June 5, 2026

Allengers Medical Systems Limited
℅ Sanjeev Marjara
Managing Director
FDA Hall, Unit-2,
Bhankarpur, Mubarakpur Road, Derabassi, Distt Mohali
SAS NANGAR MOHALI, PUNJAB 140507
INDIA

Re: K253296
Trade/Device Name: Digital C-ARM with 3D
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OXO, JAA, OWB
Dated: May 8, 2026
Received: May 8, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

GABRIELA M. RODAL -S Digitally signed by GABRIELA M. RODAL -S for

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253296

Device Name
Digital C-ARM with 3D

Indications for Use *(Describe)*
Digiscan V30 3D is X-Ray based fluoroscopy equipment. It is intended for use in visualizing complex anatomical structures and procedures such as 3D Reconstruction, endoscopy Studies (ERCP), urology, Gastro, orthopedic, neurology, Fertility studies (HSG), cholangiography, vascular angiography with and without subtraction, critical care and emergency room procedures. This equipment produces real time images of anatomy using x-rays.

Exclusion:
Device is not meant for Mammography.

Contraindications of device:
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

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:	April 24, 2026

2. Proposed Device:

Device (trade) name:	Digital C-ARM with 3D
Model Number:	HF 59R
Series Name:	Digiscan V30 3D
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:	OXO, JAA, OWB

3. Predicate Device:

Device (trade) name:	Digiscan FDX
510(K) Number :	K200218
Clearance Date :	August 7, 2022
Classification Name:	Image-Intensified Fluoroscopic X-Ray System
Classification Panel:	Radiology
Regulation Number :	21 CFR 892.1650
Device Class :	Class II
Product Code:	OXO, JAA, OWB

4. Reference Device :

Reference Device 1

Device (trade) name:	Cios Spin
510(K) Number :	K210054
Clearance Date :	February 05, 2021
Classification Name:	Image-Intensified Fluoroscopic X-Ray System,
Classification Panel:	Radiology
Regulation Number :	21 CFR 892.1650
Device Class :	Class II
Product Code:	OXO, JAA, OWB

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Reference Device 2

Device (trade) name:	Ziehm Vision RFD 3D
510(K) Number :	K243303
Clearance Date :	January 21, 2025
Classification Name:	Image-Intensified Fluoroscopic X-Ray System,
Classification Panel:	Radiology
Regulation Number :	21 CFR 892.1650
Device Class :	Class II
Product Code:	OXO, JAA, OWB

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 3030DXV	K200218
Varex Imaging corporation – Paxscan 2020DXV	K200218
MX Imaging – CFP 2222	K200218
MX Imaging – CFP 3131	K200218
IRAY Technology – Mercu 0909F	K200218
Teledyne DALSA - Xineos-3030HS	K212336
Allengers – FP3030HR	K220311

5. Device description:

The Digital C-ARM with 3D (Digiscan V30 3D) is a mobile X-Ray C-Arm fluoroscopic device used by radiation experts. Digiscan V30 3D is a digital fluoroscopic imaging system with Solid State X-Ray Image Detectors (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 V30 3D composed of C-Arm, X-Ray generating equipment (X-Ray controller, high voltage generator, X-Ray tube), FPD, and workstation (Console computer and Monitor). C-Arm unit with generator is capable of movements which are essential for patient positioning, like horizontal travel, orbital movement, vertical movement and C rotation. The X-Ray generator, X-Ray control system and collimator controls are housed in the C-Arm unit.

Synergy FP-CR imaging software is a Digital Imaging System (DIS) designed for C-arm Fluoroscopic Mobile X-Ray System. Synergy FP-CR imaging software provides useful functions to manage X-Ray images obtained from Digiscan V30 3D FPD Fluoroscopic Mobile X-Ray System.

