Allengers Medical Systems Limited
℅ Mr. Sanjeev K. Marjara
Director Technical
Bhankharpur, Mubarakpur Road
Derabassi, Distt Mohali, Punjab 140507
INDIA

October 16, 2019

Re: K192541
Trade/Device Name: DigiX FDX
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR
Dated: September 10, 2019
Received: September 16, 2019

Dear Mr. Sanjeev Marjara:

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

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)*

K192541

Device Name

DigiX FDX

Indications for Use *(Describe)*

The DigiX FDX radiographic systems are used in hospitals, clinics and medical practices. DigiX FDX enables radiographic exposure of the whole body including: Skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. It can also be used for intravenous, small interventions (like biopsy, punctures, etc.) and emergency (trauma critical ill) applications. Exposure may be taken with the Patient's sitting, standing, or in the prone/ supine position.

The DigiX FDX System is not meant for mammography.

The DigiX FDX uses an integrated or portable or fixed or wi-fi digital detector for generating diagnostic images by converting X-Ray into electronics signals. DigiX FDX is also designed to be used with conventional film/screen or Computed Radiography (CR) Cassettes.

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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Allengers Medical Systems Limited

510(k) SUMMARY
K192541

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR 807.92

1. Classification and Device Name

Device (trade) Name:	DigiX FDX
Common/usual Name:	Digital X-Ray imaging system
Classification Name:	Stationary X-Ray system, Class II
Classification:	21 CFR 892.1680
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Device Class:	Class II
Device Code:	KPR
510(K) Submission:	Special

2. Contact Person and Address

Company Name:	Allengers Medical Systems Limited
Address:	Bhankharpur, Mubarakpur Road, Derabassi, Distt Mohali-140507 India
Telephone No:	+91 1762-272600, +91 9872980168
Contact Person:	Sanjeev K. Marjara
Date Prepared:	10 September 2019

3. Predicate Device:

Predicate Device:	DigiX FDX
Classification:	21 CFR 892.1680
Classification Name:	Stationary X-Ray system
Common/usual Name:	Digital X-Ray imaging system
Device Class:	Class II
510(K) Number:	K162529
Product Code:	KPR

4. Secondary Predicate Device:

Secondary Device:	Ysio
Classification:	21 CFR 892.1680
Classification Name:	Stationary X-Ray system
Common/usual Name:	Digital X-Ray imaging system
Device Class:	Class II
510(K) Number:	K081722
Product Code:	KPR

Allengers supplies digital detectors that have been previously cleared by the FDA or tested and evaluated per Guidance for the Submission of 510(k)s for Solid State X-Ray Imaging Devices. Table 1 provides the list of solid state X-Ray image detectors used in device

***Table 1 List of Solid State X-Ray Image Detectors**

Solid State X-Ray Image Detectors	**510(K) Numbers**
Varex PaxScan 4343R – Fixed	K130318
Varex PaxScan 4343R v3– Fixed	K183541
Thales Pixium RAD 4343 C-E (Fixed)	K181279
Varex Paxscan 4343CB - Fixed	K190373
IRAY VENU 1717X – Fixed	--
Varex PaxScan 4336R – Portable	K130318
Varex (Perkin Elmer) XRPAD 4343F	K142698
Varex PaxScan 4336W – Wireless	K142049
Varex (Perkin Elmer) XRPAD 4336 – Wireless	K140551
Varex PaxScan 4336W v4 – Wireless	K183541
Varex PaxScan 4336W v4 + – Wireless	--
Thales Pixium 3543 DR-CS (Wireless)	K182517
IRAY VENU 1417V (Wireless)	--

***** *All the above mentioned Solid State X-Ray Image Detectors (Digital detectors) can be used with Dual Energy Subtraction feature.*

5. Device Description:

The DigiX FDX system is a diagnostic X-Ray system intended for general purpose radiographic imaging of the human body. It is not intended for mammographic imaging.

The DigiX FDX system is comprised of a combination of devices that include a ceiling mounted X-Ray tube suspension, vertical Bucky stand, fixed or mobile patient Bucky table, X-Ray generator, X-Ray tube, beam limiting device, and a solid-state image receptor.

The DigiX FDX systems are not intended to be operated with any other cleared devices, or to be integrated with other software/hardware devices via direct or indirect connections.

The following in Table 2 are the specific components for various configurations of the system. A complete system will consist of a selection of one of the devices in each category.

