Allengers Medical Systems Limited
% Sanjeev Marjara
Director Technical
FDA Hall, Unit II, Bhankarpur,
Mubarakpur Road, Derabassi,
Distt Mohali, Punjab 140507
INDIA

August 7, 2020

Re: K200218
Trade/Device Name: Digiscan FDX
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA, OXO

Dear Sanjeev Marjara:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 3, 2020. Specifically, FDA is updating this SE Letter as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Laurel Burk, OHT7: Office of In Vitro Diagnostics and Radiological Health, (301) 796-5933, laurel.burk@fda.hhs.gov.

Sincerely,

Laurel M. Burk -S
Digitally signed by Laurel M. Burk -S
Date: 2020.08.07 09:44:10 -04'00'

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

Allengers Medical Systems Limited
% Sanjeev Marjara
Director Technical
FDA Hall, Unit II, Bhankarpur,
Mubarakpur Road, Derabassi,
Distt Mohali, Punjab 140507
INDIA

July 15, 2020

Re: K200218
Trade/Device Name: Digiscan FDX
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA, OXO
Dated: June 9, 2020
Received: June 15, 2020

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,

Michael D. O'Hara 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200218

Device Name
Digiscan FDX

Indications for Use *(Describe)*

The Digiscan FDX Family, a Mobile C-Arm X-Ray System, is intended to provide Fluoroscopic images of the patient during diagnostic, surgical procedures.

Clinical applications may include (but not limited to) orthopedic, Fertility studies (HSG), GI procedures like endoscopy , neurology, urology, critical care and emergency room procedures.

Digiscan FDX C-Arm is indicated for visualization in real time and/or recording of surgical region of interest and anatomy, using X-Ray imaging technique.

Exclusion: Digiscan FDX Family is not recommended for Mammography.

Contraindications: Exposure of X-Ray should be avoided during pregnancy.

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

(K200218)

This summary of 510(k) is being submitted in accordance with requirements of SMDA1990 and 21 CFR Part 807.92.

1. Contact Person and Address

Company Name:	Allengers Medical Systems Limited
Company Address:	FDA Hall, Unit II, Bhankharpur, Mubarakpur Road, Derabassi, Distt Mohali-140507, India
Telephone No:	+91 1762-282600 +919872980168 rnd@allengers.net
Contact Person:	Sanjeev K. Marjara
Date Prepared:	11 July 2020

2. Proposed Device:

Device (trade) name:	Digiscan FDX
Model Number:	Digiscan FDX-V ,Digiscan FDX-R , Digiscan FDX-S
Common Name:	Flat Panel Based High Frequency C-Arm Machine
Classification Name :	Image-Intensified Fluoroscopic X-Ray System
Classification Panel:	Radiology
Regulation Number :	21 CFR 892.1650
Device Class:	Class II
Product Code:	OWB, JAA, OXO

3. Predicate Device:

Device (trade) name:	Ziehim Vision RFD
510(K) Number :	K132904
Clearance Date :	December 05, 2013
Classification Name:	Image-Intensified Fluoroscopic X-Ray System,
Classification Panel:	Radiology
Regulation Number :	21 CFR 892.1650
Device Class :	Class II
Product Code:	OWB, JAA, OXO

4. Reference devices:

Reference Device

Device (trade) name:	OEC Elite
510(K) Number :	K172550
Clearance Date :	November 16, 2017
Classification Name:	Image-Intensified Fluoroscopic X-Ray System
Classification Panel:	Radiology
Regulation Number :	21 CFR 892.1650
Device Class :	Class II
Product Code:	OWB, JAA, OXO

Reference Device

Device (trade) name: Cios Fusion
510(K) Number : K153244
Clearance Date : March 7, 2016
Classification Name: Image-Intensified Fluoroscopic X-Ray System
Classification Panel: Radiology
Regulation Number : 21 CFR 892.1650
Device Class : Class II
Product Code: OWB, JAA, OXO

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 Detectors	510(K) Numbers
Varex Imaging corporation – Paxscan 2020	K100102
Varex Imaging corporation – Paxscan 3030	K113548
MX Imaging – CFP 2222	K171755
MX Imaging – CFP 3131	K171755
Thales Group – Pixium Surgical 2121S-A	K183040
Thales Group – Pixium 2121S-AU	--
Thales Group – Pixium Surgical 3030S-A	K172822
Thales Group – Pixium 3030S-AU	--
IRAY Technology – Mercu 0909F	--

5. Device description:

The Digiscan FDX Family (Digiscan FDX-V, Digiscan FDX–R and Digiscan FDX–S) are mobile X-Ray C-Arm fluoroscopic device used by radiation experts. Digiscan FDX family is a digital fluoroscopic imaging system with Solid State X-Ray Image Detetors (FPD) used in diagnostic. The device is designed in such a way that it can be moved around and can be positioned for the required anatomical/clinical/procedural position.

