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

March 3, 2017

Allengers Medical Systems Limited
% Manmohan Singh
Deputy Manager, Regulatory Affairs
Bhankharpur, Mubarakpur Road
Derabassi, Distt Mohali, Punjab 140507
INDIA

Re: K162529
Trade/Device Name: DigiX FDX
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: September 9, 2016
Received: September 21, 2016

Dear Manmohan Singh:

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 yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162529

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 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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510(k) SUMMARY
K162529

Company Name:	Allengers Medical Systems Limited
Address:	Bhankharpur, Mubarakpur Road, Derabassi, Distt Mohali-140507 India
Telephone No:	+91-01762-662626,663602 +919888014257
Registration No.:	Not Applicable
Contact person:	Manmohan Singh
Date Prepared:	1 September 2016
Device (trade) name:	DigiX FDX Digital Radiographic System
Common/usual name:	Digital x-ray imaging system
Classification:	CFR 21 892.1680
Classification name:	Stationary x-ray system
Classification Panel:	Radiology
Device Class:	Class II
Product Code:	90 KPR

Predicate device:

Predicate device:	Siemens Ysio, (K081722)
Classification:	21 CFR 892.1680
Classification Name:	Stationary x-ray system
Common/usual name:	Digital x-ray imaging system
Device Class:	Class II
Product Code:	90 KPR

Secondary Predicate devices:
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.

Allengers utilizes image processing software that has been previously cleared by the FDA.

Allengers does not modify any software utilized for image processing or display.

Solid State Detectors	
Varian PaxScan 4343R – Fixed	K130318
Varian PaxScan 4336R – Fixed	K130318
Perkin Elmer XRPAD 4343F - Fixed	K142698
Varian PaxScan 4336W – Wireless	K142049
Perkin Elmer XRPAD 4336 – Wireless	K140551
Image Processing Software	
e-COM Technology Ltd. DROC (Digital Radiography Operator Console)	K130883

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 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.

Component	**Manufacture**	**Model**
Ceiling mounted x-ray tube suspension	Allengers	CSA ^{Adv}
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+
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	Varian	A192
X-ray Tube	Varian	A292

X-ray Tube	Varian	G292
X-ray Tube	Varian	G1092
Beam Limiting Device	Ralco	R225 ACS
Solid State X-ray Image Detector – Fixed	Varian	PaxScan 4343R
Solid State X-ray Image Detector – Fixed	Varian	PaxScan 4336R
Solid State X-ray Image Detector – Fixed	Perkin Elmer	XRPAD 4343F
Solid State X-ray Image Detector – WiFi	Varian	PaxScan 4336W
Solid State X-ray Image Detector – WiFi	Perkin Elmer	XRPAD 4336

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 position.
The DigiX FDX System is not meant for mammography.

The DigiX FDX uses an integrated (fixed) or portable wired/wireless 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.

Technological Characteristics Comparison to Predicate Device:
The DigiX FDX system is a set of components similar to the Siemens Ysio X-ray System as compared in Table 12-1 found in Section 12, 510(k) Substantial Equivalence Comparison. This table below shows that the systems are either similar, or the same, as the predicate systems.

Software Features:
The software feature set and function is essentially the same as the Siemens Ysio, with both systems complying with DICOM 3.0 specifications. Refer to section 10. Software Features of the following table for a list of top level functions.

Substantial Equivalence:
The DigiX FDX radiographic x-ray system is substantially equivalent to the commercially available Siemens Ysio diagnostic x-ray system (K081722).

Functional and specification differences are identified in the following table:

