DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 7, 2017

Shanghai PZ Medical Technology Co., Ltd.
% Jeff Moeller
Vice President
OrganizeUS, Inc.
8317 Lakeside Drive
Downers Grove, Illinois 60516

Re: K170480
Trade/Device Name: Models 3543A, 4343A, 2929A and A843B
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MQB
Dated: April 30, 2017
Received: May 5, 2017

Dear Jeff Moeller:

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,

Michael D. O'Hara For

Robert A. 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)*
K170480

Device Name
Models 3543A, 4343A, 2929A and A843B

Indications for Use *(Describe)*
Model#'s 3543A, 4343A, 2929A and A843B; Solid State X-ray Imager (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. As prescribed by a licensed physician

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.

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**OrganizeUS, Inc.**
**8317 Lakeside Drive**
**Downers Grove, IL 60516**

# 510(k) Summary

(Revised 06/30/17)

Owners name: Shanghai PZ Medical Technology Co., Ltd.
5F, Building 13 No.2 Suide Road
200331 Shanghai

Contact person / firm: OrganizeUS, Inc.
8317 Lakeside Drive
Downers Grove, IL 60516
847-337-3004
Jeff Moeller, Vice President

Date: March 17, 2017

Trade name: Models 3543A, 4343A, 2929A and A843B

Common name: Solid State X-Ray Imager (Flat Panel/Digital Imager)

Classification name: Stationary X-Ray system, 892.1680, code MQB

Predicate devices: Atlaim's model ATAL 9 – K152151
Stationary X-Ray system, 892.1680, code MQB

IRAY model 1417 – K161730
Stationary X-Ray system, 892.1680, code MQB

CareRay model Care view 1500C & 1500L – K153058
Stationary X-Ray system, 892.1680, code MQB

Description: Our device is 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 single image diagnosis applications. The flat panel detector consists of GOS 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.

Intended use: Model#'s 3543A, 4343A, 2929A and A843B; Solid State X-ray Imager (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. As prescribed by a licensed physician.

Technological: Refer to the table below (2 pages)

| **Characteristic** | **Atlaim ATAL 9 K152151** | **PZMedical 4343A,3543A,2929A,A843B** |
|---|---|---|
| Intended Use | Indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures, excluding fluoroscopic, angiographic, and mammographic applications. | Model#'s 3543A, 4343A, 2929A and A843B; Solid State X-ray Imager (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. As prescribed by a licensed physician. |
| Configuration | This submission is for the Digital Panel and Software only, no generator or stand provided. | This submission is for the Digital Panel and Software only, no generator or stand provided. |
| Digital Panel | Atlaim ATAL 9 | PZMedical 4343A,3543A,2929A,A843B |
| Scintillator | GOS/CsI | GOS/CsI |
| Pixel Pitch | 139 µm | 140 µm |
| Limiting Resolution | Over 3 lp/mm | 3.6 lp/mm |
| DQE | 26% at 2 lp/mm (CsI) Not specified for GOS | 32% at 2 lp/mm (CsI) 15% at 2 lp/mm (GOS) |
| MTF | 42% at 2 lp/mm (CsI) Not specified for GOS | 33% at 2 lp/mm (CsI) 24% at 2 lp/mm (GOS) |
| A/D Conversion | 16 bit | 16 bit |
| Active Area | 17 x 17 inch | 4343A: 430.08 x 430.08 mm or 16.9 x 16.9 inch<br>3543A: 350.00 x 427.28 mm or 13.8 x 16.8 inch<br>2929A: 286.72 x 286.72 mm or 11.3 x 11.3 inch<br>A843B: 1075.2 x 430.08 mm or 42.3 x 16.9 inch |
| Dimensions | 460(W)×461(L)×15(H) | 4343A: 460 x 460 x 15 mm<br>3543A: 383 x 460 x 15 mm<br>2929A: 316 x 316 x 15 mm<br>A843B: 1120 x 465 x 20 mm |
| Weights | 2.9kg (2.4kg w/o Battery) (up to 10 hours of battery life) | 4343A: 4.3 kg (wireless, w/ batteries) 4.3 kg (wired, w/o batteries)<br>3543A: 3.3 kg (wireless, w/ batteries) 2.9 kg (wired, w/o batteries)<br>2929A: 1.8 kg (wireless, w/ batteries) 1.5 kg (wired, w/o batteries)<br>A843B: 11.6 kg (wireless, w/ batteries) 10.9 kg (wired, w/o batteries) |

| | | |
|---|---|---|
| Pixels | 3072 x 3072 (9.4 Million) | 3543A: 2500 x 3052 (7.6 Million)<br>4343A: 3072 x 3072 (9.4 Million)<br>2929A: 2048 x 2048 (4.2 Million)<br>A843B: 7680 x 3072 (23.6 Million) |
| Interface | Wired: Gigabit Ethernet (1000Base-T)<br>Wireless: IEEE802.11ac, backward compatible | Wired: Gigabit Ethernet (1000Base-T)<br>Wireless: IEEE802.11ac, backward compatible |
| Power Source | AC Line and/or Rechargeable Lithium Battery (10 hr run time) | AC Line and/or Rechargeable Lithium Battery |
| Electrical safety and EMC | Electrical Safety per IEC 60601-1 and EMC per<br>IEC 60601-1-2 as well as IEEE 802.11ac.<br>Meets FCC requirements. | Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2 as well as IEEE 802.11ac.<br>Meets FCC requirements. |

## SOFTWARE RELATED

| **Characteristic** | **Atlaim ATAL 9 K152151** | **PZMedical 4343A,3543A,2929A,A843B** |
|---|---|---|
| Software | Outputs a DICOM image | Outputs a DICOM image |
| SW revision | K152151 | PZDR V2.0.1 |
| DICOM | Yes | Yes |
| DICOM Image Transmission | Yes | Yes |
| Image Acquisition Interface | Yes | Yes |
| Patient Body Part Selection | Yes | Yes |
| Image Processing | Yes | Yes |
| Basic Image Editing and Marking (pan, zooming, window/level adjusting, text marking) | Yes | Yes |
| Image Browsing | Yes | Yes |
| Patient Registration and Management | Yes | Yes |

Non-Clinical data:

Testing results have shown that our devices Models 3543A, 4343A, 2929A and A843B, Solid State X-Ray Imager (Flat Panel/Digital Imager) are substantially equivalent to cleared predicate devices.

Atlaim Corporation, Atal 9, K132151
Careray, Care View 1500C / Care View 1500L, K153058
IRay, Wireless Digital Flat Panel Detertor, K161730

Specifically in relation too; DQE, MTF, Quantum limited performance, Effects of aliasing, Sensitivity linearity, Lag, Change in detection sensitivity, Dose requirement and reciprocity changes, Stability of the device characteristics with time, Uniformity of device characteristics, NPS, spatial resolution, Image Acquisition time and Black level.

Clinical data:

We have included comparison images using our devices Models 3543A, 4343A, 2929A and A843B and a Atlaim Atal 9 cleared device (K132151) as direct comparison of the image quality of our devices in order to support substantial equivalence. We believe our image quality is substantially equivalent to cleared predicate devices.

Conclusions:

In accordance with 21 CFR, Part 807 and supported by the information provided in this premarket notification (K170480). Shanghai PZ Medical Technology Co., Ltd. 5F, Building 13 No.2 Suide Road 200331 Shanghai concludes that our devices Models 3543A, 4343A, 2929A and A843B Solid State X-Ray Imager (Flat Panel/Digital Imager) is substantially equivalent to predicate devices in regards to safety and effectiveness.