Table 2 Combination Detail

Component	Manufacture	Model
Ceiling Mounted X-Ray Tube Suspension	Allengers	CSA FDX
Vertical Bucky Stand	Allengers	VBS ADV
Vertical Bucky Stand	Allengers	VBS M XL
Patient Table – Fixed	Allengers	Floatex ADV
Patient Table – Fixed	Allengers	Floatex
Patient Table – Fixed	Allengers	Floatex XL
Patient Table – Mobile	Allengers	MobiT 6C
Patient Table – Mobile	Allengers	MobiT 4C
Patient Table – Mobile	Allengers	MobiT C
X-Ray Generator	Allengers	XGEN-80R
X-Ray Generator	Allengers	XGEN-65R
X-Ray Tube	Varex	A192
X-Ray Tube	Varex	A292
X-Ray Tube	Varex	G292
X-Ray Tube	Varex	G1092
X-Ray Tube	Varex	RAD14
Beam Limiting Device	Ralco	R225 ACS
Solid State X-Ray Image Detector – Fixed	Varex	PaxScan 4343R
Solid State X-Ray Image Detector – Fixed	Varex	PaxScan 4343R v3
Solid State X-Ray Image Detector – Portable Wired	Varex	PaxScan 4336R
Solid State X-Ray Image Detector – Portable Wired	Varex (Perkin Elmer)	XRPAD 4343F
Solid State X-Ray Image Detector – Fixed	Varex	PaxScan 4343CB
Solid State X-Ray Image Detector – Fixed	Thales	Pixium Rad 4343 CE

Solid State X-Ray Image Detector – Fixed	IRAY	VENU 1717X
Solid State X-Ray Image Detector – WiFi	Varex	PaxScan 4336W
Solid State X-Ray Image Detector – WiFi	Varex	PaxScan 4336W V4
Solid State X-Ray Image Detector – WiFi	Varex	PaxScan 4336W V4 +
Solid State X-Ray Image Detector – WiFi	Varex (Perkin Elmer)	XRPAD 4336
Solid State X-Ray Image Detector – WiFi	Thales	Pixium 3543DR-CS
Solid State X-Ray Image Detector – WiFi	IRAY	MARS 1417V

6. Technological Characteristics Comparison to Predicate Device:

The Subject device DigiX FDX design is based on the Allenger's DigiX FDX (K162529) including the system control, Indication for use and mechanical design.

The modifications do not affect the intended use of the device the subject device and predicate device are based on the following same fundamental scientific technologies elements:

- Energy emission to the patient – X-Ray
- Power requirement, Environmental requirement
- Mechanism to generate X-Ray
- Mechanism to acquire, process and store image data
- Use of the hardware components
- Use of software processing

This 510(k) submission describes some modifications to the previously cleared predicate devices the DigiX FDX (K162529). The changes to the predicate DigiX FDX (K162529) include:

System Software Synergy DR FDX

Synergy DR FDX comparable to ECOM DROC (K130883) added with same functionality along with below said additional features.

- **Operating System:** Updated operating system from Windows 7 to Windows 10
- **Automatic Stitching:** Image stitching is the process of overlapping two or more images taken at different viewpoints and different times to generate a wider viewing panoramic image.
- ****Dual Energy Subtraction:** Dual energy subtraction (DES) radiography, a new added feature for software Synergy DR FDX, is a technique which aims to improve the diagnostic value of an X-Ray by separating soft tissue from bones, producing two different images.

***** Dual Energy Subtraction feature can be used with all the Solid State X-Ray Image detectors (Digital detectors) listed in table 1 of this 510(k) summary.***

Component Change

- **X-Ray Tube** : RAD-14 (Make : Varex Imaging) is added
- **43x36cm Wireless Detectors** are added (Listed below),
    - Paxscan 4336W v4 manufactured by Varex Imaging
    - Pixium 3543 DR-CS manufactured by Thales.
    - MARS 1417V manufactured by IRAY technology.
- **43x43cm Fixed Detectors** are added (Listed below),
    - Paxscan 4343R v3 manufactured by Varex imaging
    - Pixium Rad 4343 C-E manufactured by Thales
    - VENU 17171X manufactured by IRAY technology.
    - Paxscan 4343CB manufactured by Varex Imaging.
- **Wireless IR Remote** (Optional) added.
- **Monitor** with 19" or more in size (touch and Non touch) added.
- **Patient Table**: Minor changes in mechanical dimensions and increase the load carrying capacity of patient tables.

Others Change

- **EMC (Electromagnetic Compatibility)** was tested according to IEC ed. 4.0.
- **Combination Name** change (Refer Table 4 for more detail)
- **Brand Name** M/s Varian to M/s Varex imaging (FPD & X-Ray Tube Manufacturer)

7. Indications for Use:

The DigiX FDX radiographic systems are used in hospitals, clinics and medical practices. DigiX FDX enables radiographic exposure of the whole body including: Skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. It can also be used for intravenous, small interventions (like biopsy, punctures, etc.) and emergency (trauma critical ill) applications.
Exposure may be taken with the Patient's sitting, standing, or in the prone/supine position.

The DigiX FDX System is not meant for mammography.

The DigiX FDX uses an integrated or portable or fixed or wi-fi digital detector for generating diagnostic images by converting X-Ray into electronics signals. DigiX FDX is also designed to be used with conventional film/screen or Computed Radiography (CR) Cassettes.

