME																				
DICOM Image Transmission	Yes	Yes	SAME																				
Image Acquisition Interface	Yes	Yes	SAME																				
Patient Body Part Selection	Yes	Yes	SAME																				
Image Processing	Yes	Yes	SAME																				
Basic Image Editing and Marking (pan, zooming, window/level adjusting, text marking)	Yes	Yes	SAME																				
Image Browsing	Yes	Yes	SAME																				

Comparable Properties	K170480 Models 3543A, 4343A, 2929A and A843B	6543Z, 4386Z, 4343Z, 4343ZF, 3543Z, 3543ZF, 3030Z, 3025Z, 3025ZF	Comparison Results
Patient Registration and Management	Yes	Yes	SAME
Local registration of patient information	Yes	Yes	SAME
Quick registration	Yes	Yes	SAME
Checking/modification of patient's information	Yes	Yes	SAME
Image acquisition interface	Yes	Yes	SAME
Deletion of record	Yes	Yes	SAME
Image processing parameter setting	Yes	Yes	SAME
Image browsing (Zooming, Marker, Text, Window/Width Adjustment, Moving, ROI, Clipping, Rotation,	Yes	Yes	SAME
Dicom image transmission	Yes	Yes	SAME
Image exporting to CD	Yes	Yes	SAME
Image printing (w/ printer setting)	Yes	Yes	SAME
System management (detector selection, storage setting)	Yes	Yes	SAME
Management of inspection (Patient size selection of large, medium, thin, children; patient position of standing or lying; patient imaging body part)	Yes	Yes	SAME
Setting of image processing methods (strong/medium/soft)	Yes	Yes	SAME
Option for image display (position, text information, etc.)	Yes	Yes	SAME
System logout	Yes	Yes	SAME

Non clinical testing: Testing was performed successfully according to the following standards:

Standard Developing Organization	Standard Designation Number And Date	Title Of Standard
ANSI/AAMI	ANSI/AAMI ES60601-1: 2005 +C1:2009 +A2:2020 +A1:3012	Medical Electrical Equipment Part 1: General Requirements For Basic Safety And Essential Performance
IEC	60601-1-2:2014	Medical Electrical Equipment Part 12: General Requirements For Basic Safety And Essential Performance Collateral Standard: Electromagnetic Disturbances Requirements And Tests

The AC to DC power supply is UL Listed as a medical grade power supply.

In recognition of possible cybersecurity threats to the software, we consulted this guidance: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff*. As a result, we updated our own internal standard operating procedures and added cybersecurity precautions to the software users' manuals.

Since the three new digital receptor panels have not had previous FDA clearance, testing was performed according to the FDA guidance document: *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices, Guidance for Industry and Food and Drug Administration Staff*.

7. Clinical testing. Not required for a determination of substantial equivalence.

8. Substantial Equivalence Discussion.

These updated digital x-ray receptor panels and software perform the same functions using the same technological methods to produce diagnostic x-ray images as the predicate. In all material aspects, the new panel models and software are substantially equivalent to each other.

9. Substantial Equivalence Conclusion:

After analyzing bench test results, risk analysis, and clinical evaluation, it is the conclusion of PZMEDICAL that the new models of digital x-ray imaging panels are as safe and effective as the predicate devices, have few technological differences, and has the same indications for use, thus rendering them substantially equivalent to the predicate device.