The following in Table 2 are the specific components for 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	XGEN-C15
X-Ray Tube	Varex Imaging	RAD15
X-Ray Tube	I.A.E	RTM 70 HS
Solid State X-Ray Image Detectors	Varex Imaging	Paxscan 3030 DXV Paxscan 2020 DXV
Solid State X-Ray Image Detectors	IRAY Technology	Mercu 0909F
Solid State X-Ray Image Detectors	MX Imaging	CFP 2222 CFP 3131
Solid State X-Ray Image Detectors	Teledyne DALSA	Xineos-3030HS
Solid State X-Ray Image Detectors	Allengers	FP3030HR

6. Indications for Use:

Digiscan V30 3D is X-Ray based fluoroscopy equipment. It is intended for use in visualizing complex anatomical structures and procedures such as 3D Reconstruction, endoscopy Studies (ERCP), urology, Gastro, orthopedic, neurology, Fertility studies (HSG), cholangiography, vascular angiography with and without subtraction, critical care and emergency room procedures. This equipment produces real time images of anatomy using x-rays.

Exclusion:

Device is not meant for Mammography.

Contraindications of device:

Exposure of X-ray should be avoided during pregnancy.

7. Technological Characteristics Comparison to Predicate Devices:

The Digiscan V30 3D having set of components similar to the Digiscan FDX, Cios Spin and Ziehm Vision RFD 3D 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 devices.

8. Software Feature

The software feature set and functions are 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 V30 3D Mobile C-Arm X-Ray Machine is substantially equivalent to the commercially available Digiscan FDX (K200218), Cios Spin (K210054) and Ziehm Vision RFD 3D (K243303). Functional and specification differences are identifying in the following table.

Table 3: Functional and specification differences

Feature	Digiscan V30 3D (Subject Device)	Digiscan FDX (Predicate Device)	Cios Spin (Reference Device 1)	Ziehm Vision RFD 3D (Reference Device 2)	Discussion of Difference
510(k)	This submission	K200218	K210054	K243303	--
2. Product Code					
Product Classification Code	OXO, JAA, OWB	OXO, JAA, OWB	OXO, JAA, OWB	OWB	Same
3. Classification					
Classification	21 CFR 892.1650	21 CFR 892.1650	21 CFR 892.1650	21 CFR 892.1650	Same
4. Intended Use					
Indications for Use	Digiscan V30 3D is X-Ray based fluoroscopy equipment. It is intended for use in visualizing complex anatomical structures and procedures such as 3D Reconstruction, endoscopy Studies (ERCP), urology, Gastro, orthopedic, neurology, Fertility studies (HSG), cholangiography, vascular angiography with and without subtraction, critical care and emergency room procedures. This equipment produces real time images of anatomy using x-rays. **Exclusion:** This Machine is not meant for Mammography.	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) 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 is not recommended for Mammography. **Contraindications:** Exposure of	The Cios Spin 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, gastro-intestinal, endoscopic, urologic, pain management, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures. The patient population may include pediatric patients.	The Ziehm Vision RFD 3D system is intended for use in providing both 2D and 3D medical imaging for all adult and pediatric populations, using pulsed and continuous fluoroscopic imaging. The device provides 2D medical imaging for fluoroscopy, digital subtraction, and acquisition of cine loops 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 cervical, thoracic, and lumbar regions of the spine and joint fractures of the upper and lower extremities, and where digital image data is required for Computer-Assisted Surgery procedures. The device is also intended to provide 3D medical imaging of patients during orthopedic,	Essentially the same *Note:* There are no Differences between the subject device and the predicate & reference devices with respect to indication and intended use.

	Contraindications of device: Exposure of X-ray should be avoided during pregnancy.	X-Ray should be avoided during pregnancy.		neurological, intra-operative surgical procedures and where the clinician benefits from 3D visualization of complex anatomical structures, such as but not limited to those of high contrast objects, bones, joints, maxillofacial, cervical, thoracic, and lumbar regions of the spine, pelvis, acetabulum and joint fractures of the upper and lower extremities, and where digital image and C-arm positioning data is required for Computer-Assisted Surgery procedures. The visualization of such anatomical structures assists the clinician in the clinical outcome. At the discretion of a physician, the device may be used for 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.	
5. X-Ray Generator					
Type	Monoblock and High Frequency Generator	Monoblock and High Frequency Generator	Monoblock and High Frequency Generator	Monoblock and High Frequency Generator	Same
Kilowatt Rating	15KW	15KW	12 kW Optional 25 kW	25 kW/ 30KW	Same as Predicate device
KV Minimum	40 KV	40 KV	40 KV	40 KV	Same
KV Maximum	120KV	120KV	125 KV	120KV	Same as Predicate and Reference Device 2
Dose Control System	Yes	Yes	Yes	Yes	Same
Dose Area Product	Yes	Yes	Yes	Yes	Same
6. X-Ray Tube					
Model	RAD 15	A145	--	--	--