8. Substantial Equivalence:

The DigiX FDX radiographic X-Ray system is substantially equivalent to the commercially available primary predicate Allenger's DigiX FDX Cleared March 3, 2017 with K162529

Mechanical dimensions was slightly change, however the changes doesn't impact the intended use of device. Table 3 provides primary and secondary predicate comparable information

Table 3 Predicate Device Comparable Properties

Predicate Device(s) Name and Manufacture	510(K) Number	Clearance Date	Comparable Properties
Primary Predicate Device DigiX FDX **Product Code:** KPR **Address:** Allengers Medical Systems Ltd. Bhankharpur, Mubarakpur Road, Derabassi, Distt Mohali-140507 India	K162529	3/3/2017	• Technical Design • Mechanical Design • System Software
Secondary Predicate Device: Ysio **Product Code:** KPR **Address:** Siemens Medical Solutions USA, Inc, 51 valley stream, Parkway E-50, Malvern PA, 19335-1406	K081722	8/25/2008	• Technical Design • Mechanical Design • System Software

Table 4: Functional and Specification Differences

Feature	Subject Device DigiX FDX	Predicate 1 DigiX FDX	Predicate 2 Siemens Ysio	Comparison Results
1. 510(K)				
510(K)	K192541	K162529	K081722	Same
2. Classification				
Classification	21 CFR 892.1680	21 CFR 892.1680	21 CFR 892.1680	Same
Clinical Characteristics				
3. Indication for Use				
Indications for Use	The DigiX FDX radiographic systems are used in hospitals, clinics and medical practices. DigiX FDX enables radiographic exposure of the whole body including: Skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. It can also be used for intravenous, small interventions (like biopsy, punctures, etc.) and emergency (trauma critical ill) applications. Exposure may be taken with the Patient's sitting, standing, or in the prone/supine position. The DigiX FDX System is not meant for mammography. The DigiX FDX uses an integrated or portable or fixed or Wi-Fi digital detector for generating diagnostic images by converting X-Ray into electronics signals.	The DigiX FDX radiographic systems are used in hospitals, clinics and medical practices. DigiX FDX enables radiographic exposure of the whole body including: Skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. It can also be used for intravenous, small interventions (like biopsy, punctures, etc.) and emergency (trauma critical ill) applications. Exposure may be taken with the Patient's sitting, standing, or in the prone/supine position. The DigiX FDX System is not meant for mammography.	The Ysio (New RAD Family) systems are the radiographic systems used in hospitals, clinics, and medical practices. Ysio enables radiographic and tomographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. It can also be used for intravenous, small interventions (like biopsy, punctures, etc.) and emergency (trauma, critical ill) applications. Exposures may be taken with the patient sitting, standing, or in the prone position. The Ysio system is not meant for mammography. The Ysio uses an integrated or portable digital detector for generating diagnostic images by converting X-Rays into electronic signals. Ysio is also designed to be used	Same as predicate 1

	DigiX FDX is also designed to be used with conventional film/screen or Computed Radiography (CR) Cassettes.	The DigiX FDX uses an integrated or portable or fixed or Wi-Fi digital detector for generating diagnostic images by converting X-Ray into electronics signals. DigiX FDX is also designed to be used with conventional film/screen or Computed Radiography (CR) Cassettes.	with conventional film/screen or Computed Radiography (CR) Cassettes	
Technical Characteristics				
4. Ceiling Mounted X-Ray Tube Suspension				
Model	*CSA FDX*	*CSA^{Adv} & CSA^{FDX}*	*Ysio*	
Longitudinal travel	300 cm	300 cm	346 cm	Same as predicate 1
Transverse travel	200 cm	200 cm	220 cm	Same as predicate 1
Vertical travel	150 cm	150 cm	190 cm	Same as predicate 1
Tube rotation (horiz.)	±180°	±180°	±180°	Same
Tube rotation (vert.)	±180°	±180°	±180°	Same
Fully automated	Yes	Yes	Yes	Same
Digital Readout	Yes	Yes	Yes	Same
5. Vertical Bucky Stand				
Model	*VBS ADV*	*VBS^{Adv}*	*BWS with Max static*	
Vertical travel	125 cm	125 cm	145 cm	Same as predicate 1
Model	*VBS M* XL	*VBS M^{XL}*	BWS wi-D	
Vertical travel	162 cm	162 cm	141 cm	Same as predicate 1
6. Patient Table				
Model	*Floatex XL*	*Floatex^{XL}*	*Bucky Table*	
Type	*4-way floating top*	*4-way floating Top*	*4-way floating top*	Same
Longitudinal travel	95 cm	95 cm,	NA	Same
Transverse travel	25 cm	25 cm,	NA	Same