Digiscan FDX family composed of C-Arm, X-Ray generating equipment (X-Ray controller, high voltage generator, X-Ray tube), FPD, and workstation (Console computer and Monitor(s)). C-Arm unit with generator is capable of movements which are essential for patient positioning, like horizontal travel, orbital movement, vertical movement, wig-wag movement and C rotation. The X-Ray generator, X-Ray control system and collimator controls are housed in the C-Arm unit.

Synergy FDX-CR imaging software is a Digital Imaging System (DIS) designed for C-arm Fluoroscopic Mobile X-Ray System. Synergy FDX-CR imaging software provides useful functions to manage X-Ray images obtained from Digiscan FDX family FPD Fluoroscopic Mobile X-Ray System.

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	
X-Ray Generator	Allengers	Digiscan FDX-V	XGEN-15
X-Ray Generator	Allengers	Digiscan FDX-R	XGEN-6
X-Ray Generator	Allengers	Digiscan FDX-S	XGEN-3.5
X-Ray Tube	Varex Imaging	Digiscan FDX-V	A-145 RAD 99 RAD 99B
		Digiscan FDX-R	
X-Ray Tube	Hangzhou Wandong	Digiscan FDX-V	XD-56 5/17
		Digiscan FDX-R	
X-Ray Tube	Hangzhou Kailong	Digiscan FDX-S	KL25-0.6/1.5-125
X-Ray Tube	C.E.I	Digiscan FDX-S	OX/110-0514
Solid State X-Ray Image Detectors	Varex Imaging	Digiscan FDX-V	Paxscan 2020 Paxscan 3030
		Digiscan FDX-R	
		Digiscan FDX-S	
Solid State X-Ray Image Detectors	IRAY Technology	Digiscan FDX-V	Mercu 0909F
		Digiscan FDX-R	
		Digiscan FDX-S	
Solid State X-Ray Image Detectors	Thales Group	Digiscan FDX-V	Pixium 2121S-AU Pixium Surgical 2121S-A Pixium 3030S-AU Pixium Surgical 3030S-A
		Digiscan FDX-R	
		Digiscan FDX-S	
Solid State X-Ray Image Detectors	MX Imaging	Digiscan FDX-V	CFP 2222 CFP 3131
		Digiscan FDX-R	
		Digiscan FDX-S	

6. Indications for Use:

The Digiscan FDX Family, a Mobile C-Arm X-Ray System, is intended to provide Fluoroscopic images of the patient during diagnostic, surgical procedures.

Clinical applications may include (but not limited to) orthopedic, Fertility studies (HSG), GI procedures like endoscopy, neurology, urology, critical care and emergency room procedures.

Digiscan FDX C-Arm is indicated for visualization in real time and/or recording of surgical region of interest and anatomy, using X-Ray imaging technique.

Exclusion: Digiscan FDX Family is not recommended for Mammography.

Contraindications: Exposure of X-Ray should be avoided during pregnancy.

7. Technological Characteristics Comparison to Predicate & Reference Devices:

The Digiscan FDX family having set of components similar to the Ziehm Vision RFD, OEC Elite and Cios fusion System as compared in Table 3 found below in this Section. This table below shows that the systems are either similar, or the same, as the predicate & reference devices.

8. Software Feature

The software feature set and functions is essentially the same as the predicate & reference devices, with the system complying with DICOM 3.0 specifications .Refer to section 11 Image processing and storage of the following table for a list of top level functions

9. Substantial Equivalence:

The Digiscan FDX Mobile C-Arm X-Ray Machine is substantially equivalent to the commercially available Ziehm Vision RFD (K132904), OEC Elite (K172550) and Cios Fusion (K153244). Functional and specification differences are identifying in the following table.