Tube Type	Rotating Anode	Rotating Anode	Rotating Anode	Rotating Anode	Same
Cooling HU/min	81000 HU/ min	70000 HU/min	91000 HU/min	102000 HU/ min	Similar (SE #1)
Anode Heat Capacity	365KHU	300 KHU	365 KHU	365 KHU	Same as Reference Device 1 & 2.
Focal Spot Size, mm	Dual Focus 0.3/0.6	Dual Focus 0.3/0.6	Dual Focus 0.3/0.5	Dual Focus 0.3/0.6	Same as Predicate and Reference Device 2
Maximum Tube Power rating , KW	35kw	25KW	25 KW	Not publically available	Similar (SE #2)
Target Angle	10°	10°	10°	Not publically available	Same
Optional Tube					
Model	RTM 70 HS	A145	--	--	--
Tube Type	Rotating Anode	Rotating Anode	Rotating Anode	Rotating Anode	Same
Cooling HU/min	104000 HU/ min	70000 HU/min	91000 HU/min	102000 HU/ min	Similar (SE #1)
Anode Heat Capacity	300KHU	300 KHU	365 KHU	365 KHU	Same as Predicate Device.
Focal Spot Size, mm	Dual Focus 0.3/0.6	Dual Focus 0.3/0.6	Dual Focus 0.3/0.5	Dual Focus 0.3/0.6	Same as Predicate and Reference Device 2
Maximum Tube Power rating , KW	45KW	25KW	25 KW	Not publically available	Similar (SE #2)
Target Angle	10°	10°	10°	Not publically available	Same
7. Radiographic Mode					
KV Range	40-120 KV	40-120 KV	40-125 KV	40-120 KV	Same as Predicate and Reference Device 2
mA Range	150 mA	Upto 150 mA	10 mA to 120 mA (12KW) 10 mA to 250 mA (25KW)	250mA/300mA	Same as Predicate Device
8. Fluoroscopic Mode					

KV Range	40-120 kV	40-120 KV	40-125 KV	40-120 KV	Same as Predicate and Reference Device 2
Pulse fluoroscopic	Yes	Yes	Yes	Yes	Same
ABS Control	Yes	Yes	Yes	Yes	Same
Snapshot Mode	Yes	Yes	Yes	Yes	Same
Max mA Range	Upto 60 mA	Upto 30 mA	3 mA to 119 mA (12KW) 3 mA to 250 mA (25KW)	0.2-250mA/ 0.2-300mA	Similar (SE #3)
Pulses per second (pps) (max)	Upto 15 (1536*1536), upto 30 (1024*1024)	Upto 15 (1536*1536), upto 30 (1024*1024)	0.5 p/s to 30 p/s	1p/s to 25 p/s	Same as Predicate Device.
9. Solid State X-Ray Image Detectors					
Make	Varex's , Paxscan 3030 DXV	Varex's , Paxscan 3030 DXV	--	30 cm aSi FPD	--
Type	Amorphous Silicon	Amorphous Silicon	CMOS with CsI scintillator	Amorphous Silicon	Same as Predicate and Reference Device 2
Active Area	298mm (h) x 298mm (v) (11.7 x 11.7 in)	298mm (h) x 298mm (v) (11.7 x 11.7 in)	300mmx300mm	300mmx300mm	Same as Predicate Device.
Pixel Matrix	1,536 (h) x 1,536 (v)	1,536 (h) x 1,536 (v)	1,952 (h) x 1,952 (v)	1,536 (h) x 1,536 (v)	Same as Predicate and Reference Device 2
DQE	80% at 0lp/mm	80% at 0lp/mm	72% at 0lp/mm	Not publically available	Same as Predicate Device.
Modulation Transfer Function (MTF)	55% at 1lp/mm	55% at 1lp/mm	58% at 1lp/mm	Not publically available	Same as Predicate Device.
A/D Conversion	16 bit	16 bit	16 bit	Not publically available	Same
Pixel Pitch	194µm	194µm	152µm	Not publically available	Same as Predicate Device.
Optional					
Make	Teledyne DALSA - Xineos-3030HS	MX CFP 3131	--	31 cm CMOS FPD	--