Table top locking	Electromagnetic	Electromagnetic	Electromagnetic	Same
Maximum patient capacity	250 kg (551 lbs)	200 kg (440 lbs)	300 kg (660 lbs)	Similar Functionality (Note 1)
Model	*Floatex ADV*	*Floatex+*	*Bucky Table*	
Type	*6-way floating top*	*6-way floating top*	*6-way floating top*	Same
Longitudinal travel	95 cm	53.5 cm	NA	Similar Functionality (Note 2)
Transverse travel	25 cm	18 cm	NA	Similar Functionality (Note 2)
Vertical travel	26.5 cm	26.5 cm	29 cm	Same as predicate 1
Table top locking	Electromagnetic	Electromagnetic	Electromagnetic	Same
Maximum patient capacity	250 kg (551 lbs)	200 kg (440 lbs)	300 kg (660 lbs)	Similar Functionality (Note 1)
Optional Model	*Floatex*	*Floatex*	*NA*	
Type	4-way floating top	4-way floating top	NA	Same
Longitudinal travel	53.5 cm	53.5 cm	NA	Same
Transverse travel	20 cm	20 cm	NA	Same
Table top locking	Electromagnetic	Electromagnetic	NA	Same
Maximum patient capacity	250 kg (551 lbs)	200 kg (440 lbs)	NA	Similar Functionality (Note 1)
Optional Model	*MobiT 6C*	*MobiT 6C*	*NA*	
Type	Mobile with floating top	Mobile with floating top	NA	Same
Longitudinal travel	60 cm	60 cm	NA	Same
Transverse travel	20 cm	20 cm,	NA	Same
Vertical travel	40 cm	40 cm,	NA	Same
Table top locking	Electromagnetic	Electromagnetic	NA	Same
Maximum patient capacity	250 kg (551 lbs)	200 kg (440 lbs)	*NA*	Similar Functionality (Note 1)
Optional	*MobiT 4C*	*MobiT 4C*	*NA*	

Model				
Type	Mobile with floating top	Mobile with floating top	NA	Same
Longitudinal travel	60 cm	60 cm	NA	Same
Transverse travel	20 cm	20 cm	NA	Same
Table top locking	Electromagnetic	Electromagnetic	NA	Same
Maximum patient capacity	250 kg (551 lbs)	200 kg (440 lbs)	NA	Similar Functionality (Note 1)
Optional Model	*Mobit C*	*Mobit C*	NA	
Type	Mobile	Mobile	NA	Same
Table top	Fixed	Fixed	NA	Same
Maximum patient capacity	200 kg (440 lbs)	200 kg (440 lbs)	NA	Same
7. X-Ray Generator				
Kilowatt rating	65 kW	65 kW standard	65 kW standard	Same
	80 kW	80 kW optional	80 kW optional	Same
kV minimum (65/80)	40/40 kV	40/40 kV	40/40 kV	Same
kV maximum (65/80)	150/150 kV	150/150 kV	150/150 kV	Same
mA maximum @ 100kV (65/80)	650/800 mA	650/800 mA	650/800 mA	Same
mAs Range (65/80)	800/10000mAs	800/1000mAs	NS	Same as predicate 1
APR programming	Yes	Yes	Yes	Same
IR Remote	Yes	No	NA	New Feature (Note 3)
8. X-Ray Tube				
Tube Type	*Varex Imaging G1092*	*Varex Imaging G1092*	*Siemens OPTITOP*	
Focal Spot sizes	0.6mm / 1.2mm	0.6mm / 1.2mm	0.6mm / 1.0mm	Same as predicate 1
Heat Units	1 MHU	1 MHU	783 KHU	Same as predicate 1
Target Angle	12°	12°	12°	Same
Target Diameter	108 mm	108 mm	100 mm	Same as predicate 1
Target Material	RTM	RTM	RTM	Same

Optional Tube	*Varex Imaging G292*	*Varex Imaging G292*	*Siemens OPTILIX*	
Focal Spot sizes	0.6mm / 1.2mm	0.6mm / 1.2mm	0.6mm / 1.0mm	Same as predicate 1
Heat Units	600 kHU	600 kHU	600 kHU	Same
Target Angle	12°	12°	16°	Same as predicate 1
Target Diameter	102 mm	102 mm	100 mm	Same as predicate 1
Target Material	RTM	RTM	RTM	Same
Optional Tube	*Varex Imaging A292*	*Varex Imaging A292*	*NA*	
Focal Spot sizes	0.6mm / 1.2mm	0.6mm / 1.2mm	NA	Same
Heat Units	400 kHU	400 kHU	NA	Same
Target Angle	12°	12°	NA	Same
Target Diameter	102 mm	102 mm	NA	Same
Target Material	RTM	RTM	NA	Same
Optional Tube	*Varex Imaging A192*	*Varex Imaging A192*	NA	
Focal Spot sizes	0.6mm / 1.2mm	0.6mm / 1.2mm	NA	Same
Heat Units	300 KHU	300 KHU	NA	Same
Target Angle	12°	12°	NA	Same
Target Diameter	102 mm	102 mm	NA	Same
Target Material	RTM	RTM	NA	Same
Optional Tube	*Varex Imaging RAD 14*	*Varex Imaging A192*	NA	
Focal Spot sizes	0.6mm / 1.2 mm	0.6mm / 1.2mm	NA	Same
Heat Units	300 kHU	300 kHU	NA	Same
Target Angle	12°	12°	NA	Same
Target Diameter	80 mm	102 mm	NA	Similar Functionality (Note 4)
Target Material	RTM	RTM	NA	Same
9. Beam Limiting Device				
Construction	Multi-leaf	Multi-leaf	Multi-leaf	Same
CFR 211020.31	Compliant	Compliant	Compliant	Same
Automatic	Yes	Yes	Yes	Same

