November 27, 2022

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

Re: K223009
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: September 29, 2022
Received: September 29, 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,

Lu Jiang
2022.11.27
20:51:59
-05'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223009

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/screen or CR system is used

Allengers Wireless/ Wired X-Ray Flat Panel Detector is 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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510(k) Summary

K223009

This summary of 510(k) is 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-140507, India
Telephone No:	+91 1762-282600, +919872980168, ra.fdaindia@allengers.net, rnd@allengers.net
Contact Person:	Sanjeev K. Marjara
Date Prepared:	Sep 26, 2022

II. PROPOSED DEVICE

Device (trade) name:	**Wireless/ Wired X-Ray Flat Panel Detectors**	
Model Name:	Wireless X-Ray Flat Panel Detectors	G4336RWC
		G4336RWG
		G4343RWC
		G4343RWG
		T4336RWC
		T4336RWG
	Wired X-Ray Flat Panel Detectors	G4336RWC
		G4336RWG
		G4343RWC
		G4343RWG
		T4336RWC
		T4336RWG
		G4343RC
		G4343RG
Regulation description:	Stationary x-ray system	
Review Panel:	Radiology	
Regulation Number :	21 CFR 892.1680	
Device Class:	Class II	
Product Code:	MQB	

III. PREDICATE DEVICE

Substantial equivalence to the following predicate device is as follows:

Device (trade) name:	Yushan X-Ray Flat Panel Detector with DROC
510(K) Number :	K201528
Manufacturer :	InnoCare Optoelectronics Corp.
Decision Date :	October 11, 2020
Regulation description:	Stationary x-ray system.
Review Panel:	Radiology
Regulation Number :	21 CFR 892.1680
Device Class :	Class II
Product Code:	MQB

Device (trade) name:	Yushan X-Ray Flat Panel Detector with DROC
510(K) Number :	K210988
Manufacturer :	InnoCare Optoelectronics Corp.
Decision Date :	April 21, 2021
Regulation description:	Stationary x-ray system.
Review Panel:	Radiology
Regulation Number :	21 CFR 892.1680
Device Class :	Class II
Product Code:	MQB

Device (trade) name:	Yushan X-Ray Flat Panel Detector with DROC
510(K) Number :	K220510
Manufacturer :	InnoCare Optoelectronics Corp.
Decision Date :	April 14, 2022
Regulation description:	Stationary x-ray system.
Review Panel:	Radiology
Regulation Number :	21 CFR 892.1680
Device Class :	Class II
Product Code:	MQB

IV. DESCRIPTION OF THE DEVICE SUBJECT TO PREMERKET NOTIFICATION

Wireless/ Wired X-Ray Flat Panel Detectors used with AWS (Acquisition Workstation Software) Synergy DR FDX/ Synergy DR is substantially equivalent product of its predicate device, Yushan X-Ray Flat Panel Detector with DROC, K201528, K210988, K220510. There are 8 models in this submission G4336RWC, G4336RWG, G4343RWC, G4343RWG, T4336RWC, T4336RWG are portable (wireless) and G4336RWC, G4336RWG, G4343RWC, G4343RWG, T4336RWC, T4336RWG, G4343RG, G4343RC are non-portable (wired) Digital detectors.
The **Wireless/ Wired X-Ray Flat Panel Detectors** is 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) or gadolinium oxy sulfide (GOS).

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 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 level of concern has been determined to be moderate based on the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

The cybersecurity risks have been addressed to assure that no new or increased cybersecurity risks were introduced as a part of device risk analysis. These risks are defined as sequence of events leading to a hazardous situation and the controls for these risks were treated and implemented as proposed in the risk analysis (e.g. requirements, verification). The device software is being used unchanged from the predicate system.

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, Annotations etc.
- Advanced Features like automatic image stitching, Dual energy, auto positioning, dose display, automatic collimation etc.

❖ Level of Concern:

According to IEC 62304:2006/Amd 1:2015 "Medical device software - Software life cycle processes", the software for this device was considered as a class B level of concern, since failures or latent flaws in the software could directly result in non-serious injury to the patient, operator, and/or bystander.