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Type	CMOS	CMOS	CMOS	CMOS	Same
Active Area	295mm (h) x 295mm (v)	309.4mm (h) x 307.2mm (v)	300mmx300mm	Not publically available	Similar (SE #4)
Pixel Matrix	1,952 (h) x 1,952 (v)	3094 (h) x 3072 (v)	1,952 (h) x 1,952 (v)	Not publically available	Same as Reference Device 1.
DQE	72% at 0lp/mm	75% at 0lp/mm	72% at 0lp/mm	Not publically available	Same as Reference Device 1.
Modulation Transfer Function (MTF)	58% at 1lp/mm	70% at 1lp/mm	58% at 1lp/mm	Not publically available	Same as Reference Device 1.
A/D Conversion	16 bit	14 bit	16 bit	Not publically available	Same as Reference Device 1.
Pixel Pitch	152 µm	100 µm	152µm	Not publically available	Same as Reference Device 1.
Optional					
Make	Allengers -3030HR	Varex's , Paxscan 3030 DXV	--	--	--
Type	Amorphous Silicon	Amorphous Silicon	NA	NA	Same as Predicate
Active Area	307.2mm (h) x307.2mm (v)	298mm (h) x 298mm (v)	NA	NA	Similar (SE #4)
Pixel Matrix	2048 (h) x 2048 (v)	1,536 (h) x 1,536 (v)	NA	NA	Similar (SE #5)
DQE	80% at 0lp/mm	80% at 0lp/mm	NA	NA	Same as Predicate device
Modulation Transfer Function (MTF)	59% at 1lp/mm	55% at 1lp/mm	NA	NA	Similar (SE #6)
A/D Conversion	16 bit	16 bit	NA	NA	Same
Pixel Pitch	150µm	194µm	NA	NA	Similar (SE #7)
Optional					
Make	MX CFP 3131	MX CFP 3131	--	--	--
Type	CMOS	CMOS	NA	NA	Same

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Active Area	309.4mm (h) x 307.2mm (v)	309.4mm (h) x 307.2mm (v)	NA	NA	Same
Pixel Matrix	3094 (h) x 3072 (v)	3094 (h) x 3072 (v)	NA	NA	Same
DQE	75% at 0lp/mm	75% at 0lp/mm	NA	NA	Same
Modulation Transfer Function (MTF)	70% at 1lp/mm	70% at 1lp/mm	NA	NA	Same
A/D Conversion	14 bit	14 bit	NA	NA	Same
Pixel Pitch	100 µm	100 µm	NA	NA	Same
Optional					
Make	Varex's , Paxscan 2020	Varex's , Paxscan 2020	--	--	--
Type	Amorphous Silicon	Amorphous Silicon	NA	Amorphous Silicon	Same
Active Area	199mm (h) x 199mm (v)	199mm (h) x 199mm (v)	NA	203mm (h) x 203mm (v)	Same as Predicate device
Limiting resolution (Max)	2.58 lp/mm	2.58 lp/mm	NA	3.1lp/mm	Same as Predicate Device
Pixel Matrix	1,024 (h) x 1,024 (v)	1,024 (h) x 1,024 (v)	NA	1,024 (h) x 1,024 (v)	Same as Predicate Device
DQE	80% at 0lp/mm	80% at 1lp/mm	NA	55% at 1lp/mm	Same as Predicate Device
Modulation Transfer Function (MTF)	55% at 1lp/mm	55% at 1lp/mm	NA	55% at 1lp/mm	Same
A/D Conversion	16 bit	16 bit	NA	16 bit	Same
Pixel Pitch	194µm	194µm	NA	194µm	Same
Optional					
Make	IRAY 's, Mercu 0909F	IRAY 's, Mercu 0909F	--	--	--
Type	Amorphous Silicon	Amorphous Silicon	NA	NA	Same
Active Area	228.6mm (h)x228.6mm (v)	228.6mm (h)x228.6mm (v)	NA	NA	Same
Pixel Matrix	1,024 (h) x 1,024 (v)	1,024 (h) x 1,024 (v)	NA	NA	Same