10. Solid State X-Ray Image Detector				
Model	*XRPAD 4343 F*	*XRPAD 4343F*	*Trixell Pixium 4600*	
FDA Cleared	Yes, K142698	Yes, K142698	Yes, K093066	
Panel Type	Single substrate amorphous silicon active TFT/diode array	Single substrate amorphous silicon active TFT/diode array	Amorphous Silicon	Same as predicate 1
Active area	432 mm X 432 mm	432 mm X 432 mm	429 mm X 429 mm	Same as predicate 1
Pixel pitch	100 µm	100 µm	143 µm	Same as predicate 1
Pixel matrix	4318 X 4320	4318 X 4320	3001 x 3001	Same as predicate 1
Scintillator	Direct deposition CsI:Tl	Direct deposition CsI:Tl	Cesium Iodide	Same or similar with same imaging results
Limiting resolution	5 lp/mm	5 lp/mm	3.6 lp/mm	Same as predicate 1
Optional Model	*Varex's PaxScan 4336R*	*Varex's PaxScan 4336R*	Thales Pixium 3543	
FDA Cleared	Yes, K130318	Yes, K130318	Yes, *K093066*	
Panel Type	Amorphous Silicon with Charge Well Pixel™ Technology	Amorphous Silicon with Charge Well Pixel™ Technology	Pixium© CsI coupled to TFT matrix aSi technology	Same as predicate 1
Pixel Area(Active)	353 mm ✕ 424mm	353mm X 424 mm	342 mm X 432 mm	Same as predicate 1
Pixel pitch	139 µm	139 µm	144 µm	Same as predicate 1
Pixel matrix	2560 X 3072	2560 X 3072	2372 X 3000	Same as predicate 1
Scintillator	Direct Deposit CsI, Detached CsI, DRZ Plus	Direct Deposit CsI, Detached CsI, DRZ Plus	Cesium Iodide	Same as predicate 1
Limiting resolution	3.6 lp/mm	3.6 lp/mm	3.6 lp/mm	Same
Model	*XRPAD 4336*	*XRPAD 4336*	*Thales Pixium 3543*	
FDA Cleared	Yes, K140551	Yes, K140551	Yes, K093066	
Panel Type	Single substrate amorphous silicon active TFT/diode array	Single substrate amorphous silicon active TFT/diode array	Pixium© CsI coupled to TFT matrix aSi technology	Same as predicate 1
Active Area	355 mm X 432 mm	355 mm X 432 mm	342 mm X 432 mm	Same as predicate 1
Pixel pitch	100 µm	100 µm	144 µm	Same as predicate 1
Pixel matrix	3556 X 4320	3556 X 4320	2372 X 3000	Same as

				predicate 1
Scintillator	Direct deposition CsI:Tl	Direct deposition CsI:Tl	Cesium Iodide	Same as predicate 1
Limiting resolution	5 lp/mm	5 lp/mm	3.6 lp/mm	Same as predicate 1
Optional Model	*Varex's PaxScan 4336W*	*Varex's PaxScan 4336W*	Thales Pixium 3543	
FDA Cleared	Yes, K142049	Yes, K142049	Yes, K093066	
Panel Type	Amorphous Silicon	Amorphous Silicon	Pixium© CsI coupled to TFT matrix aSi technology	Same as predicate 1
Active Area	353 mm X 424 mm	353 mm X 424 mm	342 mm X 432 mm	Same as predicate 1
Pixel pitch	139 µm	139 µm	144 µm	Same as predicate 1
Pixel matrix	2560 X 3072	2560 X 3072	2372 X 3000	Same as predicate 1
Scintillator	Direct Deposit CsI, DRZ +	Direct Deposit CsI, DRZ +	Cesium Iodide	Same as predicate 1
Limiting resolution	3.6 lp/mm	3.6 lp/mm	3.6 lp/mm	Same
Optional Model	*Varex's PaxScan 4336W v4*	*Varex's PaxScan 4336W*	Thales Pixium 3543	
FDA Cleared	Yes, K183541	Yes, K142049	Yes, K093066	
Panel Type	Amorphous Silicon with TFT/PIN diode Technology	Amorphous Silicon	Pixium© CsI coupled to TFT matrix aSi technology)	Similar with same imaging results
Active Area	339 mm X 424 mm	353 mm X 424 mm	342 mm X 432 mm	Similar Functionality (Note 5)
Pixel pitch	139 µm	139 µm	144 µm	Same as predicate 1
Pixel matrix	2476 X 3072	2560 X 3072	2372 X 3000	Similar Functionality (Note 5)
Scintillator	CsI, DRZ +	CsI, DRZ +	Cesium Iodide(CSI:Ti)	Same as predicate 1
Limiting resolution	3.6 lp/mm	3.6 lp/mm	3.6 lp/mm	Same
Optional Model	*Thales Pixium 3543 DR-CS*	*Varex's PaxScan 4336W*	Thales Pixium 3543	
FDA Cleared	Yes, K182517	Yes, K142049	Yes, K093066	
Panel Type	Pixium® CsI coupled to TFT matrix a-Si technology	Amorphous Silicon	Pixium© CsI coupled to TFT matrix aSi technology	Same as predicate 2
Active Area	350mm x430 mm	353 mm X 424 mm	342 mm X 432 mm	Similar Functionality (Note 5)

