October 26, 2022

Allengers Medical Systems Limited
℅ Sanjeev Marjara
Director Technical
FDA Hall Unit-2, Bhankarpur, Mubarakpur Road
Derabassi, Distt. Mohali, Punjab 140507
INDIA

Re: K223060
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 20, 2022
Received: September 30, 2022

Dear 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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Imaging Devices
and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223060

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

K223060

510(k) SUMMARY

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92.

1. Contact Person and Address

Company Name:	Allengers Medical Systems Limited
Company Address:	FDA Hall, Unit-2, Bhankarpur, Mubarakpur Road, Derabassi, Distt Mohali-140507, India
Telephone No:	+91 1762-282600 +919872980168 rnd@allengers.net
Contact Person:	Sanjeev K. Marjara
Date Prepared:	20.09.2022

2. Proposed Device:

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

3. Predicate Device:

Device (trade) name:	DigiX FDX
Common/usual Name:	Digital X-Ray imaging system
Classification Name:	Stationary X-Ray system
Classification Panel:	Radiology
Regulation Number :	21 CFR 892.1680
Device Class :	Class II
Product Code:	KPR
510(K) Number :	K192541
Clearance Date :	October 16, 2019

4. Reference devices:

Device (trade) name:	Ysio
Common/usual Name:	Digital X-Ray imaging system
Classification Name:	Stationary X-Ray system
Classification Panel:	Radiology
Regulation Number :	21 CFR 892.1680
Device Class :	Class II
Product Code:	KPR
510(K) Number :	K081722
Clearance Date :	August 25, 2008

Allengers Medical Systems Limited

Allengers Medical Systems Ltd. Supplies Solid State X-Ray Image Detectors that have been previously cleared by FDA or tested and evaluated per guidance for submission of 510(K) for solid state X-Ray imaging devices. Table 1 provides the list of solid state detectors used with device.

Table 1 List of Solid State X-Ray Image Detectors

Solid State X-Ray Image Detectors	510(K) Numbers
Fixed	
Varex PaxScan 4343R v3– Fixed	K172951
Varex Paxscan 4343DXV - Fixed	K220311
Varex Paxscan 4343RC - Fixed	K172951
IRAY VENU 1717X – Fixed	K221714
*IRAY Mercu 1717V3 – Fixed	--
Allengers FP 4343R- Fixed	--
*Allengers FP 4343RF- Fixed	--
Varex (Perkin Elmer) XRPAD 4343F- Fixed	K142698
Wired/ Wireless	
InnoCare Yushan V17Ge (Wired)	K201528
InnoCare Yushan V17Ce (Wired)	K220510
Allengers G4343RG (Wired)	--
Allengers G4343RC (Wired)	--
InnoCare Yushan F14C (Wired/Wireless)	K210988
InnoCare Yushan F14G (Wired/Wireless)	K210988
InnoCare Yushan V14C (Wired/Wireless)	K201528
InnoCare Yushan V14G (Wired/Wireless)	K201528
InnoCare Yushan V17C (Wired/Wireless)	K201528
InnoCare Yushan V17G (Wired/Wireless)	K201528
Allengers G4336RWC (Wired/Wireless)	--
Allengers G4336RWG (Wired/Wireless)	--
Allengers G4343RWC (Wired/Wireless)	--
Allengers G4343RWG (Wired/Wireless)	--
Allengers T4336RWC (Wired/Wireless)	--
Allengers T4336RWG (Wired/Wireless)	--
Varex (Perkin Elmer) XRPAD 4336 – Wireless	K140551
Varex PaxScan 4336W v4 + – Wireless	K192541
Varex PaxScan 4343W – Wireless	K211423
Varex Lumen 2530W – Wireless	--
Varex Lumen 4336W – Wireless	--
Varex Lumen 4343W – Wireless	--
Thales Pixium 3543 DR-CS (Wireless)	K182517
IRAY MARS 1417V (Wireless)	K192541
IRAY MARS 1417X (Wireless)	K210316
IRAY MARS 1717V (Wireless)	K201043
*IRAY MARS 1717Vn (Wireless)	K201043

