May 3, 2022

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

Re: K220311
Trade/Device Name: Cardiovascular Angiography System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA, OXO
Dated: January 27, 2022
Received: February 2, 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
Assistant Director
Diagnostic X-ray Systems Team
DHT 8B: Division of Radiological 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)*

K220311

Device Name

Cardiovascular Angiography System

Indications for Use *(Describe)*

The Cardiovascular Angiography System is digital system with high frequency X-Ray generator for application in cardiovascular procedures. This system used in catheterization labs uses high power x-ray pulses and digital imaging system to visualize the vascular structures of human body.

Clinical applications may include (but not limited to) interventional cardiovascular procedures, Neurovascular procedures, pacemaker implantable and high end investigations.

This system should be handled by persons who have been briefed in its professional handling and who have familiarized themselves with the product by means of instructions for use. Intended use also means following the user manual and observing the conditions for inspection and maintenance.

Exclusion: This system is not recommended for Mammography.

Contraindication: 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.

Allengers Medical Systems Limited

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:	27.01.2022

2. Proposed Device:

Device (trade) name:	Cardiovascular Angiography System
Model Name:	Proxima FDX, Altima FDX Adv Digiscan FDX-V8043, Digiscan FDX-V8030, Digiscan FDX-V8020 Digiscan FDX-V6543, Digiscan FDX-V6530, Digiscan FDX-V6520 Digiscan FDX-V4043, Digiscan FDX-V4030, Digiscan FDX-V4020 Digiscan FDX-V2743, Digiscan FDX-V2730, Digiscan FDX-V2720
Classification Name :	Image-Intensified Fluoroscopic X-Ray System
Classification Panel:	Radiology
Regulation Number :	21 CFR 892.1650
Device Class:	Class II
Product Code:	Primary Code : OWB Subsequent Code : JAA and OXO for [1]Digiscan FDX-VXXYY

3. Predicate Device:

Device (trade) name:	Allura Xper FD Series and Allura Xper OR Table series
510(K) Number :	K162859
Clearance Date :	December 2, 2016
Classification Name:	Image-Intensified Fluoroscopic X-Ray System,
Classification Panel:	Radiology
Regulation Number :	21 CFR 892.1650
Device Class :	Class II
Product Code:	Primary Code : OWB Subsequent Code : JAA

[1] Where XX may be 80/65/40/27 and YY may be 43/30/20

4. Reference devices:

Device (trade) name:	Ziehim Vision RFD
510(K) Number :	K203428
Clearance Date :	March 17, 2021
Classification Name:	Image-Intensified Fluoroscopic X-Ray System
Classification Panel:	Radiology
Regulation Number :	21 CFR 892.1650
Device Class :	Class II
Product Code:	Primary Code : OWB
	Subsequent Code : 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 DXV	K200218
Varex Imaging corporation – Paxscan 3030 DXV	K200218
Varex Imaging corporation – Paxscan 4343DXV	--
MX Imaging – CFP 2222	K171755
MX Imaging – CFP 3131	K171755
Thales Group – Pixium Surgical 2121S-A	K183040
Thales Group – Pixium 2121S-AU	K200218
Thales Group – Pixium Surgical 3030S-A	K172822
Thales Group – Pixium 3030S-AU	K200218
IRAY Technology – Mercu 0909F	K200218
Allengers Medical Systems Ltd - FP 2121 RF	--
Allengers Medical Systems Ltd - FP 2121 HR	--
Allengers Medical Systems Ltd - FP 3030 HR	--

5. Device description:

The Cardiovascular Angiography system is designed to perform fluoroscopic & digital radiographic studies and are used in interventional examinations. This system covers the complete range of angiographic applications, cardiac angiography, neuro-angiography, general angiography, surgery and surgical angiography, multipurpose angiography, rotational angiography and digital radiographic/ fluoroscopic procedures.
The following components are configured to create the Cardiovascular Angiography system:

1. Floor mounted C-arm (Altima FDX Adv) or Ceiling Mounted C-Arm (Proxima FDX) or Mobile C-Arm ([2]Digiscan FDX-VXXYY), X-ray tube assembly and Solid State X-Ray image detector
2. Patient Table
3. Ceiling suspended display(s)