V. 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/screen or CR system is used.

Allengers Wireless/ Wired X-Ray Flat Panel Detector is not intended for mammography applications.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Wireless/ Wired X-Ray Flat Panel Detectors used with AWS (Acquisition Workstation Software) Synergy DR FDX/ Synergy DR have the similar Indications for Use and substantially equivalent design, functional and technical requirements as the models in K201528, K210988, K220510. The comparisons of technological characteristics are listed in the following table.

Feature	Subject Device	Predicate Device		
510(k)	This submission	K201528	K210988	K220510
2. Product Code				
Product Classification Code	MQB	MQB	MQB	MQB
3. Product Classification				
Classification	21 CFR 892.1680	21 CFR 892.1680	21 CFR 892.1680	21 CFR 892.1680
4. Product name				
Product name	**Wireless/ Wired X-Ray Flat Panel Detectors** used with AWS (Acquisition Workstation Software) Synergy DR FDX/ Synergy DR	Yushan X-Ray Flat Panel Detector with DROC		
5. Model name				
Model name	G4336RWC	V14C	-	-
	G4336RWG	V14G	-	-
	G4343RWC	V17C	-	-

Feature	Subject Device	Predicate Device		
	G4343RWG	V17G	-	-
	G4343RG	V17Ge	-	-
	T4336RWC	-	F14C	-
	T4336RWG	-	F14G	-
	G4343RC	-	-	V17Ce
6. 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/screen or CR system is used. Allengers **Wireless/ Wired X-Ray Flat Panel Detectors** is not intended for mammography applica-	The Wireless(V14C, V14G, V17C, V17G)/Wired(V14C, V14G, V17C, V17G, V17Ge) Yushan X-Ray Flat Panel Detector with DROC is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications wherever conventional film/screen or CR systems may be used. The Yushan X-Ray Flat Panel Detector with DROC is not intended for mammography,	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,	The 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 wherever conventional film/screen or CR systems may be used. The Yushan X-Ray Flat Panel Detector is not intended for mammography, fluorosco-

Feature	Subject Device	Predicate Device		
	tions.	fluoroscopy, tomography, and angiography applications.	fluoroscopy, tomography, and angiography applications. Yushan series provide either raw X ray image or corrected image for system integrator to do further image process.	py, tomography, and angiography applications. The use of this product is not recommended for pregnant women and the risk of radioactivity must be evaluated by a physician.
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 - 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	- FDA Standards 21 CFR 892.1680 for stationary x-ray system - European Medical Devices Directive (93/42/EEC) - EN ISO 13485 - ISO 14971 - 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		
7. Technical				

Feature	Subject Device	Predicate Device		
Dimensions (inch.)	G4336RWG: (W)14X(H)17 G4336RWC: (W)14X(H)17 G4343RWG: (W)17X(H)17 G4343RWC: (W)17X(H)17 G4343RG: (W)17X(H)17 T4336RWG: (W)14X(H)17 T4336RWC: (W)14X(H)17 G4343RC: (W)17X(H)17	V14G: (W)14X(H)17 V14C: (W)14X(H)17 V17G: (W)17X(H)17 V17C: (W)17X(H)17 V17Ge: (W)17X(H)17	F14G: (W)14X(H)17 F14C: (W)14X(H)17	V17Ce: (W)17X(H)17
Weight (Kg)	G4336RWG: 2.7 G4336RWC: 2.7 G4343RWG: 3.2 G4343RWC: 3.2 G4343RG: 3.5 T4336RWG: 2.3 T4336RWC: 2.5 G4343RC: 3.6	V14G: @3 V14C: @3 V17G: @3 V17C: @3 V17Ge: @3	F14G: @2 F14C: @2	V17Ce: @3.5

Feature	Subject Device		Predicate Device		
Substrate	G4336RWG G4336RWC G4343RWG G4343RWC G4343RG G4343RC	Glass	Glass	Non-Glass (polyethylene tereph-thalate laminate)	Glass
	T4336RWG T4336RWC	Non-Glass			
Scintillator	G4336RWG G4343RWG G4343RG T4336RWG	GOS	V14G: GOS V14C: CsI V17G: GOS V17C: CsI V17Ge: GOS	F14G: GOS F14C: CsI	V17Ce: CsI
	G4336RWC G4343RWC T4336RWC G4343RC	CsI			
A/D Conversion	16 bit		16 bit	16 bit	16 bit