DQE	77% at 0lp/mm	77% at 0lp/mm	NA	NA	Same
Modulation Transfer Function (MTF)	64% at 1lp/mm	64% at 1lp/mm	NA	NA	Same
A/D Conversion	16 bit	16 bit	NA	NA	Same
Pixel Pitch	205µm	205µm	NA	NA	Same
Optional					
Make	MX CFP 2222	MX CFP 2222	--	--	--
Type	CMOS	CMOS	NA	NA	Same
Active Area	217mm (h) x 217mm (v)	217mm (h) x 217mm (v)	NA	NA	Same
Pixel Matrix	2170 (h) x 2170 (v)	2170 (h) x 2170 (v)	NA	NA	Same
DQE	75% at 0lp/mm	75% at 0lp/mm	NA	NA	Same
Modulation Transfer Function (MTF)	70% at 1lp/mm	70% at 1lp/mm	NA	NA	Same
A/D Conversion	16 bit	16 bit	NA	NA	Same
Pixel Pitch	100 µm	100 µm	NA	NA	Same
10. Viewing Monitor(s)					
Size, in	27” & 32 “ (In Single Monitor) 19” & 21” (In dual Monitors)	27” & 32 “ (In Single Monitor) 19” & 21” (In dual Monitors)	19” TFT high-brightness color display	19” Duo flat screen monitors or 32” UDH single flat screen monitor	Same as Predicate Device.
Touch Screen	Yes	Yes	Yes	Yes	Same.
11. Touch Panel					
Touch based control	Available	Available	Available	Available	Same.
12. Collimator					

Collimator system	Available	Available	Available	Available	Same.
13. Grid					
Grid Type	Removable	Removable	Removable	Removable	Same.
Lines	70 lines /cm	70 lines /cm	80 lines /cm	70 lines /cm	Same as Predicate Device & Reference Device 2.
Ratio	8:1	8:1	15:1	8:1	Same as Predicate Device & Reference Device 2.
14. 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/DVD-RW drive	Internal HDD drive, USB, CD/DVD-RW drive	Internal HDD drive, DVD drive for digital image storage on CD-R,	Internal HDD, USB and CD/DVDRW drive	Same
Image Interference	Detector Dependant	Detector Dependant	Detector Dependant	Detector Dependant	Same
Capacity Number of images	Upto 100,000	Upto 100,000	Upto 300,000	Upto 100,000	Same as Predicate & Reference Device 2.
Image matrix size	1536*1536 Pixels 1024*1024 Pixels	1536*1536 Pixels 1024*1024 Pixels	1,952 x 1,952 pixel	3,072 x 3,072	Same as Predicate Device.
LIH	Yes	Yes	Yes	Yes	Same
Dicom conformance	Yes	Yes	Yes	Yes	Same
PACS Interfaces	Wired or Wireless on Ethernet	Wired or Wireless on Ethernet	Wired or Wireless on Ethernet	Wired or Wireless on Ethernet	Same
Hard copy devices	Printer and DICOM print	Printer and DICOM print	Printer and DICOM print	Printer and DICOM print	Same
3D Imaging					
Scan technology	Iso-centric scan technology	N/A	Iso-centric scan technology	Iso-centric scan technology	Same.
Projections for 3D reconstruction	Up to 514	N/A	Up to 400	up to 400 images	Similar (SE #8)