[2] Where XX may be 80/65/40/27 and YY may be 43/30/20

4. Footswitch for releasing radiation
5. Control console for controlling the stand, patient table, collimator and imaging 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	Proxima FDX Altima FDX Adv	XGEN-100CV
X-Ray Generator	Allengers	Proxima FDX Altima FDX Adv Digiscan FDX-V8043 Digiscan FDX-V8030 Digiscan FDX-V8020	XGEN-80CV
X-Ray Generator	Allengers	Digiscan FDX-V6543 Digiscan FDX-V6530 Digiscan FDX-V6520	XGEN-65CV
X-Ray Generator	Allengers	Digiscan FDX-V4043 Digiscan FDX-V4030 Digiscan FDX-V4020	XGEN-40CV
X-Ray Generator	Allengers	Digiscan FDX-V2743 Digiscan FDX-V2730 Digiscan FDX-V2720	XGEN-27CV
X-Ray Tube	Siemens Healthcare GmbH	Proxima FDX Altima FDX Adv	Megalix CAT 125/35/80 125 GW Megalix CAT 125/15/40/80122 GW
X-Ray Tube	Canon Electron Tubes and devices	Proxima FDX Altima FDX Adv	E79039X E79030X E79016X
X-Ray Tube	Varex Imaging	Proxima FDX Altima FDX Adv Digiscan FDX-V8043 Digiscan FDX-V8030 Digiscan FDX-V8020 Digiscan FDX-V6543 Digiscan FDX-V6530 Digiscan FDX-V6520 Digiscan FDX-V4043 Digiscan FDX-V4030 Digiscan FDX-V4020	G1082, G-1582BI, G2090, G1092

X-Ray Tube	Varex Imaging	Digiscan FDX-V2743 Digiscan FDX-V2730 Digiscan FDX-V2720	A-145, RAD-99, RAD-99B, RAD-15
Solid State X-Ray Image Detectors	Varex Imaging	Proxima FDX Altima FDX Adv Digiscan FDX-V8020 Digiscan FDX-V6520 Digiscan FDX-V4020 Digiscan FDX-V2720	Paxscan 2020 DXV
Solid State X-Ray Image Detectors	Varex Imaging	Proxima FDX Altima FDX Adv Digiscan FDX-V8030 Digiscan FDX-V6530 Digiscan FDX-V4030 Digiscan FDX-V2730	Paxscan 3030 DXV
Solid State X-Ray Image Detectors	Varex Imaging	Proxima FDX Altima FDX Adv Digiscan FDX-V8043 Digiscan FDX-V6543 Digiscan FDX-V4043 Digiscan FDX-V2743	Paxscan 4343DXV
Solid State X-Ray Image Detectors	IRAY Technology	Proxima FDX Altima FDX Adv Digiscan FDX-V8020 Digiscan FDX-V6520 Digiscan FDX-V4020 Digiscan FDX-V2720	Mercu 0909F
Solid State X-Ray Image Detectors	Thales Group	Proxima FDX Altima FDX Adv Digiscan FDX-V8020 Digiscan FDX-V6520 Digiscan FDX-V4020 Digiscan FDX-V2720	Pixium 2121S-AU Pixium Surgical 2121S-A
Solid State X-Ray Image Detectors	Thales Group	Proxima FDX Altima FDX Adv Digiscan FDX-V8030 Digiscan FDX-V6530 Digiscan FDX-V4030 Digiscan FDX-V2730	Pixium 3030S-AU Pixium Surgical 3030S-A
Solid State X-Ray Image Detectors	MX Imaging	Proxima FDX Altima FDX Adv Digiscan FDX-V8020	CFP 2222

		Digiscan FDX-V6520 Digiscan FDX-V4020 Digiscan FDX-V2720	
Solid State X-Ray Image Detectors	MX Imaging	Digiscan FDX-V8030 Digiscan FDX-V6530 Digiscan FDX-V4030 Digiscan FDX-V2730	CFP 3131
Solid State X-Ray Image Detectors	Allengers	Proxima FDX Altima FDX Adv Digiscan FDX-V8020 Digiscan FDX-V6520 Digiscan FDX-V4020 Digiscan FDX-V2720	FP 2121 RF FP 2121 HR
Solid State X-Ray Image Detectors	Allengers	Proxima FDX Altima FDX Adv Digiscan FDX-V8030 Digiscan FDX-V6530 Digiscan FDX-V4030 Digiscan FDX-V2730	FP 3030 HR
Patient Table	Allengers	Proxima FDX Altima FDX Adv	C Tab F FDX C Tab FXL FDX C Tab FCV FDX
Patient Table	Allengers	Digiscan FDX-V8043 Digiscan FDX-V8030 Digiscan FDX-V8020 Digiscan FDX-V6543 Digiscan FDX-V6530 Digiscan FDX-V6520 Digiscan FDX-V4043 Digiscan FDX-V4030 Digiscan FDX-V4020 Digiscan FDX-V2743 Digiscan FDX-V2730 Digiscan FDX-V2720	C Tab M FDX Vascu Tab FDX

6. Indications for Use:

The Cardiovascular Angiography System is digital system with high frequency X-Ray generator for application in cardiovascular procedures. This system used in catheterization labs uses high power x-ray pulses and digital imaging system to visualize the vascular structures of human body.