Table 3: Functional and specification differences

Feature	Digiscan FDX (Subject Device)	Ziehm Vision RFD (Predicate Device)	OEC Elite (Reference Device)	Cios Fusion (Reference Device)	Discussion of Difference
1. 510(k)	K200218	K132904	K172550	K153244	
2. Product Code					
Product Classification Code	OXO, OWB, and JAA	OXO, OWB and JAA	OXO, OWB and JAA	OXO, OWB and JAA	Same
3. Product Classification					
Classification	21 CFR 892.1650	21 CFR 892.1650	21 CFR 892.1650	21 CFR 892.1650	Same
4. Indication for Use					
Indications for Use	The Digiscan FDX a Mobile C-Arm X-Ray System, is intended to provide Fluoroscopic images of the patient during diagnostic, surgical procedures. Clinical applications may include (but are not limited to) orthopaedic, Fertility studies (HSG) , GI procedures like endoscopy , neurology, urology, critical care and emergency room procedures. Digiscan FDX C-Arm is indicated for visualization in real time and/or recording of surgical region of interest and anatomy, using X-Ray imaging technique.	The ZIEHM VISION RFD is intended for use in providing medical imaging, using pulsed and continuous fluoroscopic digital imaging, as well as digital subtraction and cine image capture during diagnostic interventional and surgical procedures where intraoperative imaging and visualization of complex anatomical structures of both lower and higher contrast density are required. Such procedures may include but are not limited to those of interventional cardiology, heart surgery, hybrid procedures, interventional radiology, interventional angiography, electrophysiology, pediatrics, endloscopic,	The OEC Elite mobile fluoroscopy system is designed to provide fluoroscopic and digital spot images of adult and pediatric patient populations during diagnostic, interventional, and surgical procedures. Examples of a clinical application may include: orthopedic, gastrointestinal, endoscopic, urologic, neurologic, vascular, cardiac, critical care, and emergency procedures.	The Cios Fusion is a mobile X-Ray system designed to provide X-Ray imaging of the anatomical structures of patient During clinical applications. Clinical applications may include but are not limited to: interventional fluoroscopic, gastrointestinal, endoscopic, urologic, pain management, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures. The patient population may include pediatric	Essentially the same *Note:* There are no differences between the subject device and the predicate & reference devices with respect to indication and intended use.

	Exclusion: Digiscan FDX is not recommended for Mammography. **Contraindications:** Exposure of X-Ray should be avoided during pregnancy.	urological,gastroenterology, orthopedic, maxillofacial surgery, neurology, neurosurgery, critical care, emergency roomprocedures, and those procedures visualizing structures of the cervical, thoracic, and lumber regions of the spine and joint fractures of the upper and lower extremities, and where digital image data is required for computer aided surgery procedures, and whenever the clinician benefits from the high degree of geometric imaging accuracy, and where such fluoroscopic, cine and DSA imaging is required in and around high magnetic fields. The visualization of such anatomical structures assists the clinician in the clinical outcome. At the discretion of a physician, the device may be used or other imaging applications. This device does not support direct radiographic film exposures and is not intended for use in performing mammography. The system is not intended for use near MRI systems.		patients.	

5. X-Ray Generator						
Type	Monoblock and High Frequency Generator		Monoblock and High Frequency Generator	High Frequency split block	Monoblock and High Frequency Generator	Same
Kilowatt Rating	Digiscan FDX-V	15KW	20 KW Standard 7.5KW Optional	15KW	2.3 KW	Similar (SE #1)
	Digiscan FDX-R	6KW				
	Digiscan FDX-S	3.5KW				
KV Minimum	40 KV		40 KV	40 KV	40 KV	Same
KV Maximum	120KV		120 KV	120KV	110 KV	Same as Predicate Device & Reference Device OEC Elite
Dose Control System	Yes		Yes	Yes	Yes	Same
Dose Area Product	Yes		Yes	Yes	Yes	Same
6. X-Ray Tube						
Model	A-145		--	--	--	--
Tube Type	Rotating Anode		Rotating Anode	Rotating Anode	NA	Same
Cooling HU/min	70000 HU/ min		85000 HU/min	85000 HU/min	NA	Similar (SE #2)
Anode Heat Capacity	300 KHU		365 KHU	300 KHU	NA	Same as Reference Device OEC Elite.
Focal Spot Size, mm	Dual Focus 0.3/0.6		Dual Focus 0.3/0.6	Dual Focus 0.3/0.6	NA	Same
Maximum Tube Power rating , KW	25 KW		25 KW	15KW	NA	Same as Predicate Device