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3D volume size	18.5 x 18.5 x 18.5 cm	N/A	16 x 16 x 16 cm	16 x 16 x 16 cm	Similar (SE #9)
3D volume resolution	726 x 726 x 726 voxels	N/A	512 x 512 x 512 voxels	512 x 512 x 512 voxels	Similar (SE #10)
Scan speed	Less than 20 seconds	N/A	30 seconds	48 seconds	Similar (SE #11)
Orientation & 3D viewing modes	• Multiplanar reconstruction (MPR) • Simultaneous display of 3 projections (axial, coronal, and sagittal) • Single Cut • Double Cut • 2D Cell	N/A	• Simultaneous display of 3 projections (transversal, coronal, and sagittal) • MPR	MPR (Axial / Coronal / Sagittal)	Same
3D power scan option for obese patients	Yes	N/A	Yes	Yes	Same
3D volume rendering	• Volume rendering techniques VRT • Shaded surface display (SSD) • Maximum intensity projection (Max IP) • Minimum intensity projection (Max IP) MRP Slab	N/A	Volume rendering technique (VRT)	• Volume rendering techniques VRT • Surface rendering	Same
Metal artifact reduction	Yes	N/A	Yes	Yes	Same
Navigation interface	Yes	N/A	Yes	Yes	Same
Image Matrix	1536 x1536	N/A	1952 × 1952 pixels	3,072 x 3,072	Similar (SE #12)
FOV	18.5 cm	N/A	16 cm	16 cm	Similar (SE #13)

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General Functionality of 3D Viewer (Post process feature)	• MPR navigation (Segital, coronel and Axial) • Volume rotation • Slice navigation • Window level • Move volume/plane • Rotate volume /plane • Zoom/Pan	N/A	• MPR navigation, • distance & angle measurement, • annotations, • volume rotation, • slice navigation	• MPR, • measurement, • segmentation • Zoom	Same
Reconstruction Algorithm	GPU-based Filtered Back Projection	N/A	FDK-based filtered back projection	Cone Beam CT reconstruction	Similar (SE #14)
Matrix size per slice	514 x 514 pixels	N/A	512 × 512 pixels	512 × 512 pixels	Similar (SE #15)
Voxel pitch	0.3 mm isotropic resolution	N/A	0.3 mm isotropic voxel	0.31 mm	Same
Applied Features	• Lag Correction • Noise Filtering • Beam Hardening Correction • Metal Artifact Correction	N/A	• Noise Filtering • Beam Hardening Correction • Metal Artifact Correction	• Noise Filtering • Beam Hardening Correction • Metal Artifact Correction	Same
Number of Projections per Revolution	180	N/A	Up to 400 projections	Up to 400 projections	Similar (SE #16)
Angular Increment	1° per projection	N/A	~0.5° per projection (approx.)	~0.45° per projection (approx.)	Similar (SE #17)
Rotation Trajectory	-90° to +90° (total angular span = 180°)	N/A	-100° to +100° (Circular orbital trajectory ~200°)	-90° to +90° (Orbital rotation ~180°)	Same as Reference Device 2
Rotation Speed	10 degree/Sec	N/A	~6.7 degree/Sec	~3.75 degree/Sec	Similar (SE #18)
Reconstructed Volume Size:	17.7 cm × 17.7 cm x 15.4 cm	N/A	16 cm × 16 cm × 16 cm	16 cm × 16 cm × 16 cm	Similar (SE #19)
15. Power Requirement					
Power Requirement	110/230 Vac,(±10%) 50/60 Hz	110/230 Vac,(±10%) 50/60 Hz	110/230 Vac,(±10%) 50/60 Hz	100/240 Vac,(±10%) 50/60 Hz	Same

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Difference Discussion

SE- #	Substantial Equivalence discussion
SE #1, #2	**#1, #2** 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.
SE#3	**#3** 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#04, #05, #06 & #07	**#04, #05, #06 & #07** The Subject device utilized different Solid State X-Ray Image Detectors (FPD) as compare to reference devices- Digiscan FDX, Cios Fusion, Ziehm Vision RFD 3D, 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 K200218, K210054, K243303.
SE#08	**#08** Using higher projections in 3D reconstruction improves workflow efficiency by accelerating throughput in high-volume imaging centers. It also reduces system wear and energy consumption, making it especially valuable in spine and orthopedic
SE#9	**#09** A larger Field of View (FOV) in 3D scanning enables expanded anatomical coverage, allowing more of the body to be captured in a single acquisition. This minimizes the need for multiple scans or patient repositioning—an essential advantage in procedures like L-Spine screw placement, where precise alignment and uninterrupted anatomical context are critical for effective surgical navigation
SE#10	**#10** Higher resolution (591X591X514) gives more details therefore it captures finer anatomical detail and Better for advanced post-processing (e.g., segmentation, 3D reconstruction etc)
SE#11	**#11** Shorter scan time enhances patient comfort and compliance, while significantly improving surgical workflow efficiency—particularly in time-sensitive procedures where rapid imaging supports precise planning and execution
SE#12 & #15	**#12 & #15** The differences in Image Matrix (1536 x 1536) and Matrix size per slice (591X591) represent an optimization of the reconstruction pipeline. These parameters ensure that the spatial resolution is maximized for the specific detector used in the subject device without introducing artifacts or compromising the diagnostic integrity compared to the predicate devices.
SE#13	**#13** The Subject Device features a larger Field of View (FOV) of 18.5 cm compared to the 16 cm FOV of the reference devices. As noted in the clinical discussion, a larger FOV enables expanded anatomical coverage in a single acquisition, which is particularly beneficial for spine and pelvic procedures