IRAY MARS 1717X (Wireless)	K210314
IRAY LUNA 1012X (Wireless)	K221345
Allengers FP 4336RW (Wireless)	--
Allengers FP 4343RW (Wireless)	--
Allengers FP 4336RW-HR (Wireless)	--
Allengers FP 4343RW-HR (Wireless)	--
*Allengers FP 4343RW-DE (Wireless)	--
Allengers FP 2430RW-FLX (Wireless)	--

Note: *The Solid State X-Ray Image Detectors (Digital detectors) marked with '*' 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 Details

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 v3
Solid State X-Ray Image Detector – Fixed	Varex	Paxscan 4343DXV

Solid State X-Ray Image Detector – Fixed	Varex	Paxscan 4343RC
Solid State X-Ray Image Detector – Fixed	IRAY	VENU 1717X
Solid State X-Ray Image Detector – Fixed	IRAY	Mercu 1717V3
Solid State X-Ray Image Detector – Fixed	Allengers	FP 4343R
Solid State X-Ray Image Detector – Fixed	Allengers	FP 4343RF
Solid State X-Ray Image Detector –Wired	Varex (Perkin Elmer)	XRPAD 4343F
Solid State X-Ray Image Detector – Wired	InnoCare	Yushan V17Ge
Solid State X-Ray Image Detector – Wired	InnoCare	Yushan V17Ce
Solid State X-Ray Image Detector – Wired	Allengers	G4343RG
Solid State X-Ray Image Detector – Wired	Allengers	G4343RC
Solid State X-Ray Image Detector – WiFi	Varex (Perkin Elmer)	XRPAD 4336
Solid State X-Ray Image Detector – WiFi	Varex	PaxScan 4336W V4 +
Solid State X-Ray Image Detector – WiFi	Varex	PaxScan 4343W
Solid State X-Ray Image Detector – WiFi	Varex	Lumen 2530W
Solid State X-Ray Image Detector – WiFi	Varex	Lumen 4336W
Solid State X-Ray Image Detector – WiFi	Varex	Lumen 4343W
Solid State X-Ray Image Detector – WiFi	Thales	Pixium 3543DR-CS
Solid State X-Ray Image Detector – WiFi/Wired	InnoCare	Yushan V14C
Solid State X-Ray Image Detector – WiFi/Wired	InnoCare	Yushan V14G
Solid State X-Ray Image Detector – WiFi/Wired	InnoCare	Yushan F14C
Solid State X-Ray Image Detector – WiFi/Wired	InnoCare	Yushan F14G
Solid State X-Ray Image Detector – WiFi/Wired	InnoCare	Yushan V17C
Solid State X-Ray Image Detector – WiFi/Wired	InnoCare	Yushan V17G
Solid State X-Ray Image Detector – WiFi	IRAY	MARS 1417V
Solid State X-Ray Image Detector – WiFi	IRAY	MARS 1417X
Solid State X-Ray Image Detector – WiFi	IRAY	MARS 1717V
Solid State X-Ray Image Detector – WiFi	IRAY	MARS 1717Vn
Solid State X-Ray Image Detector – WiFi	IRAY	MARS 1717X
Solid State X-Ray Image Detector – WiFi	IRAY	LUNA 1012X
Solid State X-Ray Image Detector – WiFi	Allengers	FP 4336RW
Solid State X-Ray Image Detector – WiFi	Allengers	FP 4336RW-HR
Solid State X-Ray Image Detector – WiFi	Allengers	FP 4343RW
Solid State X-Ray Image Detector – WiFi	Allengers	FP 4343RW-HR
Solid State X-Ray Image Detector – WiFi	Allengers	FP 4343RW-DE
Solid State X-Ray Image Detector – WiFi	Allengers	FP 2430RW-FLX
Solid State X-Ray Image Detector – WiFi/Wired	Allengers	G4336RWC
Solid State X-Ray Image Detector – WiFi/Wired	Allengers	G4336RWG
Solid State X-Ray Image Detector – WiFi/Wired	Allengers	G4343RWC
Solid State X-Ray Image Detector – WiFi/Wired	Allengers	G4343RWG
Solid State X-Ray Image Detector – WiFi/Wired	Allengers	T4336RWC
Solid State X-Ray Image Detector – WiFi/Wired	Allengers	T4336RWG
Image processing Software	e-Com	DROC
Image Processing Software	Allengers	Synergy DR FDX

6. 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.