Clinical applications may include (but not limited to) interventional cardiovascular procedures, Neurovascular procedures, pacemaker implantable and high end investigations.

This system should be handled by persons who have been briefed in its professional handling and who have familiarized themselves with the product by means of instructions for use. Intended use also means following the user manual and observing the conditions for inspection and maintenance.

Exclusion: This system is not recommended for Mammography.

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

7. Technological Characteristics Comparison to Predicate & Reference Devices:

The Cardiovascular Angiography Systems having set of components similar to the Allura Xper FD Series and Allura Xper OR Table series (K162859) and Ziehm Vision RFD (K203428) 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 device.

8. Software Feature

Synergy FP FDX & Synergy FDX-CR imaging software is a Digital Imaging System (DIS) provides useful functions to manage X-Ray images obtained from Cardiovascular Angiography 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 section 9 Image processing and storage of the table 3 for a list of top level functions

9. Substantial Equivalence:

The Cardiovascular Angiography system are substantially equivalent to the commercially available Allura Xper FD series and Allura Xper OR Table series (K162859) & Ziehm Vision RFD (K203428). Functional and specification differences are identifying in the following table.

Table 3: Functional and specification differences

Feature	Cardiovascular Angiography System (Subject Device)	Allura Xper FD Series and Allura Xper OR Table series (Predicate Device)	Ziehm Vision RFD (Reference Device)	Justification for differences
1. 510(k)	This submission	K162859	K203428	
2. Product Code				
Product Classification Code	OWB, JAA & OXO for [3]Digiscan FDX-VXXYY	OWB and JAA	OWB , JAA & OXO	Same
3. Product Classification				
Classification	21 CFR 892.1650	21 CFR 892.1650	21 CFR 892.1650	Same
4. Indication for Use				
Indications for Use	The Cardiovascular Angiography system is digital system with high frequency X-Ray generator for application in cardiovascular procedures. This system used in catheterization labs uses high power x-ray pulses and digital imaging system to visualize the vascular structures of human body. Clinical applications may include (but not limited to) interventional cardiovascular procedures, Neurovascular procedures, pacemaker implantable and high end investigations. This system should be handled by persons who have been briefed in its professional handling and who have familiarized themselves with the product by means of instructions for use. Intended use also means following the user manual and observing the conditions for inspection and maintenance. **Exclusion:** This system is not recommended for Mammography. **Contraindications**: Exposure of X-Ray should be avoided during pregnancy.	The Allura Xper series and the Allura Xper OR Table series (within the limits of the used OR table) are intended for use on human patients to perform: • Vascular, cardiovascular and neurovascular imaging applications, including diagnostic, interventional and minimally invasive procedures. This includes, e.g., peripheral, cerebral, thoracic and abdominal angiography, as well as PTAs, stent placements, embolisations and thrombolysis. • Cardiac imaging applications including diagnostics, interventional and minimally invasive procedures (such as PTCA, stent placing, atherectomies), pacemaker implantations, and electrophysiology (EP). • Non-vascular interventions such as drainages, biopsies and vertebroplasties procedures. Additionally: • The Allura Xper and Allura Xper OR Table series is compatible with a hybrid Operating Room. • Allura Xper FD10 is compatible with specified magnetic navigation systems. • Combined with a	The Ziehm Vision RFD is intended for use in providing medical imaging for adult and pediatric populations, using pulsed and continuous fluoroscopic digital imaging, as well as digital subtraction and cine image capture during diagnostic interventional and surgical procedures where intra-operative 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, endoscopic, urological, gastroenterology, orthopedic, maxillofacial surgery, neurology, neurosurgery, critical care, emergency room procedures, and those procedures visualizing structures of the	Essentially the same *Note:* There are no differences between the subject device and the predicate with respect to indication and intended use.