Feature	Subject Device	Predicate Device		
Pixels	G4336RWG: 2500 x 3052 G4336RWC: 2500 x 3052 G4343RWG: 3072 x 3072 G4343RWC: 3072 x 3072 G4343RG: 3072 x 3072 T4336RWG: 2500 x 3052 T4336RWC: 2500 x 3052 G4343RC: 3072 x 3072	V14G: 2500 x 3052 V14C: 2500 x 3052 V17G: 3072 x 3072 V17C: 3072 x 3072 V17Ge: 3072 x 3072	F14G: 2500 x 3052 F14C: 2500 x 3052	V17Ce: 3072 x 3072
Interface	Wired: Gigabit Ethernet Wireless: IEEE802.11 ac /a/g/n	Wired: Gigabit Ethernet Wireless: IEEE802.11 ac /a/g/n	Wired: Gigabit Ethernet Wireless: IEEE802.11 ac /a/g/n	Wired: Gigabit Ethernet
Power	Rechargeable Lithium Battery *G4343RG, G4343RC Have no Battery	Rechargeable Lithium Battery * V17Ge has no Battery	Rechargeable Lithium Battery	No Battery
8. 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.	All material contact with patients is in accordance with ISO 10993.
9. Others				

Feature	Subject Device	Predicate Device		
Accessories	- Battery (Optional)* * G4343RG, 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)* * V17Ge is not applicable - Power supply (Adapter) - SE cable (Back-up cable) - Power Cord	- Battery (Optional) - Power supply (Adapter) - SE cable (Back-up cable) - Power Cord (Optional) - Charger (Optional) - Charger Adapter (Optional) - DROC Dongle (Optional)	- Power supply (Adapter) - SE cable (Back-up cable) - Power Cord

VII. PERFORMANCE DATA

Non-clinical Performance Data: **Wireless/ Wired X-Ray Flat Panel Detectors** used with 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 Software Contained in Medical Devices (issued on May 11, 2005)* was followed to evaluate the level of concern as moderate; *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (issued on October 02, 2014)* was also followed to consider issues related to cybersecurity in the design and development process of this device. 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. Biocompatibilities were demonstrated through ISO 10993 series to prove the using material safe and effective. 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.
Clinical Performance Data: No clinical study has been performed. The substantial equivalence has been demonstrated by non-clinical studies.

For 8 models in this submission, G4336RWC, G4336RWG, G4343RWC, G4343RWG, T4336RWC, T4336RWG, G4343RG, G4343RC, which are the subsequently equivalent model in K201528, K210988, K220510, only with slight change of product name, appearance and the labeling, therefore the performance data is the same and need no extra validation.
Please refer to the following comparison table for models difference

Table 1

Manufacturer	InnoCare Optoelectronics Corp.		Allengers Medical Systems Limited
Product Name	Yushan X-Ray Flat Panel Detector with DROC		Wireless/ Wired X-Ray Flat Panel Detectors
Model Name	FDA Cleared Device: K201528	V14C	G4336RWC
		V14G	G4336RWG
		V17C	G4343RWC
		V17G	G4343RWG
		V17Ge	G4343RG
	FDA Cleared Device: K210988	F14C	T4336RWC
		F14G	T4336RWG
	FDA Cleared Device: K220510	V17Ce	G4343RC

VIII. Description of Non Clinical & Clinical testing

Non Clinical performance testing has been performed on the **Wireless/ Wired X-Ray Flat Panel Detectors** used with AWS (Acquisition Workstation Software) Synergy DR FDX/ Synergy DR system and it demonstrates compliance with the following relevant voluntary FDA Recognized Consensus Standards as listed in the table below:

Standard/ Guidance	**Standard Title**	**Status**	**FDA Consensus Number**	**Self- Declared**	**Comments/ Deviations**
Standard	AAMI / ANSI ES60601-1:2005/(R) 2012 And A1: 2012, C1:2009/(R) 2012 And A2:2010/ (R) 2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005,	Met all requirements	19-4	Yes	No deviations from standard