7. Technological Characteristics Comparison to Predicate & Reference Devices:

The Subject device DigiX FDX design is based on the Allenger's DigiX FDX (K192541) 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 (K192541). The changes to the predicate DigiX FDX (K192541) include:

System Software Synergy DR FDX

- **Graphical user interface (GUI):** GUI of system software updated in order to improve the look and feel of user interface for better visibility & faster workflow.
- Updated to support all hardware modifications. Verification and Validation testing concluded no impact on safety and effectiveness.

Component Change

- **25x30cm Wireless Detectors** are added (Listed below),
    - Lumen 2530W manufactured by Varex Imaging
    - Luna 1012X manufactured by IRAY technology
    - FP 2430RW-FLX manufactured by Allengers

- **43x36cm Wired/Wireless Detectors** are added (Listed below),
  - Lumen 4336W manufactured by Varex Imaging
  - MARS 1417X manufactured by IRAY technology.
  - Yushan V14C manufactured by InnoCare Optoelectronics.
  - Yushan V14G manufactured by InnoCare Optoelectronics.
  - Yushan F14C manufactured by InnoCare Optoelectronics.
  - Yushan F14G manufactured by InnoCare Optoelectronics.
  - FP 4336RW manufactured by Allengers
  - FP 4336RW-HR manufactured by Allengers
  - T4336RWC manufactured by Allengers
  - T4336RWG manufactured by Allengers
  - G4336RWC manufactured by Allengers
  - G4336RWG manufactured by Allengers

- **43x43cm Wired/Wireless Detectors** are added (Listed below),
  - Paxscan 4343W manufactured by Varex imaging
  - Lumen 4343W manufactured by Varex Imaging
  - MARS 1717V manufactured by IRAY technology.
  - MARS 1717Vn manufactured by IRAY technology.
  - MARS 1717X manufactured by IRAY technology.
  - Yushan V17C manufactured by InnoCare Optoelectronics.
  - Yushan V17G manufactured by InnoCare Optoelectronics.
  - Yushan V17Ge manufactured by InnoCare Optoelectronics.
  - Yushan V17Ce manufactured by InnoCare Optoelectronics.
  - FP 4343RW manufactured by Allengers
  - FP 4343RW-HR manufactured by Allengers
  - FP 4343W-DE manufactured by Allengers
  - G4343RWC manufactured by Allengers
  - G4343RWG manufactured by Allengers
  - G4343RG manufactured by Allengers
  - G4343RC manufactured by Allengers

- **43x43cm Fixed Detectors** are added (Listed below),
  - Paxscan 4343RC manufactured by Varex imaging
  - Mercu 1717V3 manufactured by IRAY technology.
  - FP 4343R manufactured by Allengers
  - FP 4343RF manufactured by Allengers

8. Software Feature

Synergy DR FDX imaging software manufactured by Allengers Medical systems Limited is a Digital Imaging System (DIS) provides useful functions to manage X-Ray images obtained from digital radiography system.

The software feature set and functions is essentially the same as the device, with the system complying with DICOM 3.0 specifications .Refer to ‘Image processing and storage’ in Section 13 (Page 5-0-10 to page 5-0-12) under table 4 of this document for a list of top level functions.

9. Substantial Equivalence:

The DigiX FDX radiographic X-Ray system is substantially equivalent to the commercially available predicate Allenger's DigiX FDX Cleared October 16, 2019 with K192541 and Ysio (K081722).

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
Predicate Device DigiX FDX **Product Code:** KPR **Address:** Allengers Medical Systems Ltd. Bhankharpur, Mubarakpur Road, Derabassi, Distt Mohali-140507 India	K192541	10/16/2019	• Technical Design • Mechanical Design • System Software
Reference 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	DigiX FDX (Subject Device)	DigiX FDX (Predicate Device)	Siemens Ysio (Reference Device)	Justification for differences
1. 510(k)	This submission	K192541	K081722	
2. Product Code				
Product Classification Code	KPR	KPR	KPR	Same
3. Product Classification				
Classification	21 CFR 892.1680	21 CFR 892.1680	21 CFR 892.1680	Same
4. 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. DigiX FDX is also designed to be used with conventional film/screen or Computed Radiography (CR) Cassettes.	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.	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 with conventional film/screen or Computed Radiography (CR) Cassettes	Essentially the same *Note:* There are no differences between the subject device and the predicate with respect to indication and intended use.