Optional					
Model	RAD 99B	--	--	--	--
Tube Type	Rotating Anode	Rotating Anode	Rotating Anode	NA	Same
Cooling HU/min	85280 HU/ min	85000 HU/min	85000 HU/min	NA	Similar (SE #2)
Anode Heat Capacity	300 KHU	365 KHU	300 KHU	NA	Same as Reference Device OEC Elite.
Focal Spot Size, mm	Dual Focus 0.3/0.6	Dual Focus 0.3/0.6	Dual Focus 0.3/0.6	NA	Same
Maximum Tube Power rating , KW	22.5 KW	25 KW	15KW	NA	Similar (SE #4)
Optional					
Model	RAD 99	--	--	--	--
Tube Type	Rotating Anode	Rotating Anode	Rotating Anode	NA	Same
Cooling HU/min	70000 HU/ min	85000 HU/min	85000 HU/min	NA	Similar (SE #2)
Anode Heat Capacity	300 KHU	365 KHU	300 KHU	NA	Same as Reference Device OEC Elite.
Focal Spot Size, mm	Dual Focus 0.3/0.6	Dual Focus 0.3/0.6	Dual Focus 0.3/0.6	NA	Same
Maximum Tube Power rating , KW	22.5 KW	25 KW	15KW	NA	Similar (SE #4)
Optional					

Model	XD56-5/17/130	--	--	--	
Tube Type	Rotating Anode	Rotating Anode	Rotating Anode	NA	Same
Cooling HU/min	25000 HU/ min	85000 HU/min	85000 HU/min	NA	Similar (SE #2)
Anode Heat Capacity	300 KHU	365 KHU	300 KHU	NA	Same as Reference Device OEC Elite.
Focal Spot Size, mm	Dual Focus 0.3/0.6	Dual Focus 0.3/0.6	Dual Focus 0.3/0.6	NA	Same
Maximum Tube Power rating , KW	17 KW	25 KW	15KW	NA	Similar (SE #4)
Optional					
Model	KL25-0.6/1.5-125	--	--	--	
Tube Type	Stationary Anode	NA	NA	Stationary Anode	Same
Cooling HU/min	58800 HU/ min	NA	NA	37300 HU/ min	Similar (SE #2)
Anode Heat Capacity	42 KHU	NA	NA	61.1 KHU	Similar (SE #3)
Focal Spot Size, mm	Dual Focus 0.6/1.5	NA	NA	0.6	Similar (SE #5)
Maximum Tube Power rating , KW	4 KW	NA	NA	2.3 KW	Similar (SE #4)
Optional					
Model	OX/110-0514	--	--	--	
Tube Type	Stationary Anode	NA	NA	Stationary Anode	Same as Reference device Cios Fusion.

Cooling HU/min	46200 HU/ min		NA	NA	37300 HU/ min	Similar (SE #2)
Anode Heat Capacity	42 KHU		NA	NA	61.1 KHU	Similar (SE #3)
Focal Spot Size, mm	Dual Focus 0.5/1.4		NA	NA	0.6	Similar (SE #5)
Maximum Tube Power rating , KW	4.5 KW		NA	NA	2.3 KW	Similar (SE #4)
7. Radiographic Mode						
KV Range	40-120 KV		40-120 KV	40-120 KV	40-110 KV	Same as Predicate Device & Reference Device OEC Elite.
mA Range	Digiscan FDX-V	150 mA	7.5 KW -1.5 – 75 mA 20 KW - 1.5 – 200 mA	Upto 75 mA	Upto 25 mA	Similar (SE #6)
	Digiscan FDX-R	120 mA				
	Digiscan FDX-S	80 mA				
8. Fluoroscopic Mode						
KV Range	40-120 kV		40-120 KV	40-120 KV	40-110 KV	Same as Predicate Device & Reference Device OEC Elite.
Pulse fluoroscopic	Yes		Yes	Yes	Yes	Same
ABS Control	Yes		Yes	Yes	Yes	Same
Snapshot Mode	Yes		Yes	Yes	Yes	Same