Feature	DigiX FDX	Predicate Siemens Ysio	Same or Similar to predicate
510(k)	K162529	K081722	
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 position. The DigiX FDX System is not meant for mammography. The DigiX FDX uses an integrated (fixed) or portable wired/wireless 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	Predicate Siemens Ysio	Same or Similar to predicate
2. Ceiling mounted x-ray tube suspension			
Model	*CSA^{Adv} & CSA^{FDX}*	*Ysio*	
Longitudinal travel	300 cm	346 cm	Similar with less travel, provides full patient coverage. Does not affect safety or effectiveness.
Transverse travel	200 cm	220 cm	Similar with less travel, provides full patient coverage
Vertical travel	150 cm	190 cm	Similar with less travel, provides full patient coverage
Tube rotation (horiz.)	±180°	±180°	Same
Tube rotation (vert.)	±180°	±180°	Same
Fully automated	Yes	Yes	Same
Digital Readout	Yes	Yes	Same
3. Vertical Bucky Stand			
Model	*VBS^{Adv}*	*BWS with Max static*	
Vertical travel	125 cm	145 cm	Similar with less travel, provides full patient coverage
Model	*VBS M ^{XL}*	*BWS wi-D*	
Vertical travel	162 cm	141 cm	Similar with more travel, provides full patient coverage
4. Patient Table			
Model	*Floatex^{XL}*	*Bucky Table*	
Type	*4-way float top*	*4-way Float Top*	Same
Longitudinal travel	95 cm, ±10 mm	N/A	Similar, provides patient positioning. Does not affect safety or effectiveness.
Transverse travel	25 cm, ±10 mm	N/A	Similar, provides patient positioning. Does not affect safety or effectiveness.
Table top locking	Electromagnetic	Electromagnetic	Same

Feature	DigiX FDX	Predicate Siemens Ysio	Same or Similar to predicate
Maximum patient capacity	200 kg (440 lbs)	300 kg (660 lbs)	Similar with less capacity. Does not affect safety or effectiveness.
Optional Model	*Floatex+*	*Bucky Table*	
Type	6-way float top	6-way float top	Same
Longitudinal travel	53.5 cm, ±10mm	N/A	N/A
Transverse travel	18 cm, ±10mm	N/A	N/A
Vertical travel	26.5 cm, ±10mm	29 cm	Similar with less travel. Does not affect safety or effectiveness.
Table top locking	Electromagnetic	Electromagnetic	Same
Maximum patient capacity	200 kg (440 lbs)	300 kg (660 lbs)	Similar with less capacity. Does not affect safety or effectiveness.
Optional Model	*Floatex*	*N/A*	N/A
Type	4-way floating top	N/A	N/A
Longitudinal travel	53.5 cm, ±10mm	N/A	N/A
Transverse travel	20 cm, ±10mm	N/A	N/A
Table top locking	Electromagnetic	N/A	N/A
Maximum patient capacity	200 kg (440 lbs)	N/A	N/A
Optional Model	*MobiT 6C*	N/A	N/A
Type	Mobile with float top	N/A	N/A
Longitudinal travel	60 cm, ±10 mm	N/A	N/A
Transverse travel	20 cm, ±10 mm	N/A	N/A
Vertical travel	40 cm, ±10 mm	N/A	N/A
Table top locking	Electromagnetic	N/A	N/A
Maximum patient capacity	200 kg (440 lbs)	N/A	N/A

Feature	DigiX FDX	Predicate Siemens Ysio	Same or Similar to predicate
Optional Model	*MobiT 4C*	N/A	N/A
Type	Mobile with float top	N/A	N/A
Longitudinal travel	60 cm, ±10 mm	N/A	N/A
Transverse travel	20 cm, ±10 mm	N/A	N/A
Table top locking	Electromagnetic	N/A	N/A
Maximum patient capacity	200 kg (440 lbs)	N/A	N/A
Optional Model	*Mobit C*	N/A	N/A
Type	Mobile	N/A	N/A
Table top	Fixed	N/A	N/A
Maximum patient capacity	200 kg (440 lbs)	N/A	N/A
5. X-ray Generator			
Kilowatt rating	65 kW standard	65 kW standard	Same
	80 kW optional	80 kW optional	Same
kV minimum (65/80)	40/40 kV	40/40 kV	Same
kV maximum (65/80)	150/150 kV	150/150 kV	Same
mA maximum @ 100kV (65/80)	650/800 mA	650/800 mA	Same
APR programming	Yes	Yes	Same
6. X-ray Tube			
Tube Type	*Varian G1092*	*Siemens OPTITOP*	
Focal Spot sizes	0.6mm / 1.2mm	0.6mm / 1.0mm	Similar Provides essentially the same imaging resolution on both focal spots
Heat Units	1 MHU	783 kHU	Similar G1092 higher loading
Target Angle	12°	12°	Same
Target Diameter	108 mm	100 mm	Similar G1092 higher loading