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SE#14	**#14** The use of a GPU-based Filtered Back Projection reconstruction algorithm is technically equivalent to the FDK-based or Cone Beam CT algorithms used by the predicates. The use of GPU acceleration allows for faster processing of the higher-resolution voxel grid while maintaining the same fundamental filtered back-projection principle
SE#16, #17 & #18	**#16, #17 & #18** The subject device utilizes 180 projections per revolution with an angular increment of 1°, whereas predicates use up to 400 projections. While the number of projections is lower, this is a deliberate design choice to reduce total X-ray dose and system wear while still providing sufficient data for high-quality 3D reconstruction in orthopedic and neurosurgical applications
SE#19	**#19** The Reconstructed Volume Size (17.7 x 17.7 x 15.4 cm) is slightly larger than the reference devices (16 x 16 x 16 cm). This difference is a result of the larger detector active area and does not introduce new safety risks; rather, it enhances clinical utility by providing more anatomical context

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 V30 3D are identical to those of the predicate & reference devices. Digiscan V30 3D 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 Digiscan FDX (K200218), Cios Spin (K210054) and Ziehm Vision RFD 3D (K243303). Based on the recognized standard conformity evidences related to electro-mechanical, software-, and risk management, Allengers Medical Systems certifies that technological characteristics of Digiscan V30 3D are substantially equivalent to Digiscan FDX, Cios Spin and Ziehm Vision RFD 3D, the predicate & reference devices.

The Digital C-ARM with 3D 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 evaluation of all motions systems against 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). System performance demonstration and imaging performance evaluation were also conducted. Safety compliance was assessed according to IEC 60601-1: 2020. Allengers Medical Systems Ltd certifies conformance to Voluntary standards covering electrical and Mechanical safety.

Bench testing was further performed to characterize and demonstrate the 3D imaging capability with FPDs. So, comprehensive system-level testing, including 3D image quality and dose characterization, has been performed. This included evaluation of critical performance parameters such as

- C-arm or gantry positioning accuracy
- In-plane uniformity assessment
- Spatial resolution with Modulation Transfer Function (MTF) in x-y plane
- Reconstruction section thickness characterization
- Noise measurements (pixel standard deviation in x-y plane or 2D noise power spectrum)
- Contrast to noise ratio (CNR) assessment
- Radiation dose measurements (CTDI and DLP)
- Metal Artifact Reduction

These parameters were successfully characterized to justify that the Digiscan V30 3D device fulfills the requirements for 3D imaging capabilities.

In Conclusion: Performance testing activities confirmed that device requirements were met, system functionality is consistent with user needs and intended uses, and the device performs as designed without raising new questions regarding safety or effectiveness. Therefore, when compared to predicate devices, the Digiscan V30 3D supports a determination of substantial equivalence. It is the opinion of Allengers Medical Systems Ltd. that the Digital C-ARM with 3D is as safe and effective as the predicate and reference devices.

12. Software Features and Testing:

Software documentation prepared at the *Basic Documentation Level*, in accordance with FDA's guidance document *"Guidance for the Content of Premarket Submissions for Device Software Functions"*, is included as part of this submission. This documentation provides detailed information on software architecture, design specifications, verification and validation activities, and risk management processes to demonstrate that the software functions perform as intended and support the overall safety and effectiveness of the device.