Max mA Range	Digiscan FDX-V	0.2 mA-15 mA (Normal Mode) 0.2 mA –30 mA (HLF)	---	0.2- 10 mA (Normal mode) 0.2 – 20 mA (HLF)	3 mA to 25 mA	Similar (SE #6)
	Digiscan FDX-R	0.2 mA-15 mA (Normal Mode) 0.2 mA –30 mA (HLF)				
	Digiscan FDX-S	0.2 mA-10 mA (Normal Mode) 0.2 mA –20 mA (HLF)				
Pulses per second (pps) (max)	Upto 15 (1536*1536) , upto 30 (1024*1024)		1 to 25	upto 30	upto 30	Similar (SE #7)
Cine (fps) (max)	Upto 15 (1536*1536) , upto 30 (1024*1024)		1-25 frames/s	upto 30 frames/s	upto 30 frame/s	Similar (SE #8)
9. Solid State X-Ray Image Detectors						
Make	Varex's , Paxscan 3030		Varex's , Paxscan 3030	--	--	--
Type	Amorphous Silicon		Amorphous Silicon	CMOS	Amorphous Silicon	Same as Predicate Device & Reference Device Cios Fusion
Active Area	298mm (h) x 298mm (v) (11.7 x 11.7 in)		298mm (h) x 298mm (v) (11.7 x11.7 in)	--	305mm (h) x 305mm (v) (12 x12 in)	Same as Predicate Device
Limiting resolution (Max)	2.58 lp/mm		2.58 lp/mm	3.5 lp/mm	2.5 lp/mm	Same as Predicate Device
Pixel Matrix	1,536 (h) x 1,536 (v)		1,536 (h) x 1,536 (v)	1548 (h) x 1524 (v)	1536 (h) x 1,536 (v)	Same as Predicate Device &

					Reference Device Cios Fusion
DQE	80% at 0lp/mm	80% at 0lp/mm	72%	55% at 1lp/mm	Same as Predicate Device
Modulation Transfer Function (MTF)	55% at 1lp/mm	55% at 1lp/mm	---	55% at 1lp/mm	Same as Predicate Device & Reference Device Cios Fusion
A/D Conversion	16 bit	16 bit	16 bit	16 bit	Same
Pixel Pitch	194µm	194µm	198.0 µm	194µm	Same as Predicate Device & Reference Device Cios Fusion
Optional					
Make	Varex's , Paxscan 2020	Varex's , Paxscan 2020	--	--	--
Type	Amorphous Silicon	Amorphous Silicon	CMOS	Amorphous Silicon	Same as Predicate Device & Reference Device Cios Fusion
Active Area	199mm (h) x 199mm (v)	199mm (h) x 199mm (v)	--	203mm (h) x 203mm (v)	Same as Predicate Device
Limiting resolution (Max)	2.58 lp/mm	2.58 lp/mm	3.5 lp/mm	3.1lp/mm	Same as Predicate Device
Pixel Matrix	1,024 (h) x 1,024 (v)	1,024 (h) x 1,024 (v)	1536 (h) x 1496 (v)	1,024 (h) x 1,024 (v)	Same as Predicate Device & Reference Device Cios Fusion
DQE	80% at 0lp/mm	80% at 1lp/mm	72%	55% at 1lp/mm	Same as Predicate Device

Modulation Transfer Function (MTF)	55% at 1lp/mm	55% at 1lp/mm	--	55% at 1lp/mm	Same as Predicate Device & Reference Device Cios Fusion
A/D Conversion	16 bit	16 bit	16 bit	16 bit	Same
Pixel Pitch	194µm	194µm	135.3 µm	194µm	Same as Predicate Device & Reference Device Cios Fusion
Optional					
Make	IRAY 's, Mercu 0909F	Varex, Paxscan 3030	--	--	--
Type	Amorphous Silicon	Amorphous Silicon	NA	NA	Same
Active Area	228.6mm (h)x228.6mm (v)	199mm (h) x 199mm (v)	NA	NA	Similar (SE #9)
Pixel Matrix	1,024 (h) x 1,024 (v)	1,024 (h) x 1,024 (v)	NA	NA	Same
DQE	77% at 0lp/mm	80% at 1lp/mm	NA	NA	Similar (SE #9)
Modulation Transfer Function (MTF)	64% at 1lp/mm	55% at 1lp/mm	NA	NA	Similar (SE #9)
A/D Conversion	16 bit	16 bit	NA	NA	Same
Pixel Pitch	205µm	194µm	NA	NA	Similar (SE #9)
Optional					
Make	Thales, Pixium 2121S-AU	Varex's , Paxscan 2020	--	--	--
Type	Amorphous Silicon	Amorphous Silicon	NA	NA	Same
Active Area	205mm (h) x 205mm (v)	199mm (h) x 199mm (v)	NA	NA	Similar (SE #9)