Pixel pitch	160 µm	139 µm	144 µm	Similar Functionality (Note 5)
Scintillator	Cesium Iodide(CSI:Ti)	CsI, DRZ +	Cesium Iodide	Same
Optional Model	*Varex's PaxScan 4343R*	*Varex's PaxScan 4343R*	*Trixell Pixium 4600*	
FDA Cleared	Yes, K130318	Yes, K130318	Yes, K093066	
Panel Type	Amorphous Silicon with Charge Well Pixel™Technology	Amorphous Silicon with Charge Well Pixel™Technology	Amorphous Silicon	Same as predicate 1
Active Area	424 mm X 424 mm	424 mm X 424 mm	429 mm X 429 mm	Same as predicate 1
Pixel pitch	139 µm	139 µm	143 µm	Same as predicate 1
Pixel matrix	3072 X 3072	3072 X 3072	3001 x 3001	Same as predicate 1
Scintillator	Direct Deposit CsI, Detached CsI, DRZ Plus	Direct Deposit CsI, Detached CsI, DRZ Plus	Cesium Iodide	Same as predicate 1
Limiting resolution	3.6 lp/mm	3.6 lp/mm	3.6 lp/mm	Same
Optional Model	*VENU 1717X*	Varex Paxscan 4343R	*Trixell Pixium 4600*	
Panel Type	Amorphous Silicon	Amorphous Silicon with Charge Well Pixel™Technology	Amorphous Silicon	Same as predicate 2
Active Area	427 × 427 mm	424 mm X 424 mm	429 mm X 429 mm	Essentially the Same imaging Area doesn't affect the patient safety or effectiveness.
Pixel pitch	139 µm	139 µm	143 µm	Same as predicate 1
Pixel matrix	3072 × 3072	3072 X 3072	3001 x 3001	Same as predicate 1
Scintillator	CsI	Direct Deposit CsI, Detached CsI, DRZ Plus	CsI	Same as predicate 2
Limiting resolution	3.6 lp/mm	3.6 lp/mm	3.6 lp/mm	Same
Optional Model	*Varex's PaxScan 4343R v3*	*Varex's PaxScan 4343R*	*Trixell Pixium 4600*	

FDA Cleared	Yes, K183541	Yes, K130318	Yes, K093066	
Panel Type	Amorphous Silicon with PIN Technology	Amorphous Silicon with Charge Well Pixel™Technology	Amorphous Silicon	Same or similar with same imaging results
Active Area	424 mm X 424 mm	424 mm X 424 mm	429 mm X 429 mm	Same as predicate 1
Pixel pitch	139 µm	139 µm	143 µm	Same as predicate 1
Pixel matrix	3072 X 3072	3072 X 3072	3001 x 3001	Same as predicate 1
Scintillator	CsI, DRZ+	Direct Deposit CsI, Detached CsI, DRZ Plus	Cesium Iodide	Same or Similar with same imaging results
Limiting resolution	3.6 lp/mm	3.6 lp/mm	3.6 lp/mm	Same
Optional Model	*Pixium RAD 4343 C-E*	*Varex's PaxScan 4343R*	*Trixell Pixium 4600*	
FDA Cleared	Yes, K181279	Yes, K130318	Yes, K093066	
Panel Type	Amorphous Silicon	Amorphous Silicon with Charge Well Pixel™Technology	Amorphous Silicon	Same as predicate 2
Active Area	423.3 x 425.4	424 mm X 424 mm	429 mm X 429 mm	Similar Functionality (Note 5)
Pixel pitch	148 µm	139 µm	143 µm	Similar Functionality (Note 5)
Pixel matrix	2860 X 2874	3072 X 3072	3001 x 3001s	Similar Functionality (Note 5)
Scintillator	Cesium Iodide(CSI)	Direct Deposit CsI, Detached CsI, DRZ	Cesium Iodide	Same as predicate 2
Optional Model	*Paxscan 4343CB*	*Varex's PaxScan 4343R*	*Trixell Pixium 4600*	
FDA Cleared	Yes, K190373	Yes, K130318	Yes, K093066	
Panel Type	Amorphous Silicon	Amorphous Silicon with Charge Well Pixel™Technology	Amorphous Silicon	Similar with Same imaging result
Active Area	427mm x 427 mm	427mm x 427 mm	429 mm X 429 mm	Same as predicate 1
Pixel pitch	139 µm	139 µm	143 µm	Same as

