April 18, 2025

Allengers Medical Systems Limited
% Sanjeev K. Marjara
Managing Director
FDA Hall, Unit-2,
Bhankarpur, Mubarakpur Road, Derabassi, Distt Mohali
SAS Nagar Mohali, PUNJAB 140507
INDIA

Re: K243734
Trade/Device Name: Wireless/ Wired X-Ray Flat Panel Detectors
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MQB
Dated: November 27, 2024
Received: March 21, 2025

Dear Sanjeev K. 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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

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.

Submission Number *(if known)*

K243734

Device Name

Wireless/ Wired X-Ray Flat Panel Detectors

Indications for Use *(Describe)*

Allengers Wireless/ Wired X-Ray Flat Panel Detectors used with AWS (Acquisition Workstation Software) Synergy DR FDX/Synergy DR is used to acquire/Process/Display/Store/Export radiographic images of all body parts using Radiographic techniques. It is intended for use in general radiographic applications wherever a conventional film/screener CR system is used.

Allengers Wireless/Wired X-ray Flat Panel Detectors are not intended for mammography applications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Allengers Medical Systems Limited

510(k) Summary

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

I. SUBMITTER

Company Name:	Allengers Medical Systems Limited
Company Address:	FDA Hall, Unit-2, Bhankarpur, Mubarakpur Road, Derabassi, Distt Mohali, SAS Nagar Mohali, Punjab, 140507, India
Telephone No:	+91-1762-272600, +919872980168 ra.fdaindia@allengers.net, rnd@allengers.net
Contact Person:	Sanjeev K. Marjara
Prepared Date:	27 November 2024
510K Number	K243734

II. PROPOSED DEVICE

510(k) Submission:	Special Type
Device (Trade) Name:	**Wireless/ Wired X-Ray Flat Panel Detectors**
Model Number:	Wireless : G4336RWC, G4343RWC, T4336RWC, Wired : G4336RWC, G4343RWC, T4336RWC, G4343RC
Regulation Description:	Stationary x-ray system.
Review Panel	Radiology
Product Code:	MQB
Regulation Number:	21 CFR 892.1680
Device Class:	Class II

III. Predicate Device

Device (Trade) Name:	**Wireless/ Wired X-Ray Flat Panel Detectors (K223009)**
Model Number:	Wireless : G4336RWC, G4343RWC, T4336RWC, Wired : G4336RWC, G4343RWC, T4336RWC, G4343RC
Regulation Description:	Stationary x-ray system.
Review Panel	Radiology
Product Code:	MQB
Regulation Number:	21 CFR 892.1680
Device Class:	Class II

IV. Reference Device

Reference Device	Yushan X-Ray Flat Panel Detector with DROC (K201528, K210988, K220510)
Manufactured by:	InnoCare Optoelectronics Corp
Regulation description:	Stationary x-ray system.
Review Panel:	Radiology
Regulation Number :	21 CFR 892.1680
Device Class :	Class II

V. DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

Wireless/ Wired X-Ray Flat Panel Detectors used with

Accessory: "AWS (Acquisition Workstation Software) Synergy DR FDX/ Synergy DR" is Subject Device with equivalent product of its predicate device with K223009 and Yushan X-Ray Flat Panel Detector with DROC, K201528, K210988, and K220510. There are 4 models in this submission G4336RWC, G4343RWC, T4336RWC, are portable (wireless) and G4336RWC, G4343RWC, T4336RWC, G4343RC are non-portable (wired) Digital detectors.

The **Wireless/ Wired X-Ray Flat Panel Detectors** are designed to be used in any environment that would typically use a radiographic cassette for examinations. Detectors can be placed in a wall bucky for upright exams, a table bucky for recumbent exams, or removed from the bucky for non-grid or free cassette exams. These medical devices have memory exposure mode, and extended image readout feature. Additionally, rounded-edge design for easy handling, image compression algorithm for faster image transfer, LED design for easy detector identification, extra protection against ingress of water. This Device is currently indicated for general projection radiographic applications and the scintillator material is using cesium iodide (CsI). The Wireless/ Wired X-Ray Flat Panel Detectors sensor can automatically collect x-ray from an x-ray source. It collects the x-ray and converts it into digital image and transfers it to Desktop computer / Laptop/ Tablet for image display. The x-ray generator (an integral part of a complete x-ray system), is not part of the submission. The sensor includes a flat panel for x-ray acquisition and digitization and a computer (including proprietary processing software) for processing, annotating and storing x-ray images, the personal computer is not part of this submission.