Feature	DigiX FDX	Predicate Siemens Ysio	Same or Similar to predicate
Target Material	RTM	RTM	Same
Optional Tube	*Varian G292*	*Siemens OPTILIX*	
Focal Spot sizes	0.6mm / 1.2mm	0.6mm / 1.0mm	Small Focal Spot the Same. Large focal spot provides essentially the same imaging results.
Heat Units	600 KHU	600 kHU	Same
Target Angle	12°	16°	Similar Provides full coverage at 40” SID
Target Diameter	102 mm	100 mm	Similar Provides higher instantaneous focal spot loading
Target Material	RTM	RTM	Same
Optional Tube	*Varian A292*	*N/A*	N/A
Focal Spot sizes	0.6mm / 1.2mm	N/A	N/A
Heat Units	400 kHU	N/A	N/A
Target Angle	12°	N/A	N/A
Target Diameter	102 mm	N/A	N/A
Target Material	RTM	N/A	N/A
Optional Tube	*Varian A192*	*N/A*	N/A
Focal Spot sizes	0.6mm / 1.2mm	N/A	N/A
Heat Units	400 kHU	N/A	N/A
Target Angle	12°	N/A	N/A
Target Diameter	102 mm	N/A	N/A
Target Material	RTM	N/A	N/A
7. Beam Limiting Device			
Construction	Multi-tier	Multi-leaf	Same
CFR 211020.31	Compliant	Compliant	Same
Automatic	Yes	Yes	Same
8. Solid State X-ray Image Detectors			
Model	*P-E XRPAD 4343F*	*Trixell Pixium 4600*	
FDA Cleared	Yes, K142698	Yes, K093066	
Panel Type	Thin Film Transistor,	Thin Film Transistor,	Same

Feature	DigiX FDX	Predicate Siemens Ysio	Same or Similar to predicate
	a-Si, wired (integrated)	a-Si, wired (integrated)	
Active area	432 mm X 432 mm	429 mm X 429 mm	Essentially the Same imaging area
Pixel pitch	100 µm	143 µm	Similar, provides higher resolution
Pixel matrix	4318 X 4320	3001 X 3001	Similar, provides higher resolution
Input scintillator	Cesium Iodide	Cesium Iodide	Same
Limiting resolution	5 lp/mm	3.57 lp/mm	Similar, provides higher resolution
Model	*P-E XRPAD 4336*	*Thales Pixium 3543*	
FDA Cleared	Yes, K140551	Yes, K093066	
Panel Type	Thin Film Transistor, a-Si, wireless (portable)	Thin Film Transistor, a-Si, wireless (portable)	Same
Active Area	355 mm X 432 mm	342 mm X 432 mm	Essentially the Same imaging area
Pixel pitch	100 µm	144 µm	Similar, provides higher resolution
Pixel matrix	3556 X 4320	2372 X 3000	Similar, provides higher resolution
Input scintillator	Cesium Iodide	Cesium Iodide	Same
Limiting resolution	5 lp/mm	3.57 lp/mm	Similar, provides higher resolution
Optional Model	*Varian PaxScan 4343R*	*Trixell Pixium 4600*	
FDA Cleared	Yes, K130318	Yes, K093066	See Section 18-2
Panel Type	Thin Film Transistor, a-Si, wired (integrated)	Thin Film Transistor, a-Si, wired (integrated)	Same
Active Area	424 mm X 424 mm	429 mm X 429 mm	Essentially the Same imaging area
Pixel pitch	139 µm	143 µm	Similar, provides higher resolution
Pixel matrix	3072 X 3072	3001 X 3001	Similar, provides higher resolution
Input scintillator	Cesium Iodide	Cesium Iodide	Same
Limiting resolution	3.6 lp/mm	3.57 lp/mm	Similar, provides higher resolution
Optional Model	*Varian PaxScan 4336R*	*Thales Pixium 3543*	Secondary Predicate