				predicate 1
Pixel matrix	3072 X 3072	3072 X 3072	3001 x 3001	Same as predicate 1
Scintillator	Integral columnar CsI:Tl	Direct Deposit CsI, Detached CsI, DRZ	Cesium Iodide	Similar Functionality (Note 5)
Optional Model	*Varex's PaxScan 4336W v4 +*	*Varex's PaxScan 4336W*	Thales Pixium 3543	
Panel Type	Amorphous Silicon with TFT/PIN diode Technology	Amorphous Silicon with TFT/PIN diode Technology	Pixium© CsI coupled to TFT matrix aSi technology	Same as predicate 1
Active Area	339 mm X 424 mm	353 mm X 424 mm	342 mm X 432 mm	Similar Functionality (Note 6)
Pixel pitch	139 µm	139 µm	144 µm	Same as predicate 1
Pixel matrix	2476 X 3072	2560 X 3072	2372 X 3000	Similar Functionality (Note 6)
Scintillator	CsI, DRZ +	CsI, DRZ +	Cesium Iodide	Same as predicate 1
Limiting resolution	3.6 lp/mm	3.6 lp/mm	3.6 lp/mm	Same
Optional Model	*MARS 1417V*	*Varex's PaxScan 4336W*	Thales Pixium 3543	
Panel Type	a-Si (Amorphous Silicon) TFT	Amorphous Silicon	Pixium© CsI coupled to TFT matrix aSi technology	Same or Similar Functionality (Note 7)
Active Area	346 × 420	353 mm X 424 mm	342 mm X 432 mm	Same or Similar Functionality (Note 7)
Pixel pitch	150 µm	139 µm	144 µm	Same or Similar Functionality (Note 7)
Pixel matrix	2304 × 2800	2560 X 3072	2372 X 3000	Same or Similar Functionality (Note 7)
Scintillator	CsI	CsI, DRZ +	Cesium Iodide	Same as predicate 2
Limiting Resolution	3.4 lp/mm	3.6 lp/mm	3.6 lp/mm	Same or Similar Functionality (Note 7)

11. Viewing Monitors					
Monitor (minimum Size)	19 inch or more (Touch and Non Touch)		19 inch Monitor	19 inch Monitor	Similar Functionality (Note 8)
12. Software Feature					
Model	Synergy DR FDX	DROC	DROC	DelWorks DR System	
FDA Cleared	--	K130883	Yes, K130883	Yes, K140825	
Operating System	Microsoft Windows 7/ Microsoft Window 10	Microsoft Windows7 / Microsoft Window 10	Microsoft Windows7	Microsoft Windows7	Similar Functionality (Note 9)
Network	Ethernet/ Wifi	Ethernet/ Wifi	Ethernet/ Wifi	Ethernet/ Wifi	Same
User	Mouse, Keyboard,	Mouse, Keyboard,	Mouse, Keyboard,	Mouse, Keyboard,	Same
Interaction/input	Touch Monitor,	Touch Monitor,	Touch Monitor,	Touch Monitor,	Same
Multi-user	Available	Available	Available	Available	Same
Import/Export images	Yes	Yes	Yes	Yes	Same
Acquisition device	Computed Radiography Digital X-Ray Detector	Computed Radiography Digital X-Ray Detector	Computed Radiography Digital X-Ray Detector	Computed Radiography Digital X-Ray Detector	Same
Image Interferences	Detector dependent	Detector dependent	Detector dependent	Detector dependent	Same
Image Organization	Yes Patient ID/Name/ Study instance UID Patient ID/Name/ Study instance UID	Yes Patient ID/Name/ Study instance UID Patient ID/Name/ Study instance UID	Yes Patient ID/Name/Study instance UID Patient ID/Name/Study instance UID	Yes Patient ID/Name/Study instance UID Patient ID/Name/Study instance UID	Same
Image Search available	Yes	Yes	Yes	Yes	Same
Image Storage	Yes	Yes	Yes	Yes	Same
Database	Yes	Yes	Yes	Yes	Same

storage					
Database Software	MS-Access	MS-Access	MS-Access	MS-Access	Same
Image Viewing	Yes	Yes	Yes	Yes	Same
Image measurement	Yes	Yes	Yes	Yes	Same
Image Annotation	Yes	Yes	Yes	Yes	Same
Image Operation	Yes	Yes	Yes	Yes	Same
Image Stitching	Automatic	Manual	Manual	Manual	Similar Functionality (Note 9)
Same Security	Yes(Priority by User)	Yes(Priority by User)	Yes(Priority by User)	Yes(Priority by User)	Same
DICOM 3.0 Compatibility	Yes	Yes	Yes	Yes	Same
Generator Control	Yes	Yes	Yes	Yes	Same
Generator Control Protocols	Generator dependent	Generator dependent	Generator dependent	Generator dependent	Same
Raw image Data Processing	Yes	Yes	Yes	Yes	Same
Post image data processing	Yes	Yes	Yes	Yes	Same
RIS code manager	Yes	Yes	Yes	Yes	Same
Dual Energy Subtraction	Yes	No	No	No	New Feature added (Note 10)
13. Biological Characteristics					
Table Top Material	Carbon Composite Material		Carbon Composite Material	Carbon Composite Material	Same