In addition, cybersecurity considerations have been addressed in alignment with FDA recommendations and international best practices.

Conclusion: The inclusion of software documentation at the Basic Documentation Level, together with a proactive cybersecurity risk management framework, ensures that the Digital C-ARM with 3D meets regulatory expectations for both functional performance and protection against cybersecurity vulnerabilities.

13. Description of Non Clinical tests

Non Clinical performance testing has been performed on the Digiscan V30 3D machine and it demonstrates compliance 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
19-49	General	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance	60601-1 Edition 3.2 2020-08 Consolidated Version	IEC
19-36	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 [Including AMD 1:2021]	ANSI AAMI IEC
12-336	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 2.2 2021-01 CONSOLIDATED VERSION	IEC
12-309	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 3.0 2017-06	IEC
12-351	Radiology	Particular requirements for the safety of X-Ray equipment for interventional procedures	60601-2-43 Edition 3.0, 2022	IEC
12-348	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 2.0 2022).	IEC
13-79	General	Medical device software – Software life cycle processes	62304 (Edition 1.1, 2015)	IEC
5-132	General	Medical Electrical Equipment Part 1-6: General Requirements• for Basic Safety and Essential Performance- Collateral Standard: Usability	60601-1-6, Edition 3.2 2020-07 CONSOLIDATED VERSION	IEC
5-129	General	Application of Usability Engineering to Medical Devices	62366-1 015+AMD1:2020	IEC
5-125	General I (QS/RM)	Medical devices – application of risk management to medical devices	14971 Third Edition 2019-12	ISO
12-273	Radiology	Safety of laser products – Part 1: Equipment classification, and requirements	60825-1 Edition 2.0 2007-03	IEC
5-134	General I (QS/RM)	ISO 15223-1 Fourth edition 2021-07 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	15223-1 Fourth edition 2021-07	ISO

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 5, 2022
2	Guidance for Industry and Food and Drug Administration Staff: Electronic Submission Template for Medical Device 510(k) Submissions Document issued on October 2, 2023.
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: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Document Issued on June 27, 2025
7	Guidance for Industry and FDA Staff: Off-The-Shelf Software Use in Medical Devices Document issued on August 11, 2023.
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: Electromagnetic Compatibility (EMC) of Medical Device Document issued on June 6, 2022
11	Guidance for Industry and FDA Staff: Content of Premarket Submission for Device Software Functions Document issued on June 14, 2023.

Non-clinical verification test results demonstrate that the Digiscan V30 3D complies with the aforementioned international and FDA recognized consensus standards and FDA guidance documents.

14. Description of clinical tests

Independent clinical evaluations were obtained from specialists in Urology, Orthopedics, Gastroenterology, Cardiology, and Neurology. Each specialist reviewed the imaging performance, and the acquired 2D and 3D images were determined to be of adequate diagnostic quality for the indicated clinical applications.

The acquired images included examinations of:

- Lumbar Spine (2D & 3D)
- Cervical Spine (2D & 3D)
- Orthopedic Spine (2D & 3D)
- Vascular imaging
- Extremities
- Gastrointestinal imaging
- Orthopedic procedures
- Digital spot imaging
- Fluoroscopic LIH (Last Image Hold) sequences
- Cardiac imaging
- Neurological imaging
- Urological imaging

The validation activities confirmed that the device consistently produced images of sufficient diagnostic quality across these anatomical regions and procedural applications. The results demonstrated that the system is safe and effective for its intended use.

In Conclusion: The Digital C-ARM with 3D was found to provide adequate image quality for the specific views and procedures identified in the Instructions for Use (IFU). Independent expert reviews and validation testing support that the device fulfills its intended imaging performance requirements, thereby reinforcing its safety and effectiveness profile.

15. Substantial Equivalence Conclusion:

Digital C-ARM with 3D does not introduce any new indications for use, nor does the use of the systems result in any new potential hazards. The Digital C-ARM with 3D, the subject device is substantially equivalent to the predicate & reference devices, Digiscan FDX (K200218), Cios Spin (K210054) and Ziehm Vision RFD 3D (K243303). 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.