Feature	DigiX FDX	Predicate Siemens Ysio	Same or Similar to predicate
FDA Cleared	Yes, K130318	Yes, K093066	
Type	Thin Film Transistor, a-Si, wired(Ethernet) (Portable)	Thin Film Transistor, a-Si, wired(Ethernet) (portable)	Same
Active Area	353mm X 424 mm	342 mm X 432 mm	Essentially the Same imaging area
Pixel pitch	139 µm	144 µm	Similar, provides higher resolution
Pixel matrix	2560 X 3072	2372 X 3000	Similar, provides higher resolution
Input scintillator	Cesium Iodide	Cesium Iodide	Same
Limiting resolution	3.6 lp/mm	3.57 lp/mm	Similar, provides higher resolution
Optional Model	*Varian PaxScan 4336W*	*Thales Pixium 3543*	Secondary Predicate
FDA Cleared	Yes, K142049	Yes, K093066	
Type	Thin Film Transistor, a-Si, wireless (portable)	Thin Film Transistor, a-Si, wireless (portable)	Same
Active Area	353 mm X 424 mm	342 mm X 432 mm	Similar, provides higher resolution
Pixel pitch	139 µm	144 µm	Similar, provides higher resolution
Pixel matrix	2560 X 3072	2372 X 3000	Essentially the Same
Input scintillator	Cesium Iodide	Cesium Iodide	Similar, provides higher resolution
Limiting resolution	3.6 lp/mm	3.57 lp/mm	Similar, provides higher resolution
9. Viewing Monitors			
Monitor	19 inch Medical Monitor(1280 X 1024)	19 inch Medical Monitor(1280 X 1024)	Same
10. Software Features			
Model	DROC	DelWorks DR System	Secondary Predicate
FDA Cleared	Yes, K130883	Yes, K140825	
Operating System	Microsoft Windows 7	Microsoft Windows 7	Same
Network	Ethernet / Wifi	Ethernet / Wifi	Same
User	Mouse, Keyboard,	Mouse, Keyboard,	Same

Feature	DigiX FDX	Predicate Siemens Ysio	Same or Similar to predicate
interaction/input	Touch Monitor,	Touch Monitor,	
Multi-user	Available	Available	Same
Import/Export images	Yes	Yes	Same
Acquisition device	Computed Radiography Digital X-ray Detector	Computed Radiography Digital X-ray Detector	Same
Image Interferences	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**	Same
Image Search available	Yes	Yes	Same
Image Storage	Yes	Yes	Same
Database storage	Yes	Yes	Same
Database Software	MS-Access	MS-Access	Same
Image Viewing	Yes	Yes	Same
Image Measurement	Yes	Yes	Same
Image Annotation	Yes	Yes	Same
Image Operations	Yes	Yes	Same
Same Security	Yes(Priority by User)	Yes(Priority by User)	Same
DICOM 3.0 Compatibility	Yes	Yes	Same
Generator Control	Yes	Yes	Same
Generator Control Protocols	Generator dependent	Generator dependent	Same
Raw image Data Processing	Yes	Yes	Same

Feature	DigiX FDX	Predicate Siemens Ysio	Same or Similar to predicate
Post image data processing	Yes	Yes	Same
RIS code manager	Yes	Yes	Same

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. It was determined that clinical evaluation was not required as all imaging devices have been previously cleared by the FDA.

Safety information:

- The Allengers Medical Systems Limited systems comply with the applicable requirements of 21 CFR 1020.30 and 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
  - EN 60601-1-2:2007+AC:2010,
  - IEC 60601-1-3:2008+A1:2013
  - IEC 60601-2-54:2009+A1:2015
  - EN ISO 14971:2012
  - EN 62366:2008
  - EN 62304:2006/AC:2008

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 with the results shown in Section 18 of this submission. All functions met the design requirements and the image performance criteria satisfactorily.

Software Features and Testing:

Both the Allengers DigiX FDX and the Siemens Ysio provide DICOM 3.0 format output imaging with a similar operational feature set. Therefore, Allengers conducted Software/Firmware testing to verify all functions between the DROC software and the IntegraX firmware functioned as intended. The Firmware Verification Summary Report appears in Section 16-1 of this submission, and indicates that all functions passed the testing criteria.

Substantial Equivalence Discussion:

The Allengers Medical Systems Limited systems perform the same functions as the Siemens Ysio system utilizing the same technology. The operator interface functions are essential equivalent. All imaging procedures are conducted essentially the same on both systems.

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. Allengers Medical Systems Limited considers the DigiX FDX diagnostic x-ray systems to be substantially equivalent with the predicate devices with respect to safety and effectiveness.