[3] Where XX may be 80/65/40/27 and YY may be 43/30/20

Feature	Cardiovascular Angiography System (Subject Device)		Allura Xper FD Series and Allura Xper OR Table series (Predicate Device)	Ziehm Vision RFD (Reference Device)	Justification for differences
			qualified, compatible OR table, the Allura Xper OR Table series can be used for imaging in the Hybrid OR within the applications domains Neuro, Vascular, Non Vascular and Cardiac. The OR table can also be used standalone for surgical use in the OR.	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. The visualization of such anatomical structures assists the clinician in the clinical outcome. 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.	
5. X-Ray Generator					
Type	Microprocessor-controlled, high frequency converter generator		Microprocessor-controlled, high frequency converter generator	Monoblock and High Frequency Generator	Same as Predicate device
Power Rating	XGEN-100CV	100KW	100 KW	30 KW 25 KW	Similar (SE #1)
	XGEN-80CV	80KW			
	XGEN-65CV	65KW			
	XGEN-40CV	40KW			
	XGEN-27CV	27KW			
Nominal power (highest electrical power)	100 kW(1000mA at 100kV) 80 KW(800 mA at 100 KV) 65 KW(650 mA at 100 KV) 40 KW(400 mA at 100 KV) 27 KW(270 mA at 100 KV)		100 kW (1000 mA at 100 kV)	30 kW(300mA at 100 kV) 25 KW(250mA at 100 kV)	Similar (SE #2)
Digital Radiographic Mode					
Radiographic mA (Max.)	1-1000 mA		1-1000 mA	1-300 mA	Same as predicate device
Radiographic KV	40-125		40-125	40-120	Same as Predicate Device

Feature	Cardiovascular Angiography System (Subject Device)	Allura Xper FD Series and Allura Xper OR Table series (Predicate Device)	Ziehm Vision RFD (Reference Device)	Justification for differences
Fluoroscopic Mode				
Fluoroscopic mA	Pulsed 200 mA max	Pulsed 200 mA max	Pulsed 300 mA max	Same as Predicate Device
Fluoroscopic KV	40-125	40-125	40-120	Same as Predicate Device
Pulsed fluoroscopy	Upto 30 fps	upto 30 fps	upto 25 fps	Same as Predicate Device
ABS Control	Yes	Yes	Yes	Same
6. X-Ray Tube				
Model	Megalix CAT 125/35/80 125 GW	MRC-GS 0508	--	--
Tube Type	Rotating Anode	Rotating Anode	Rotating Anode	Same
Max. anode heat storage	3 MHU	2.4 MHU	365 KHU	Similar (SE #3)
Focal Spot Size, mm	Dual Focus 0.4/0.8	Dual Focus 0.5/0.8	Dual Focus 0.3/0.6	Similar (SE #3)
Anode Angle	8.5º	9º	--	Similar (SE #3)
Optional				
Model	Megalix CAT125/15/40/80 122 GW	MRC-GS 0508	--	--
Tube Type	Rotating Anode	Rotating Anode	Rotating Anode	Same
Max. anode heat storage	3 MHU	2.4 MHU	365 KHU	Similar (SE #3)
Focal Spot Size, mm	Triple Focus 0.3/0.6/1.0	Dual Focus 0.5/0.8	Dual Focus 0.3/0.6	Similar (SE #3)
Anode Angle	12.5º	9º	--	Similar (SE #3)
Optional				
Model	E79039X	MRC-GS 0508	--	--
Tube Type	Rotating Anode	Rotating Anode	Rotating Anode	Same
Max. anode heat storage	2.1 MHU	2.4 MHU	365 KHU	Similar (SE #3)
Focal Spot Size, mm	Dual Focus 0.6/1.0	Dual Focus 0.5/0.8	Dual Focus 0.3/0.6	Similar (SE #3)
Anode Angle	11º	9º	--	Similar (SE #3)
Optional				
Model	E79030X	MRC-GS 0508	--	--
Tube Type	Rotating Anode	Rotating Anode	Rotating Anode	Same
Max. anode heat storage	3 MHU	2.4 MHU	365 KHU	Similar (SE #3)
Focal Spot	Dual Focus 0.6/1.0	Dual Focus 0.5/0.8	Dual Focus 0.3/0.6	Similar