Pixel Matrix	1,024 (h) x 1,024 (v)	1,024 (h) x 1,024 (v)	NA	NA	Same
DQE	78 % at 0lp/mm	80% at 0lp/mm	NA	NA	Similar (SE #9)
Modulation Transfer Function (MTF)	53 % at 1lp/mm	55% at 1lp/mm	NA	NA	Similar (SE #9)
A/D Conversion	16 bit	16 bit	NA	NA	Same
Pixel Pitch	200 µm	194 µm	NA	NA	Similar (SE #9)
Optional					
Make	Thales, Pixium Surgical 2121S-A	Varex's , Paxscan 2020	--	--	--
Type	Amorphous Silicon	Amorphous Silicon	NA	NA	Same
Active Area	207mm (h) x 207mm (v)	199mm (h) x 199mm (v)	NA	NA	Similar (SE #9)
Pixel Matrix	1,344 (h) x 1,344 (v)	1,344 (h) x 1,024 (v)	NA	NA	Similar (SE #9)
DQE	76 % at 0lp/mm	65% at 1lp/mm	NA	NA	Similar (SE #9)
Modulation Transfer Function (MTF)	59% at 1lp/mm	55% at 1lp/mm	NA	NA	Similar (SE #9)
A/D Conversion	16 bit	16 bit	NA	NA	Same
Pixel Pitch	154 µm	194µm	NA	NA	Similar (SE #9)
Optional					
Make	MX CFP 2222	Varex, Paxscan 3030	--	--	--
Type	CMOS	Amorphous Silicon	CMOS	NA	Same as Reference Device OEC Elite

Active Area	217mm (h) x 217mm (v)	199mm (h) x 199mm (v)	--	NA	Similar (SE #9)
Pixel Matrix	2170 (h) x 2170 (v)	1,024 (h) x 1,024 (v)	1536 (h) x 1496 (v)	NA	Similar (SE #9)
DQE	75% at 0lp/mm	80% at 1lp/mm	72%	NA	Similar (SE #9)
Modulation Transfer Function (MTF)	70% at 1lp/mm	55% at 1lp/mm	Information not available	NA	Similar (SE #9)
A/D Conversion	16 bit	16 bit	16 bit	NA	Same
Pixel Pitch	100 µm	194 µm	135.3 µm	NA	Similar (SE #9)
Optional					
Make	MX CFP 3131	Varex, Paxscan 3030	--	--	--
Type	CMOS	Amorphous Silicon	CMOS	NA	Same as Reference Device OEC Elite.
Active Area	309.4mm (h) x 307.2mm (v)	199mm (h) x 199mm (v)	--	NA	Similar (SE #9)
Pixel Matrix	3094 (h) x 3072 (v)	1,024 (h) x 1,024 (v)	1536 (h) x 1496 (v)	NA	Similar (SE #9)
DQE	75% at 0lp/mm	80% at 1lp/mm	72%	NA	Similar (SE #9)
Modulation Transfer Function (MTF)	70% at 1lp/mm	55% at 1lp/mm	Information not available	NA	Similar (SE #9)
A/D Conversion	14 bit	16 bit	16 bit	NA	Similar (SE #9)
Pixel Pitch	100 µm	194µm	135.3 µm	NA	Similar (SE #9)
Optional					
Make	Thales, Pixium Surgical 3030S-A	Varex Paxscan 3030	--	--	--

Type	Amorphous Silicon	Amorphous Silicon	NA	NA	Same
Active Area	301mm (h) x301mm (v)	298mm (h) x 298mm (v)	NA	NA	Similar (SE #9)
Pixel Matrix	1,956 (h) x 1,956 (v)	1,536 (h) x 1,536 (v)	NA	NA	Similar (SE #9)
DQE	75 % at 0lp/mm	80% at 0lp/mm	NA	NA	Similar (SE #9)
Modulation Transfer Function (MTF)	59% @ 1lp/mm	55% at 1lp/mm	NA	NA	Similar (SE #9)
A/D Conversion	16 bit	16 bit	NA	NA	Same
Pixel Pitch	154 µm	194 µm	NA	NA	Similar (SE #9)
Optional					
Make	Thales, Pixium 3030S-AU	Varex Paxscan 3030	--	--	--
Type	Amorphous Silicon	Amorphous Silicon	NA	NA	Same
Active Area	300mm (h) x300mm (v)	298mm (h) x 298mm (v) (11.7 x11.7 in)	NA	NA	Similar (SE #9)
Pixel Matrix	1,536 (h) x 1,536 (v)	1,536 (h) x 1,536 (v)	NA	NA	Same
DQE	78 % at 0lp/mm	80% at 0lp/mm	NA	NA	Similar (SE #9)
Modulation Transfer Function (MTF)	59% @ 1lp/mm	55% at 1lp/mm	NA	NA	Similar (SE #9)
A/D Conversion	16 bit	16 bit	NA	NA	Same
Pixel Pitch	200 µm	194µm	NA	NA	Similar (SE #9)
10. Viewing Monitor(s)					
Size, in	27” & 32 “ (In Single Monitor)	19”	27”	19”	Similar (SE #10)