Feature	DigiX FDX (Subject Device)	DigiX FDX (Predicate Device)	Siemens Ysio (Reference Device)	Justification for differences
5. X-Ray Generator				
Power Rating (KW)	XGEN-80R : 80KW	XGEN-80R : 80KW	80KW Standard	Same
	XGEN-65R : 65KW	XGEN-65R : 65KW	65KW Optional	
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)	800/1000mAs	800/1000mAs	NS	Same as predicate device
APR programming	Yes	Yes	Yes	Same
IR Remote	Yes	Yes	NA	Same as predicate device
6. X-Ray Tube				
Make / Model	Varex Imaging/ G1092 Varex Imaging/ G292 Varex Imaging/ A292 Varex Imaging/ A192 Varex Imaging/RAD14	Varex Imaging/G1092 Varex Imaging/ G292 Varex Imaging/ A292 Varex Imaging/ A192 Varex Imaging/RAD14	Siemens OPTITOP Siemens OPTILIX	Same as Predicate Device
7. Solid State X-Ray Image Detectors				
Make / Model	Varex's PaxScan 4343R v3 Varex's PaxScan 4343DXV Varex's, Paxscan 4343RC Iray, VENU 1717X Iray, Mercu 1717V3 Allengers, FP 4343R Allengers, FP 4343RF InnoCare's, Yushan V17Ce InnoCare's,Yushan V17Ge Allengers, G4343RC Allengers, G4343RG	Varex's PaxScan 4343R v3 Varex's, Paxscan 4343CB Iray, VENU 1717X	Trixell Pixium 4600	Additional Solid state X-Ray Image detectors from the predicate can be used with the system. The system has been tested and there is "No negative impact on safety or efficacy" . There is no new potential or increased safety risks concerning were raised because of this difference.
	Varex's, XRPAD 4343 F Varex's, XRPAD 4336 Varex's PaxScan 4336Wv4+ Varex's PaxScan 4343W Varex's Lumen 2530W Varex's Lumen 4336W Varex's Lumen 4343W Thales Pixium 3543 DR-CS InnoCare's,Yushan F14C InnoCare's,Yushan F14G InnoCare's,Yushan V14C InnoCare's,Yushan V14G InnoCare's,Yushan V17C InnoCare's,Yushan V17G Iray, MARS 1417V Iray, MARS 1417X Iray's MARS 1717V Iray, MARS 1717Vn	Varex's, XRPAD 4343 F Varex's, XRPAD 4336 Varex's PaxScan 4336W v4 + Varex's PaxScan 4336W Varex's PaxScan 4336W V4 Thales Pixium 3543 DR-CS Iray, MARS 1417V	Trixell Pixium 4600 Thales Pixium 3543	