Feature	Cardiovascular Angiography System (Subject Device)	Allura Xper FD Series and Allura Xper OR Table series (Predicate Device)	Ziehm Vision RFD (Reference Device)	Justification for differences
Size, mm				(SE #3)
Anode Angle	11º	9º	--	Similar (SE #3)
Optional				
Model	E79016X	MRC-GS 0508	--	
Tube Type	Rotating Anode	Rotating Anode	Rotating Anode	Same
Max. anode heat storage	3 MHU	2.4 MHU	365 KHU	Similar (SE #3)
Focal Spot Size, mm	Triple Focus 0.3/ 0.6/1.0	Dual Focus 0.5/0.8	Dual Focus 0.3/0.6	Similar (SE #3)
Anode Angle	11º	9º	--	Similar (SE #3)
Optional				
Model	G2090TRI	MRC-GS 0508	--	
Tube Type	Rotating Anode	Rotating Anode	Rotating Anode	Same
Max. anode heat storage	2 MHU	2.4 MHU	365 KHU	Similar (SE #3)
Focal Spot Size, mm	Triple Focus 0.3/ 0.6/1.0	Dual Focus 0.5/0.8	Dual Focus 0.3/0.6	Similar (SE #3)
Anode Angle	12º	9º	--	Similar (SE #3)
Optional				
Model	G1582BI	MRC-GS 0508	--	
Tube Type	Rotating Anode	Rotating Anode	Rotating Anode	Same
Max. anode heat storage	1.5 MHU	2.4 MHU	365 KHU	Similar (SE #3)
Focal Spot Size, mm	Triple Focus 0.3/ 0.6/1.0	Dual Focus 0.5/0.8	Dual Focus 0.3/0.6	Similar (SE #3)
Anode Angle	10º	9º	--	Similar (SE #3)
Optional				
Model	G1082	MRC-GS 0508	--	
Tube Type	Rotating Anode	Rotating Anode	Rotating Anode	Same
Max. anode heat storage	1 MHU	2.4 MHU	365 KHU	Similar (SE #3)
Focal Spot Size, mm	Dual Focus 0.3/1.0	Dual Focus 0.5/0.8	Dual Focus 0.3/0.6	Similar (SE #3)
Anode Angle	10º	9º	--	Similar (SE #3)
Optional				
Model	G1092	MRC-GS 0508	--	
Tube Type	Rotating Anode	Rotating Anode	Rotating Anode	Same
Max. anode heat storage	1 MHU	2.4 MHU	365 KHU	Similar (SE #3)

Feature	Cardiovascular Angiography System (Subject Device)	Allura Xper FD Series and Allura Xper OR Table series (Predicate Device)	Ziehm Vision RFD (Reference Device)	Justification for differences
Focal Spot Size, mm	Dual Focus 0.6/1.2	Dual Focus 0.5/0.8	Dual Focus 0.3/0.6	Similar (SE #3)
Anode Angle	12º	9º	--	Similar (SE #3)
Optional				
Model	RAD-15	MRC-GS 0508	--	
Tube Type	Rotating Anode	Rotating Anode	Rotating Anode	Same
Max. anode heat storage	365 KHU	2.4 MHU	365 KHU	Same as Reference Device
Focal Spot Size, mm	Dual Focus 0.3/0.6	Dual Focus 0.5/0.8	Dual Focus 0.3/0.6	Same as Reference Device
Anode Angle	10º	9º	--	Similar (SE #3)
Optional				
Model	RAD-99 / RAD-99B	MRC-GS 0508	--	
Tube Type	Rotating Anode	Rotating Anode	Rotating Anode	Same
Max. anode heat storage	300 KHU	2.4 MHU	365 KHU	Similar (SE #3)
Focal Spot Size, mm	Dual Focus 0.3/0.6	Dual Focus 0.5/0.8	Dual Focus 0.3/0.6	Same as Reference Device
Anode Angle	10º	9º	--	Similar (SE #3)
Optional				
Model	A-145	MRC-GS 0508	--	
Tube Type	Rotating Anode	Rotating Anode	Rotating Anode	Same
Max. anode heat storage	300 KHU	2.4 MHU	365 KHU	Similar (SE #3)
Focal Spot Size, mm	Dual Focus 0.3/0.6	Dual Focus 0.5/0.8	Dual Focus 0.3/0.6	Same as Reference Device
Anode Angle	10º	9º	--	Similar (SE #3)
7. Solid State X-Ray Image Detectors				
Make	Thales, Pixium Surgical 2121S-A	--	---	--
Type	Amorphous Silicon	--	Amorphous Silicon	Same as Reference device
Active Area	21 cm x 21 cm	21 cm x21 cm	19.9 cm x 19.9 cm	Same as predicate device
Pixel Matrix	1,344 x 1,344	1,344 x 1,344	1,024 x 1,024	Same as predicate