Wireless/ Wired X-Ray Flat Panel Detectors used with

Accessory: "AWS (Acquisition Workstation Software) Synergy DR FDX/ Synergy DR", runs on a Windows based Desktop computer/ Laptop/ Tablet as a user interface for radiologist to perform a general radiography exam. The function includes:

1. User Login
2. Display Connectivity status of hardware devices like detector
3. Patient entry (Manual, Emergency and Worklist)
4. Exam entry
5. Image processing
6. Search patient Data
7. Print DICOM Image
8. Exit

The software documentation level has been determined to be "Basic" based on the "Guidance for the Content of Premarket Submissions for Device Software Functions".

Software System: "AWS (Acquisition Workstation Software) Synergy DR FDX/ Synergy DR" is the user interface application of the Digital Radiography System. New patient register/ Work list retrieving, exposure control, image acquisition, image processing and data transmitting are all achieved at the Synergy DR FDX/ Synergy DR. The Synergy DR FDX/ Synergy DR also provide the control functions responsible for synchronizing the states of detector with the X-Ray generator. Synergy DR FDX/ Synergy DR Features:

- Patient entry and Patient information storage
- Image Acquisition, processing and storage
- DICOM 3.0 MWL, MPPS, DICOM send, DICOM print
- Post processing such as Zoom, PAN, and Annotations etc.
- Advanced Features like automatic image stitching, dual energy, auto positioning, dose display, automatic collimation etc.

VI. Indications for Use

Allengers Wireless/ Wired X-Ray Flat Panel Detectors used with AWS (Acquisition Workstation Software) Synergy DR FDX/Synergy DR is used to acquire/Process/Display/Store/Export radiographic images of all body parts using Radiographic techniques. It is intended for use in general radiographic applications wherever a conventional film/screener CR system is used.

Allengers Wireless/Wired X-ray Flat Panel Detectors are not intended for mammography applications.

VII. Technological Characteristics Comparison to Predicate & Reference Devices:

Wireless/ Wired X-Ray Flat Panel Detectors used with

Accessory: "AWS (Acquisition Workstation Software) Synergy DR FDX/ Synergy DR" is Subject Device and only made changes in the DQE, MTF and thickness in the Subject Device **Wireless/ Wired X-Ray Flat Panel Detectors** used with **Accessory:** "AWS (Acquisition Workstation Software) Synergy DR FDX/ Synergy DR of Allengers Medical Systems Limited. The AWS software is unmodified compared to the predicate device.

This 510(k) submission describes some modifications to the Subject Device **Wireless/ Wired X-Ray Flat Panel Detectors** used with Accessory: "AWS (Acquisition Workstation Software) Synergy DR FDX/ Synergy DR. Change in the thickness of Scintillator trigger differences in image quality metrics (DQE, MTF) in the Subject Device as compared to the Predicate Device (K223009). However, these changes do not affect the intended use of device and its performance. However, modifications into the DQE, MTF, and Scintillator thickness maintain the device's diagnostic image quality as compared to the predicate device.

The details of changes to the Subject Device include:

DQE (Detective Quantum Efficiency)

- CsI: at 0.5 lp/mm, 0.85 (Max.).
- CsI: at 1 lp/mm, 0.69 (Max.).
- CsI: at 2 lp/mm, 0.54 (Max.).

MTF (Modulation Transfer Function)

- CsI: at 0.5 lp/mm, 0.95 (Max.)
- CsI: at 1 lp/mm, 0.70 (Max.).
- CsI: at 2 lp/mm, 0.41 (Max.).

Thickness of Scintillator

- Thickness of Scintillator: 600um

Sensitivity

- Sensitivity: ≥ 801 LSB/uGy (Max.)

Wireless/ Wired X-Ray Flat Panel Detectors used with

Accessory: "AWS (Acquisition Workstation Software) Synergy DR FDX/ Synergy DR" are Subject Device equivalent with its predicate device "Wireless/ Wired X-Ray Flat Panel Detectors with AWS (Acquisition Workstation Software) Synergy DR FDX/Synergy DR with K223009" and there is no change in accordance with Model Name, indented use, appearance & software. Only change in DQE, MTF, Sensitivity and thickness of Scintillator and due to this change there are no new safety and effectiveness issues being raised.

The comparisons of technological characteristics are listed in the following table below.

Feature	Subject Device	Predicate Device	Reference Device
510(k)	This submission	K223009	K201528 K210988 K220510
Product Code			
Product Classification Code	MQB	MQB	MQB
Product Classification			
Classification	21 CFR 892.1680	21 CFR 892.1680	21 CFR 892.1680
Product name			
Product name	Wireless/ Wired X-Ray Flat Panel Detectors	Wireless/ Wired X-Ray Flat Panel Detectors	Yushan X-Ray Flat Panel Detector with DROC
Model Name			
Model name	G4336RWC	G4336RWC	V14C
	G4343RWC	G4343RWC	V17C
	T4336RWC	T4336RWC	F14C
	G4343RC	G4343RC	V17Ce