	19” & 21” (In dual Monitors)				
Touch Screen	Yes	Yes	No	Yes	Same as Predicate Device & Reference Device Cios Fusion.
11. Image Processing and storage					
Imaging Mode	• Pulsed Fluoroscopy • Digital Spot	• Pulsed Fluoroscopy • Digital Spot	• Pulsed Fluoroscopy • Digital Spot	• Pulsed Fluoroscopy • Digital Spot	Same
Video storage type	Internal HDD drive, USB, CD/DV D-RW drive	Internal HDD drive, USB, CD/DV D-RW drive	Digital Memory, USB , HDD	Internal HDD drive, USB, CD/DV D-RW drive	Same as Predicate Device & Reference Device Cios Fusion.
Image Interference	Detector Dependant	Detector Dependant	Detector Dependant	Detector Dependant	Same
Capacity Number of images	Upto 100,000	Upto 100,000	Upto 50,000	Upto 150,000	Same as Predicate Device
Image matrix size	1536*1536 Pixels 1024*1024 Pixels	1536*1536 Pixels 1024*1024 Pixels	1.5K x 1.5K CFD	Upto 1.5K x 1.5K	Same as Predicate Device
LIH	Yes	Yes	Yes	Yes	Same
Dicom conformance	Yes	Yes	Yes	Yes	Same
PACS Interfaces	Ethernet or WLAN	Ethernet or WLAN	Ethernet	Ethernet or WLAN	Same
Hard copy devices	Printer and DICOM print	Printer Pyngaper and/or Film , DICOM print	Integrated film/ thermal printers/paper	USB, CD/DVD, Paper film	Same as Predicate Device
12. Power Requirement					
Power Requirement	110/230 Vac,(±10%) 50/60 Hz	110/240 VAC,(±10%) 50/60 Hz	230/110 Vac,(±10%) 50/60 Hz	110/240 VAC,(±10%) 50/60 Hz	Same

Difference Discussion

SE- #	Substantial Equivalence discussion
SE #1	**#1** Digiscan FDX Family Fluoroscopic Mobile X-Ray System requires less X-Ray source and therefore less capacity for the X-Ray generator and tube heat storage compared to predicate & reference devices. Such differences in performance do not raise additional risk concerns. A typical fluoroscopy mode for Predicate & Reference devices and Digiscan FDX family requires the power of 1 kW or less. Therefore, the generator outputs for Digiscan FDX family and predicate & reference devices in fluoroscopy mode is not significantly different.
SE#2, #3, #4 & #5	**#2, #3, #4** There are many X-Ray tubes available due to equipment design considerations. The tubes were tested and information is included in the Operator and Service Manuals. Any differences between the subject device and predicate & reference devices do not change or add new potential safety risks. Therefore, it is our determination that there is “No impact on safety or efficacy” and there are no new potential or increased safety risks concerning this difference. **#5** The focal spot on the X-Ray tube (Stationary anode) is different between the subject device and the Reference device Cios Fusion (K153244). The “focal spot” is the area of the anode surface which receives the beam of electrons from the cathode. The size and shape of the focal spot is determined by the size and shape of the electron beam when it strikes the anode. Size and shape of the electron beam is determined by: dimensions of the filament tungsten coil, construction of the focusing cup, and position of the filament in the focusing cup. Since the subject device and Reference device (i. Cios Fusion K153244) are using different X-Ray tube manufactures, the focal spot is different. The differences between the subject device and reference device (Cios Fusion (K153244) do not change or add new potential safety risks. Therefore, it is our determination that there is “No impact on safety or efficacy” and there are no new potential or increased safety risks concerning this difference.
SE#6, #7 & #8	**#6, #7 & #8** The differences in the X-Ray current produced by the generators made by Allengers do not raise any new questions of safety and effectiveness between the subject and Predicate & reference devices, as the subject device has successfully passed electrical safety testing per IEC 60601-1, and IEC 60601-2-54.
SE#09	**#09** The Subject device utilized different Solid State X-Ray Image Detectors (FPD) as compare to reference devices OEC Elite (K172550) & Cios Fusion (K153244), however Detector technology is comparable to predicate and reference devices as per the SSXI Guidance document .The FPD used along with subject device are already cleared by FDA and does not raise the level of safety concern and affect any effectiveness. The relevant 510(k) approval numbers are K100102, K113548, K183040, and K172822 & K171755.
SE#10	**#10** The Digiscan FDX family monitor(s) has the same resolution as the predicate & reference devices which were Ziehm Vision RFD (K 132904), OEC Elite (K172550) & Cios Fusion (K153244), however the screen size is similar or slightly bigger. Therefore it is our determination that there is “No impact on safety or efficacy” and there are no new potential or increased safety risks.