Feature	Cardiovascular Angiography System (Subject Device)	Allura Xper FD Series and Allura Xper OR Table series (Predicate Device)	Ziehm Vision RFD (Reference Device)	Justification for differences
				device
DQE	77 % at 0lp/mm	77% at 0lp/mm	80% at 0lp/mm	Same as predicate device
Modulation Transfer Function (MTF) at 1lp/mm	59%	59%	55%	Same as predicate device
A/D Conversion	16 bit	16 bit	16 bit	Same
Pixel Pitch	154 µm	154µm	194µm	Same as predicate device
Optional				
Make	Varex's , Paxscan 4343DXV	--	--	--
Type	Amorphous Silicon	---	Amorphous Silicon	Same as Reference device
Active Area	42.7cm x 42.7cm	38 cm x 30 cm	29.8 cm x 29.8 cm	Similar (SE #4)
Pixel Matrix	3,072 x 3,072	2,480 x 1,920	1,536 x 1,536	Similar (SE #4)
DQE	78% at 0lp/mm	77% at 0lp/mm	80% at 0lp/mm	Similar (SE #4)
Modulation Transfer Function (MTF) at 1lp/mm	54%	60%	55%	Similar (SE #4)
A/D Conversion	16 bit	16 bit	16 bit	Same
Pixel Pitch	139µm	154µm	194µm	Similar (SE #4)
Optional				
Make	Varex's , Paxscan 3030 DXV	--	--	--
Type	Amorphous Silicon	--	Amorphous Silicon	Same as Reference device
Active Area	29.8 cm x 29.8 cm	29 cm x26 cm	29.8 cm x 29.8 cm	Same as Reference device
Pixel Matrix	1,536 x 1,536	1,560 x 1,440	1,536 x 1,536	Same as Reference device
DQE	80% at 0lp/mm	70% at 0lp/mm	80% at 0lp/mm	Same as Reference device
Modulation Transfer	55%	59%	55%	Same as Reference

Feature	Cardiovascular Angiography System (Subject Device)	Allura Xper FD Series and Allura Xper OR Table series (Predicate Device)	Ziehm Vision RFD (Reference Device)	Justification for differences
Function (MTF) at 1lp/mm				device
A/D Conversion	16 bit	16 bit	16 bit	Same
Pixel Pitch	194µm	184µm	194µm	Same as Reference device
Optional				
Make	Varex's , Paxscan 2020 DXV	--	--	--
Type	Amorphous Silicon	--	Amorphous Silicon	Same as Reference device
Active Area	19.9 cm x 19.9 cm	21 cm x 21 cm	19.9 cm x 19.9 cm	Same as Reference device
Pixel Matrix	1,024 x 1,024	1,344 x 1,344	1,024 x 1,024	Same as Reference device
DQE	80% at 0lp/mm	77% at 0lp/mm	80% at 0lp/mm	Same as Reference device
Modulation Transfer Function (MTF) at 1lp/mm	55%	59%	55%	Same as Reference device
A/D Conversion	16 bit	16 bit	16 bit	Same
Pixel Pitch	194µm	154µm	194µm	Same as Reference device
Optional				
Make	IRAY 's, Mercu 0909F	--	--	--
Type	Amorphous Silicon	--	Amorphous Silicon	--
Active Area	22.9 cm x 22.9 cm	21 cm x 21 cm	19.9 cm x 19.9 cm	Similar (SE #4)
Pixel Matrix	1,024 x 1,024	1,344 x 1,344	1,024 x 1,024	Same as Reference Device
DQE	77% at 0lp/mm	77% at 0lp/mm	80% at 0lp/mm	Same as Predicate device
Modulation Transfer Function (MTF) at 1lp/mm	61%	59%	55%	Similar (SE #4)
A/D Conversion	16 bit	16 bit	16 bit	Same
Pixel Pitch	205µm	154µm	194µm	Similar

Feature	Cardiovascular Angiography System (Subject Device)	Allura Xper FD Series and Allura Xper OR Table series (Predicate Device)	Ziehm Vision RFD (Reference Device)	Justification for differences
				(SE #4)
Optional				
Make	Thales, Pixium 2121S-AU	--	--	--
Type	Amorphous Silicon	--	Amorphous Silicon	Same as Reference device
Active Area	20.5 cm x 20.5 cm	21 cm x 21 cm	19.9 cm x 19.9 cm	Similar (SE #4)
Pixel Matrix	1,024 x 1,024	1,344 x 1,344	1,024 x 1,024	Same as Reference Device
DQE	78 % at 0lp/mm	77% at 0lp/mm	80% at 0lp/mm	Similar (SE #4)
Modulation Transfer Function (MTF) at 1lp/mm	53 %	59%	55%	Similar (SE #4)
A/D Conversion	16 bit	16 bit	16 bit	Same
Pixel Pitch	200 µm	154µm	194µm	Similar (SE #4)
Optional				
Make	MX CFP 2222	--	--	--
Type	CMOS	--	Amorphous Silicon	Similar (SE #4)
Active Area	21.7 cm x 21.7 cm	21 cm x 21 cm	29.8 cm x 29.8 cm	Similar (SE #4)
Pixel Matrix	2,170 x 2,170	1,344 x 1,344	1,536 x 1,536	Similar (SE #4)
DQE	72% at 0lp/mm	77% at 0lp/mm	80% at 0lp/mm	Similar (SE #4)
Modulation Transfer Function (MTF) at 1lp/mm	60%	59%	55%	Similar (SE #4)
A/D Conversion	16 bit	16 bit	16 bit	Same
Pixel Pitch	100 µm	154µm	194µm	Similar (SE #4)
Optional				
Make	MX CFP 3131	--	--	--
Type	CMOS	--	Amorphous Silicon	Similar (SE #4)
Active Area	30.9 cm x 30.7 cm	29 cm x 26 cm	29.8 cm x 29.8 cm	Similar (SE #4)
Pixel Matrix	3,096 x 3,072	1,560 x 1,440	1,536 x 1,536	Similar (SE #4)