Feature	Subject Device	Predicate Device	Reference Device
Clinical			
Indications for Use	Allengers Wireless/ Wired X-Ray Flat Panel Detectors used with AWS (Acquisition Workstation Software) Synergy DR FDX/Synergy DR is used to acquire/Process/Display/Store/Export radiographic images of all body parts using Radiographic techniques. It is intended for use in general radiographic applications wherever a conventional film/screener CR system is used. Allengers Wireless/ Wired X-Ray Flat Panel Detectors are not intended for mammography applications.	Allengers Wireless/ Wired X-Ray Flat Panel Detectors used with AWS (Acquisition Workstation Software) Synergy DR FDX/Synergy DR is used to aquire/Process/Display/Store/Export radiographic images of all body parts using Radiographic techniques. It is intended for use in general radio-graphic applications wherever a conventional film/screener CR system issued. Allengers Wireless/ Wired X-Ray Flat Panel Detectors are not intended for mammography applications.	The Wireless/Wired Yushan X-Ray Flat Panel Detector is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications including pediatric and neonatal exams wherever conventional film/screen or CR systems may be used. The Yushan X-Ray Flat Panel Detector is not intended for mammography, fluoroscopy, tomography, and angiography applications. Yushan series provide either raw X ray image or corrected image for system integrator to do further image process.
Compliance standard	FDA Standards 21 CFR 892.1680 for stationary x-ray system ISO 13485 ISO 14971 ANSI/AAMI ES60601-1 IEC 62220-1-1ISO 20417	FDA Standards 21 CFR 892.1680 for stationary x-ray system ISO 13485 ISO 14971 ANSI/AAMI ES60601-1 IEC 62220-1-1ISO 20417	FDA Standards 21 CFR 892.1680 for stationary x-ray system European Medical Devices Directive (93/42/EEC) EN ISO 13485 ISO 14971

Feature	Subject Device	Predicate Device	Reference Device
	IEC 60601-1-2 IEC 62304 IEC 60601-1-6 IEC 62366-1 ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 15223-1 ANSI AAMI HE75	IEC 60601-1-2 IEC 62304 IEC 60601-1-6 IEC 62366-1 ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 15223-1 ANSI AAMI HE75	ANSI/AAMI ES60601-1 CAN/CSA C22.2 No. 60601-1:14 IEC 60601-1-2 IEC 62304 IEC 60601-1-6 IEC 62366-1 ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 15223-1 ANSI AAMI HE75
Technical			
Dimensions (inch.)	G4336RWC (W)14X(H)17 G4343RWC (W)17X(H)17 T4336RWC: (W)14X(H)17 G4343RC: (W)17X(H)17	G4336RWC: (W)14X(H)17 G4343RWC (W)17X(H)17 T4336RWC: (W)14X(H)17 G4343RC: (W)17X(H)17	V14C: (W)14X(H)17 V17C: (W)17X(H)17 F14C: (W)14X(H)17 V17Ce: (W)17X(H)17
Weight (Kg)	G4336RWC: 2.9 G4343RWC: 3.55 T4336RWC: 2.9 G4343RC: 3.9	G4336RWC: 2.7 G4343RWC: 3.2 T4336RWC: 2.5 G4343RC: 3.6	V14C: @3 V17C: @3 F14C: @2 V17Ce: @3.5

Feature	Subject Device		Predicate Device		Reference Device	
Substrate	G4336RWC G4343RWC G4343RC	Glass	G4336RWC G4343RWC G4343RC	Glass	V14C V17C V17Ce	Glass
	T4336RWC	Non-Glass	T4336RWC	Non-Glass	F14C	Non-Glass
Scintillator	CsI		CsI		CsI	
A/D Conversion	16 bit		16 bit		16 bit	
Pixels	G4336RWC: 2500 x 3052 G4343RWC: 3072 x 3072 T4336RWC: 2500 x 3052 G4343RC: 3072 x 3072		G4336RWC: 2500 x 3052 G4343RWC: 3072 x 3072 T4336RWC: 2500 x 3052 G4343RC: 3072 x 3072		V14C: 2500 x 3052 V17C: 3072 x 3072 F14C: 2500 x 3052 V17Ce: 3072 x 3072	
MTF @ 0.5 lp/mm (Max.)	0.95		G4343RC, G4343RWC, G4336RWC	0.90	V14C V17C V17Ce	0.90
			T4336RWC	0.85	F14C	0.85
MTF @1 lp/mm (Max.)	0.70		G4343RWC, G4336RWC, G4343RC	0.76	V14C V17C V17Ce	0.76
			T4336RWC	0.69	F14C	0.69