Feature	DigiX FDX (Subject Device)		DigiX FDX (Predicate Device)		Siemens Ysio (Reference Device)	Justification for differences
	Iray's MARS 1717X Iray's Luna 1012X Allengers,FP 4336RW Allengers,FP 4343RW Allengers,FP 4336RW-HR Allengers, FP 4343RW-HR Allengers, FP 4343RW-DE Allengers, FP 2430RW-FLX Allengers, G4336RWC Allengers,G4336RWG Allengers, G4343RWC Allengers,G4343RWG Allengers, T4336RWC Allengers, T4336RWG					
8. Ceiling Mounted X-Ray Tube Suspension						
Model	CSA FDX		CSA FDX		Ysio	Same as Predicate device
9. Vertical Bucky Stand						
Model	VBS ADV VBS M XL		VBS ADV VBS M XL		BWS with Max static BWS wi-D	Same as Predicate device
10. Patient Table						
Model	Floatex XL Floatex ADV Floatex MobiT 6C MobiT 4C Mobit C		Floatex XL Floatex ADV Floatex MobiT 6C MobiT 4C Mobit C		Bucky Table	Same as Predicate device
11. Beam Limiting Device						
Construction	Multi-leaf		Multi-leaf		Multi-leaf	Same
CFR 21 1020.31	Compliant		Compliant		Compliant	Same
Automatic	Yes		Yes		Yes	Same
12. Viewing Monitors						
Monitor (minimum Size)	19 inch or more (Touch and Non Touch)		19 inch or more (Touch and Non Touch)		19 inch Monitor	Same as Predicate device
13. Image Processing and storage						
Model	Synergy DR FDX	DROC	Synergy DR FDX	DROC	DelWorks DR System	--
FDA Cleared	--	K130883	K192541	K130883	Yes, K140825	--
Operating System	Microsoft Windows7/ Microsoft Window 10	Microsoft Windows7/ Microsoft Window 10	Microsoft Windows 7/ Microsoft Window 10	Microsoft Windows7/ Microsoft Window 10	Microsoft Windows7	Same as Predicate device
Network	Ethernet/ Wifi	Ethernet/ Wifi	Ethernet/ Wifi	Ethernet/ Wifi	Ethernet/ Wifi	Same
User	Mouse, Keyboard,	Mouse, Keyboard	Mouse, Keyboard	Mouse, Keyboard	Mouse, Keyboard,	Same
Interaction	Touch	Touch	Touch	Touch	Touch Monitor,	Same

Feature	DigiX FDX (Subject Device)		DigiX FDX (Predicate Device)		Siemens Ysio (Reference Device)	Justification for differences
/input	Monitor,	Monitor,	Monitor,	Monitor,		
Multi-user	Available	Available	Available	Available	Available	Same
Import/Export images	Yes	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	Computed Radiography Digital X-Ray Detector	Same
Image Interferences	Detector dependent	Detector dependent	Detector dependent	Detector dependent	Detector dependent	Same
Image Organization	Yes Patient ID / Name /Age / DOB/ Study instance UID	Yes Patient ID / Name /Age / DOB/ Study instance UID	Yes Patient ID / Name /Age / DOB/ Study instance UID	Yes Patient ID / Name /Age / DOB/ Study instance UID	Yes Patient ID / Name /Age / DOB/ Study instance UID	Same
Image Search available	Yes	Yes	Yes	Yes	Yes	Same
Image Storage	Yes	Yes	Yes	Yes	Yes	Same
Database storage	Yes	Yes	Yes	Yes	Yes	Same
Database Software	MS-Access	MS-Access	MS-Access	MS-Access	MS-Access	Same
Image Viewing	Yes	Yes	Yes	Yes	Yes	Same
Image measurement	Yes	Yes	Yes	Yes	Yes	Same
Image Annotation	Yes	Yes	Yes	Yes	Yes	Same
Image Operation	Yes	Yes	Yes	Yes	Yes	Same
Image Stitching	Automatic	Manual	Automatic	Manual	Manual	Same as Predicate device
DICOM 3.0 Compatibility	Yes	Yes	Yes	Yes	Yes	Same
Generator Control	Yes	Yes	Yes	Yes	Yes	Same
Generator Control Protocols	Generator dependent		Generator dependent		Generator dependent	Same

Feature	DigiX FDX (Subject Device)		DigiX FDX (Predicate Device)		Siemens Ysio (Reference Device)	Justification for differences
Raw image Data Processing	Yes	Yes	Yes	Yes	Yes	Same
Post image data processing	Yes	Yes	Yes	Yes	Yes	Same
RIS code manager	Yes	Yes	Yes	Yes	Yes	Same
Dual Energy Subtraction	Yes	No	Yes	No	No	Same as Predicate device
14. Power Requirement						
Power Requirement	400 VAC ,(±10%) 50/60 Hz		400 VAC,(±10%) 50/60 Hz		400 VAC, (±10%)50/60 Hz	Same
15. Biological Characteristics						
Table Top Material	Carbon Composite Material		Carbon Composite Material		Carbon Composite Material	Same

10. Reason for Submission

Modification of cleared device

11. Description of Non Clinical & Clinical testing

Non-clinical testing included verification and validation testing, image evaluation, testing, and safety testing. 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.