Feature	Cardiovascular Angiography System (Subject Device)	Allura Xper FD Series and Allura Xper OR Table series (Predicate Device)	Ziehm Vision RFD (Reference Device)	Justification for differences
DQE	72% at 0lp/mm	70% at 0lp/mm	80% at 0lp/mm	Similar (SE #4)
Modulation Transfer Function (MTF) at 1lp/mm	60%	59%	55%	Similar (SE #4)
A/D Conversion	14 bit	16 bit	16 bit	Same
Pixel Pitch	99 µm	184µm	194µm	Similar (SE #4)
Optional				
Make	Thales, Pixium Surgical 3030S-A	--	--	--
Type	Amorphous Silicon	--	Amorphous Silicon	Same as Reference Device
Active Area	30.1 cm x 30.1 cm	29 cm x 26 cm	29.8 cm x 29.8 cm	Similar (SE #4)
Pixel Matrix	1,956 x 1,956	1,560 x 1,440	1,536 x 1,536	Similar (SE #4)
DQE	75 % at 0lp/mm	70% at 0lp/mm	80% at 0lp/mm	Similar (SE #4)
Modulation Transfer Function (MTF) at 1lp/mm	59%	59%	55%	Same as Predicate Device
A/D Conversion	16 bit	16 bit	16 bit	Same
Pixel Pitch	154 µm	184µm	194µm	Similar (SE #4)
Optional				
Make	Thales, Pixium 3030S-AU	--	--	--
Type	Amorphous Silicon	--	Amorphous Silicon	Same as Reference Device
Active Area	30 cm x 30 cm	29 cm x 26 cm	19.9 cm x 19.9 cm	Similar (SE #4)
Pixel Matrix	1,536 x 1,536	1,560 x 1,440	1,024 x 1,024	Similar (SE #4)
DQE	78 % at 0lp/mm	70% at 0lp/mm	80% at 0lp/mm	Similar (SE #4)
Modulation Transfer Function (MTF) at 1lp/mm	59%	59%	55%	Same as Predicate device
A/D Conversion	16 bit	16 bit	16 bit	Same
Pixel Pitch	200 µm	184µm	194µm	Similar

Feature	Cardiovascular Angiography System (Subject Device)	Allura Xper FD Series and Allura Xper OR Table series (Predicate Device)	Ziehm Vision RFD (Reference Device)	Justification for differences
				(SE #4)
Optional				
Make	Allengers, FP 2121RF	--	--	--
Type	Amorphous Silicon TFT/PD matrix panel	--	Amorphous Silicon	--
Active Area	21 cm x 21 cm	21 cm x 21 cm	19.9 cm x 19.9 cm	Same as Predicate Device
Pixel Matrix	1,024 x 1,024	1,344 x 1,344	1,024 x 1,024	Same as Reference Device
DQE	77% at 0lp/mm	77% at 0lp/mm	80% at 0lp/mm	Same as Predicate device
Modulation Transfer Function (MTF) at 1lp/mm	61%	59%	55%	Similar (SE #4)
A/D Conversion	16 bit	16 bit	16 bit	Same
Pixel Pitch	205µm	154µm	194µm	Similar (SE #4)
Optional				
Make	Allengers, FP 2121HR	--	--	--
Type	Amorphous Silicon TFT/PD matrix panel	--	Amorphous Silicon	--
Active Area	21.3 cm x 21.3 cm	21 cm x 21 cm	19.9 cm x 19.9 cm	Similar (SE #4)
Pixel Matrix	1,536 x 1,536	1,344 x 1,344	1,024 x 1,024	Similar (SE #4)
DQE	73% at 0lp/mm	77% at 0lp/mm	80% at 0lp/mm	Similar (SE #4)
Modulation Transfer Function (MTF) at 1lp/mm	61%	59%	55%	Similar (SE #4)
A/D Conversion	16 bit	16 bit	16 bit	Same
Pixel Pitch	139 µm	154µm	194µm	Similar (SE #4)
Optional				
Make	Allengers, FP 3030 HR	--	--	--
Type	Amorphous Silicon TFT/PD matrix panel	--	Amorphous Silicon	Same as Reference device
Active Area	30.7 cm x 30.7 cm	29 cm x26 cm	29.8 cm x 29.8 cm	Similar (SE #4)