Feature	Subject Device	Predicate Device		Reference Device	
MTF @2 lp/mm (Max.)	0.41	G4343RC, G4343RWC, G4336RWC	0.47	V14C V17C V17Ce	0.47
		T4336RWC	0.42	F14C	0.42
DQE @ 0.5 lp/mm (Max.)	0.85	G4343RC, G4343RWC, G4336RWC	0.78	V14C V17C V17Ce	0.78
		T4336RWC	0.79	F14C	0.79
DQE @1 lp/mm (Max.)	0.69	G4343RWC, G4336RWC, G4343RC	0.55	V14C V17C V17Ce	0.55
		T4336RWC	0.58	F14C	0.58
DQE @2 lp/mm (Max.)	0.54	G4343RC, G4343RWC, G4336RWC	0.47	V14C V17C V17Ce	0.47
		T4336RWC	0.49	F14C	0.49
Thickness of Scintillator	600 um	400 um		400 um	
Sensitivity (Typ.)	715 LSB/uGy	574 LSB/uGy		574 LSB/uGy	

Feature	Subject Device	Predicate Device	Reference Device
Max. Resolution	3.57 lp/mm	3.57 lp/mm	3.57 lp/mm
Interface	Wired: Gigabit Ethernet Wireless: IEE E802.11 ac /a/g/n	Wired: Gigabit Ethernet Wireless: IEEE802.11 ac /a/g/n	Wired: Gigabit Ethernet Wireless: IEEE802.11 ac /a/g/n
Power	Rechargeable Lithium Battery *G4343RC Have no Battery	Rechargeable Lithium Battery *G4343RC Have no Battery	Rechargeable Lithium Battery *V17Ce have No Battery
Biological			
Biological safety	All material contact with patients is in accordance with ISO 10993.	All material contact with patients is in accordance with ISO 10993.	All material contact with patients is in accordance with ISO 10993.
Others			
Accessories	Battery (Optional)* *G4343RC are not applicable Power supply (Adapter) SE cable (Back-up cable) Power Cord (Optional) Charger (Optional) Charger Adapter (Optional) AWS (Acquisition Workstation Software) Synergy DR FDX/ Synergy DR	- Battery (Optional)* - * G4343RC are not applicable - Power supply (Adapter) - SE cable (Back-up cable) - Power Cord (Optional) - Charger (Optional) - Charger Adapter (Optional) - AWS (Acquisition Workstation Software) Synergy DR FDX/ Synergy DR	Battery (Optional)* * V17Ce are not applicable Power supply (Adapter) SE cable (Back-up cable) Power Cord Power Cord (Optional) Charger (Optional) Charger Adapter (Optional) DROC Dongle (Optional)

PERFORMANCE DATA

Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence. Performance testing included functional testing i.e. Bench testing to evaluate the impact of different scintillator thicknesses on the image quality of FPDs. The non-clinical testing identified in the guidance for submission of 510(k)s for Solid state X-Ray imaging devices (SSXI) was performed and demonstrated adequate system performance and Imaging performance.

Non-clinical Performance Data: Wireless/ Wired X-Ray Flat Panel Detectors used with Accessory: "AWS (Acquisition Workstation Software) Synergy DR FDX/ Synergy DR" confirms to the voluntary standards such as AAMI/ANSI ES60601-1, IEC 60601-1, IEC 60601-1-2, IEC 62304, IEC 60601-1-6, ANSI AAMI IEC 62366-1 and ANSI/AAMI HE75. In addition, the FDA's Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices (issued on September 1, 2016) was followed to describe the detector characteristics; Guidance for the Content of Premarket Submissions for Device Software Functions (issued on June 14, 2023) was followed to evaluate the level of documentation as "Basic". Additionally, the risk analysis, necessary verification and validation activities were performed. Load-bearing characteristics and protection against ingress of water were tested and passed. The internal circuit design was demonstrated through EMC emission testing: IEC 60601-1-2 and the results were satisfactory. Furthermore, the image quality evaluation confirmed that the image quality of the Wireless/ Wired X-Ray Flat Panel Detectors is substantially equivalent to that of the predicate device.

There are 4 models in this submission, **G4336RWC, G4343RWC, T4336RWC, and G4343RC** which are equivalent to the Predicate device. There is no change in accordance with Model Name, intended use, appearance & software. Only change in DQE, MTF, Sensitivity and thickness of Scintillator and due to this change there are no new safety and effectiveness issues being raised.

In conclusion, the modification of the 600µm CsI scintillator has been thoroughly evaluated and is deemed acceptable, as it does not significantly impact the safety, effectiveness, or intended use of the cleared model. This modification maintains compliance with fundamental scientific technology and the identified risk of electrical hazards was successfully mitigated.

Experimental results also confirm that the 600µm CsI provides superior noise performance and smoother image quality compared to the 400µm CsI, without clinically significant degradation of details or edges. Hence, this modification maintains diagnostic image quality as compared to the predicate. The data supports the substantial equivalence of the subject device to the predicate.