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:

This system demonstrates compliance with the following 21 CFR Federal Performance Standards:

- 1020.30 Diagnostic X-Ray Systems and their major components
- 1020.31 Radiographic equipment

and with the following relevant voluntary FDA Recognized Consensus Standards as listed in the table below:

Recognition Number	Product Area	Title of standard	Reference Number and date	Standard Development organization
19-4	General	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance	60601-1:2012, ed. 3.1	IEC

19-8	General	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility – Requirements and tests	60601-1-2 Edition 4.0 2014-02	IEC
12-269	Radiology	Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance.-Collateral Standard: Radiation Protection in Diagnostic X-Ray Equipment.	60601-1-3 Edition 2.1 2013-04	IEC
12-296	Radiology	Medical Electrical Equipment- Part 2-54: Particular Requirements for the Basic Safety and Essential Performance of X-Ray Equipment for Radiography and Radioscopy	60601-2-54, (Edition 1.1 2015).	IEC
13-79	General	Medical device software – Software life cycle processes	62304 (Edition 1.1, 2015)	IEC
5-89	General	Medical Electrical Equipment Part 1-6: General Requirements• for Basic Safety and Essential Performance- Collateral Standard: Usability	60601-1-6, (Edition 3.1 2013).	IEC
5-114	General	Application of Usability Engineering to Medical Devices	62366-1 Edition 1.0 2015-02	IEC
5-125	General I (QS/RM)	Medical devices – application of risk management to medical devices	14971 Third Edition 2019-12	ISO
12-273	Radiology	Safety of laser products – Part 1: Equipment classification, and requirements	60825-1 Edition 2.0 2007-03	IEC

Table 4: FDA Guidance Documents

FDA Guidance Documents and Effective Date	
1	Guidance for Industry and FDA Staff – User Fees and Refunds for Premarket Notification Submissions 510(k) Document issued on October 2, 2017
2	Guidance for Industry and Food and Drug Administration Staff: Refuse to Accept Policy for 510(k)s Document issued on April 21, 2022.
3	Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s - Guidance for Industry and FDA Staff Document issued on September 13, 2019.
4	Guidance for Industry and Food and Drug Administration Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Document Issued on July 28, 2014
5	Guidance for Industry and FDA Staff: Guidance for the Submission Of 510(k)'s for Solid State X-ray Imaging Devices Document issued on September 1, 2016
6	Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submission for Software in Medical Devices Document issued on May 11, 2005
7	Guidance for Industry and FDA Staff: Guidance for Off-The-Shelf Software Use in Medical Devices Document issued on September 27, 2019.

8	Guidance for Industry and FDA Staff: Applying Human Factors and Usability Engineering to Medical Devices. Document issued February 3, 2016
9	Guidance for Industry and FDA Staff: Pediatric Information for X-ray Imaging Device Premarket Notifications. Document issued on November 28, 2017
10	Guidance for Industry and FDA Staff: Content of Premarket Submissions for management of Cybersecurity in Medical devices. Document issued on October 2, 2014
11	Guidance for Industry and FDA Staff: Electromagnetic Compatibility (EMC) of Medical Devices Document issued on June 6, 2022

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.

Non-clinical verification test results demonstrate that the Digital Radiographic system complies with the aforementioned international and FDA recognized consensus standards and FDA guidance documents. Also No clinical data is necessary to evaluate safety or effectiveness for purposes of determining substantial equivalence of the proposed device. Hence, clinical testing is not applicable due to the fact that no new clinical applications were introduced to the system. Bench testing was performed to assess the device safety and effectiveness.

12. Substantial Equivalence Conclusion:

DigiX FDX, Digital Radiography System does not introduce any new indications for use, nor does the use of the systems result in any new potential hazards. The subject device is substantially equivalent to the DigiX FDX (K192541) and Ysio (K081722) . The intended use, the design principle, and the applicable standards for the subject device are identical to those of the predicate & reference device. Some characteristics, for example, their appearance, the user interfaces and the physical dimensions are different. However, the performance test and non-clinical consideration result demonstrate that these differences do not raise any new questions of safety and effectiveness. Therefore, it is the Allengers opinion that the subject device appears to be as safe and effective as the predicate & reference device.