Table 5 Justification for Differences

Note	Description
Note 1	Allengers DigiX FDX (Subject Device) is capable for carrying patient weight up to 250kg without raising any new risk related to patient safety or effectiveness.
Note 2	Patient table (Floatex ADV) modified with more travel which provide full patient coverage which doesn't affect the safety or effectiveness of device.

Note 3	Optional Wireless IR Remote (make Tech switch) has same functionality as wired hand switch for Exposure. Wireless version doesn't raise any new safety or effectiveness issue. This feature is in EMC compliant and meet all necessary requirements pertaining to hand switch design as stated in 21 CFR
Note 4	Varex Rad 14 X-Ray tube is new X-Ray tube for existing device. However, the X-Ray tube used by subject device is already cleared by FDA under Stationary Digital radiography X-Ray device under 510(K) number K183541. Having same focal spot with different X-Ray tube loading and target diameter which provide essentially the same imaging results, which doesn't affect the safety or effectiveness.
Note 5	The subject device utilizes different X-Ray flat panel detectors; however, the flat panel detectors used by the subject device are already previously cleared by the FDA and does not raise the level of safety concern and affect any effectiveness. The relevant 510(k) approval number are K183541, K181279 & K182517
Note 6	New Detector Paxscan 4336W v4 + added in subject device. The flat panel detector have all the technical specifications like Image area, Pixel Pitch, Active area, resolution same to detector Paxscan 4336 W v4 (Previously cleared under 510 (K) No. K183541) with light weight facility. The new additional Flat panel detector (Varex Paxscan 4336W v4+) doesn't affect the patient safety or effectiveness.
Note 7	The Subject Device utilized different Flat panel X-Ray detector (i.e. MARS 1417V) ,However the flat panel detector used by subject device is updated version of previously cleared FPD having 510(K) number K161730 with same imaging area , pixel pitch and same spatial resolution. The new additional Flat panel detector (MARS 1417V) doesn't affect the patient safety or effectiveness.
Note 8	Monitors with 19" or more in sizes (Touch and Non touch) are utilized in subject device with same imaging results which doesn't affect the patient safety or effectiveness.
Note 9	The subject device utilizes additional System software (SYNERGY DR FDX) with same and updated functionalities like automatic Image stitching, Dual Energy feature and update operating system. However Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 is also included as part of this submission. The new software doesn't raise the level of safety concern and affect any effectiveness.
Note 10	Dual-energy subtraction chest radiography improves the radiologist's ability to detect and accurately diagnose a wide variety of chest lesions. The major advantage of this technique is that it makes calcification more conspicuous, an essential aid in characterizing pulmonary nodules. Thus this new feature doesn't affect the patient safety or effectiveness.

9. Reason for Submission

Modification of cleared device

10. Non-Clinical and Clinical Testing:

Non-clinical testing included verification and validation testing, image evaluation, testing, and safety testing. All devices subject to CDRH performance standards are certified to comply with the standard by their respective manufacturers. Risk Analysis was performed on the entire system.

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 is also included as part of this submission.

The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria. Testing for verification and validation for the device was found acceptable to support the claims of substantial equivalence.

EMC/electrical safety was evaluated according to the IEC Standards. Allengers certify conformance to Voluntary Standards covering Electrical hazards was mitigated and is substantially equivalent to the predicate device in terms of safety and effectiveness. All testing and validation has been completed.

Safety Information:

- The Allengers Medical Systems Limited systems comply with the applicable requirements of 21 CFR 1020.30, 21 CFR 1020.31.
- The Allengers Medical Systems Limited systems comply with the international safety standards:
    - IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+AM1:2012
    - IEC 60601-1-2:2014
    - IEC 60601-1-3:2008+A1:2013
    - IEC 60601-2-54:2009+A1:2015
    - EN ISO 14971:2012
    - IEC 62366-1:2015
    - IEC 62304:2006+AMD1:2015

Performance Testing:

Performance testing included functional testing of all motions of the system(s) with respect to the design specifications. Image performance testing was conducted and results included in the submission. All functions met the design requirements and the image performance criteria satisfactorily.

Clinical testing is not applicable due to the fact that no new clinical applications were introduced to the system.

11. Substantial Equivalence Conclusion:

The Allengers Medical Systems Limited systems do not introduce any new indications for use, nor does the use of the systems result in any new potential hazards. The operating environment and mechanical design is similar. Allengers Medical Systems Limited considers the DigiX FDX diagnostic X-Ray systems to be substantially equivalent with the predicate devices (K162529 & K081722) with respect to safety and effectiveness.