10. Technological characteristics comparison to predicate & reference devices:

The indications for use, operating principle, technical specifications such as X-Ray tube head and generator as well as safety characteristics of Digiscan FDX family are identical to those of the predicate & reference devices. Digiscan FDX family is designed as a set of components (X-Ray tube and housing, detector, digital imaging system, collimator, generator etc.) similar to the predicate & reference device Ziehm Vision RFD (K132904), OEC Elite (K172550) & Cios Fusion (K153244). Based on the recognized standard conformity evidences related to electro-mechanical, software-, and risk management, Allengers Medical Systems certifies that technological characteristics of Digiscan FDX family are substantially equivalent to Ziehm Vision RFD, OEC Elite and Cios Fusion, the predicate & reference devices.

The Digiscan FDX mobile X-Ray C-Arm is a set of components similar to the predicate & reference devices as compared in table 3 of this 510(K) summary. This table above show that the system are either similar or the same, as the predicate & reference devices..

11. Performance Testing

Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence. Performance testing included functional testing of all motions systems with respect to design specifications. Additional engineering bench testing was performed including: the non-clinical testing identified in the guidance for submission of 510(k)s for Solid state X-Ray imaging devices (SSXI); Demonstration of system performance and an Imaging performance evaluation. Safety compliance checking was evaluated according to IEC 60601-1: 2005/ A1:2012. Allengers Medical Systems Ltd certifies conformance to Voluntary standards covering electrical and Mechanical safety.

In conclusion, the identified risk of electrical hazards was mitigated and it is the Allengers opinion that Digiscan FDX Family appears to be as safe and effective as predicate & reference devices..

12. Software Features and Testing:

Software Documentation for a Moderate Level of concern software per FDA's Guidance document "Guidance for the Content of Premarket Submission for software contained in Medical Device" is also included as part of this submission. Non Clinical tests were conducted on the subject device Digiscan FDX software version 1.0.0.0 during product development.

13. Description of Non Clinical tests

Non Clinical performance testing has been performed on the Digiscan FDX machine and it demonstrates compliance with the following 21 CFR Federal Performance Standards:

- 1020.30 Diagnostic X-Ray Systems and their major components
- 1020.32 Fluoroscopic equipment
- 1040.10 Laser products

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
12-204	Radiology	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	60601-2-28 Edition 2.0 2010-03	IEC
12-308	Radiology	Particular requirements for the safety of X-Ray equipment for interventional procedures	60601-2-43 Edition 2.1, 2017	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
5-40	General I (QS/RM)	Medical devices – application of risk management to medical devices	14971 Second Edition 2007-03	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 September 13, 2019.
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: Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices Document issued on July 11, 2016

Non-clinical verification test results demonstrate that the Digiscan FDX complies with the aforementioned international and FDA recognized consensus standards and FDA guidance documents.

14. Description of clinical tests

Independent views of Urologist, orthopedic, Gastroenterologist, Cardiologists, Neurologist were obtained on the imaging performances and the acquired images were of adequate quality for the indicated use. The acquired images included examination of the Cardiac, neurology, fluoroscopic loop, Fluoroscopic LIH and Digital spot images. The results of the validation activities confirmed that the device is safe and effective for its intended application.

The Digiscan FDX was found to provide adequate image quality for the specific view and procedures identified in the IFU.

15. Substantial Equivalence Conclusion:

Digiscan FDX Family do not introduce any new indications for use, nor does the use of the systems result in any new potential hazards. The Digiscan FDX Family, the subject device is substantially equivalent to the predicate & reference devices, Ziehm Vision RFD (K132904), OEC Elite (K172550) and Cios Fusion (K153244). The intended use, the design principle, and the applicable standards for the subject device are identical to those of the predicate & reference devices. 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 devices.