Feature	Cardiovascular Angiography System (Subject Device)	Allura Xper FD Series and Allura Xper OR Table series (Predicate Device)	Ziehm Vision RFD (Reference Device)	Justification for differences
Pixel Matrix	2,048 x 2,048	1,560 x 1,440	1,536 x 1,536	Similar (SE #4)
DQE	67% at 0lp/mm	70% at 0lp/mm	80% at 0lp/mm	Similar (SE #4)
Modulation Transfer Function (MTF) at 1lp/mm	55%	59%	55%	Same as Reference device
A/D Conversion	16 bit	16 bit	16 bit	Same
Pixel Pitch	150 µm	184µm	194µm	Similar (SE #4)
8. Ceiling Suspension Viewing Monitors				
Size, in (Min) (Examination Room)	55”	58”	N/A	Similar (SE #5)
Size, in (Min) (Console Room)	19”	18”	N/A	Similar (SE #5)
Touch Screen	Yes	Yes	N/A	Same as Predicate device
9. Image Processing and storage				
Imaging Mode	• 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	Internal HDD drive, USB, CD/DV D-RW drive	Same
Image Interference	Detector Dependant	Detector Dependant	Detector Dependant	Same
LIH	Yes	Yes	Yes	Same
Dicom conformance	Yes	Yes	Yes	Same
PACS Interfaces	Ethernet or WLAN	Ethernet or WLAN	Ethernet or WLAN	Same
Hard copy devices	Printer and DICOM print	Printer and DICOM print	Printer and DICOM print	Same
10. Power Requirement				
Power Requirement	400 VAC ,(±10%) 50/60 Hz (Except 40KW & 27KW machines) 110/230 VAC,(±10%) , 50/60 Hz (For 40KW & 27KW machines)	400 VAC,(±10%) 50/60 Hz	110/240 VAC,(±10%) 50/60 Hz	Essentially the Same as predicate & reference device

Difference Discussion

SE- #	Substantial Equivalence discussion
SE#1 & #2	**#1 & #2** The subject device provides with different X-Ray Generators perform similar or better compared to predicate and Reference device in terms of performance specification. For XGEN-100CV, the performance specification is almost identical to predicate device in terms of kV and tube current. For XGEN-80CV, XGEN-65CV, XGEN-40CV & XGEN-27CV, the generator capacity is sufficient to meet the fluoroscopic and digital radiographic exposure requirements and have higher maximum power output as compare to Reference device. Such differences in performance do not raise additional risk concerns.
SE#3	**#3** 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 device 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#4	**#4** The Subject device utilized different Solid State X-Ray Image Detectors (FPD) as compare to predicate device Allura Xper FD Series and Allura Xper OR Table series (K162859) & reference device Ziehm Vision RFD (K203428), however Detector technology is comparable to predicate device and reference device 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 K171755, K183040 K172822 and K200218.
SE #5	**#5** The Cardiovascular Angiography System utilized monitors with same resolution as the predicate device Allura Xper FD Series and Allura Xper OR Table series (K162859) and Reference device Ziehm Vision RFD (K203428), however the screen size is 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 concerning this difference.

10. Technological characteristics comparison to predicate & Reference device:

The indications for use, operating principle, technical specifications such as X-Ray tube head and generator as well as safety characteristics of Cardiovascular Angiography system models are identical to those of the predicate & reference device. This System is designed as a set of components (X-Ray tube and housing, detector, digital imaging system, collimator, generator etc.) similar to the predicate device Allura Xper FD Series and Allura Xper OR Table series (K162859) and Reference device Ziehm Vision RFD (K203428). Based on the recognized standard conformity evidences related to electro-mechanical, software-, and risk management, Allengers Medical Systems certifies that technological characteristics of Cardiovascular Angiography system models are substantially equivalent to Allura Xper FD Series and Allura Xper OR Table series (K162859), the predicate device and Ziehm Vision RFD (K203428) the reference device.

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) 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 Cardiovascular Angiography system appears to be as safe and effective as predicate & reference device.

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.

13. Description of Non Clinical & Clinical testing

Non Clinical performance testing has been performed on the Cardiovascular Angiography system 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
12-308	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 Cardiovascular Angiography 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. Bench testing was performed to assess the device safety and effectiveness.

14. Substantial Equivalence Conclusion:

Cardiovascular Angiography 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 Allura Xper FD Series and Allura Xper OR Table series (K162859). 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.