	Mod). (General II (ES/EMC))				
Standard	IEC 60601-1-2: 2014_ Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests	Met all requirements	19-8	Yes	No deviations from standard
Standard	IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes	Met all requirements	13-79	Yes	No deviations from standard
Standard	IEC 60601-1-6 Edition 3.1 2013-10, Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability. (General I (QS/RM))	Met all requirements	5-89	Yes	No deviations from standard
Standard	ANSI AAMI IEC 62366-1 Edition 1.0 2015-02 Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]	Met all requirements	5-114	Yes	No deviations from standard
Standard	ISO 10993-1 Fifth edition 2018-08 Biological evalua-	Met all require-	2-258	Yes	No deviations from standard

	tion of medical devices - Part 1: Evaluation and testing within a risk management process	ments			
Standard	ISO 10993-10: Fourth edition 2021-11_ Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	Met all requirements	2-174	Yes	No deviations from standard
Standard	ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices	Met all requirements	5-125	Yes	No deviations from standard
Standard	ISO 15223-1 Third edition 2016-11-01_ Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	Met all requirements	5-117	Yes	No deviations from standard
Standard	ANSI AAMI HE75:2009/ (R)2013 Human factors engineering - Design of medical devices	Met all requirements	5-57	Yes	No deviations from standard
Standard	ISO 10993-5 Third edition 2009-06-01Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Met all requirements	2-245	Yes	No deviations from standard

Standard	IEC 62220-1-1 Edition 1.0 2015-03 Medical electrical equipment-Characteristics of digital X-ray imaging devices Part 1-1: Determination of the detective quantum efficiency Detectors used in radiographic imaging	Met all requirements	12-289	Yes	No deviations from standard
Standard	IEC 62133-2 Edition1.0 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems	Met all requirements	19-33	Yes	No deviations from standard
Standard	ISO 20417 First edition 2021-04 Corrected version 2021-12 Medical devices - Information to be supplied by the manufacturer	Met all requirements	15-135	Yes	No deviations from standard
Guidance	Submission of 510(k)s for Solid State X-ray Imaging Devices (issued on September 1, 2016)	Met all requirements	N/A	Yes	No deviations from guidance
Guidance	Content of Premarket Submissions for Management of Cybersecurity in Medical De-	Met all require-	N/A	Yes	No deviations from guidance

	vices (issued on October 2, 2014)	ments			
Guidance	eCopy Program for Medical Device Submissions (issued on April 27, 2020)	Met all require-ments	N/A	Yes	No deviations from guidance
Guidance	Guidance for the Content of Premarket Submissions for Software Contained in Medi-cal Devices (issued on May 11, 2005)	Met all require-ments	N/A	Yes	No deviations from guidance
Guidance	Appropriate Use of Volun-tary Consensus Standards in Premarket Submissions for Medical Devices (issued on September 14,2018)	Met all require-ments	N/A	Yes	No deviations from guidance
Guidance	Use of International Stand-ard ISO 10993-1, "Biological evaluation of medical devic-es - Part 1: Evaluation and testing within a risk man-agement process (issued on September 4, 2020)	Met all require-ments	N/A	Yes	No deviations from guidance
Guidance	Information to Support a Claim of Electromagnetic Compatibility (EMC) of Elec-trically-Powered Medical Devices (issued on July 11, 2016)	Met all require-ments	N/A	Yes	No deviations from guidance

Non-clinical verification test results demonstrate that the **Wireless/ Wired X-Ray Flat Panel Detectors** used with AWS (Acquisition Workstation Software) Synergy DR FDX/ Synergy DR system complies with the aforementioned international and FDA recognized consensus standards and FDA guidance documents. Also Non 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.

IX. CONCLUSIONS

Wireless/ Wired X-Ray Flat Panel Detectors used with AWS (Acquisition Workstation Software) Synergy DR FDX/ Synergy DR is substantially equivalent to the predicate device in technical characteristics, design features, operating principles, functional and performance characteristics, and for the intended uses in the stated medical specialties.

Wireless/ Wired X-Ray Flat Panel Detectors are designed to comply with applicable federal and international safety and performance standards.

Based upon the supporting data summarized above, only changing on the product name, product appearance and labeling will not raise extra concerns on safety and effectiveness perspective.