November 12, 2024

Prognosys Medical Systems Private Limited
% Giridhar Tumba
Management Representative & Assistant General Manager
168/1, Machohalli, Dasanapura Hobli,
Bangalore North, Bangalore 560091
INDIA

Re: K240771
Trade/Device Name: PRORAD X-Ray Flat Panel Detector with DROC
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: October 15, 2024
Received: October 16, 2024

Dear Giridhar Tumba:

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.

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,

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)*
K240771

Device Name
PRORAD X-Ray Flat Panel Detector with DROC

Indications for Use *(Describe)*
The Wireless(V14 CLARITY, V14 HC, V17 CLARITY, V17 HC, F14 CLARITY, F14 HC)/Wired(V14 CLARITY, V14 HC, V17 CLARITY, V17 HC, F14 CLARITY, F14 HC, W17 Clarity, W17 HC) PRORAD 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 PRORAD X-Ray Flat Panel Detector with DROC is not intended for mammography, fluoroscopy, 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.

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
K240771

I. SUBMITTER

PROGNOSYS MEDICAL SYSTEMS PRIVATE LIMITED

168/1, Machohalli, Dasanapura Hobli, Bangalore North, Bangalore, India. PIN: 560091.

TEL: +91-80-49325700

Email: giri.tumba@prognosysmedical.com

Contact Person: GIRIDHAR TUMBA

II. DEVICE

Trade name: PRORAD X-Ray Flat Panel Detector with DROC

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

Substantial equivalence to the following predicate device is as follows:

1. Trade/Device Name: Yushan X-Ray Flat Panel Detector with DROC

FDA 510(k) clearance number: K201528

Manufacturer: InnoCare Optoelectronics Corp.

Decision Date: 10/11/2020

Regulation description: Stationary x-ray system.

Review panel: Radiology

Product code: MQB

Regulation number: 21 CFR 892.1680

Device class: Class II

2. Trade/Device Name: Yushan X-Ray Flat Panel Detector with DROC

FDA 510(k) clearance number: K210988

Manufacturer: InnoCare Optoelectronics Corp.

Decision Date: 4/21/2021

Regulation description: Stationary x-ray system.

Review panel: Radiology

Product code: MQB

Regulation number: 21 CFR 892.1680

3. Trade/Device Name: Yushan X-Ray Flat Panel Detector with DROC

FDA 510(k) clearance number: K220510

Manufacturer: InnoCare Optoelectronics Corp.

Decision Date: 4/14/2022

Regulation description: Stationary x-ray system.

Review panel: Radiology

Product code: MQB

Regulation number: 21 CFR 892.1680

IV. DESCRIPTION OF THE DEVICE SUBJECT TO PREMERKET NOTIFICATION

PRORAD X-Ray Flat Panel Detector with DROC is the similar product to the predicate, Yushan X-Ray Flat Panel Detector with DROC, K201528, K210988, K220510. There are 8 models in this submission, **V14 Clarity, V14 HC, V17 Clarity, V17 HC, W17 HC, F14 Clarity, F14 HC, W17 Clarity** are a portable(wireless)/non-portable(wired) digital detector. The PRORAD X-Ray Flat Panel Detector with DROC 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.

The PRORAD X-Ray Flat Panel Detector with DROC is currently indicated for gen-

eral projection radiographic applications and the scintillator material is using cesium iodide (Csl) or gadolinium oxysulfide (GOS).

The PRORAD X-Ray Flat Panel Detector with DROC sensor can automatically collects x-ray images from an x-ray source. It collects x-rays and digitizes the images for their transfer and display to a computer. 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.

PRORAD series is working by using DROC. This is a software running on a Windows PC as an user interface for radiologist to perform a general radiography exam. The function include:

1. Detector status update
2. Xray exposure workflow
3. Image viewer and measurement.
4. Post image process and DICOM file I/O
5. Image database: DROC support the necessary DICOM Services to allow a smooth integration into the clinical network

The software documentation level for the PRORAD X-Ray Flat Panel Detector with DROC has been determined Basic based on the “Guidance for the Content of Premarket Submissions for Device Software Functions”, and the software for the Prorad X-Ray detectors is unchanged from the predicate.

The cybersecurity risks of the PRORAD X-Ray Flat Panel Detector with DROC 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.

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

PRORAD X-Ray Flat Panel Detector with DROC have the same Indications for Use, and similar design, functional and technical requirements as the models in K201528, K210988, K220510. The comparison of technological characteristics is listed in the following table.

	Subject Device	**Predicate Device**		
Manufacturer	PROGNOSYS MEDICAL SYSTEMS PRIVATE LIMITED	InnoCare Optoelectronics Corp.		
Product name	PRORAD X-Ray Flat Panel Detector with DROC	Yushan X-Ray Flat Panel Detector with DROC		
FDA Cleared	-	K201528	K210988	K220510
Model name	**V14 Clarity**	V14C	-	-
	V14 HC	V14G	-	-
	V17 Clarity	V17C	-	-
	V17 HC	V17G	-	-
	W17 HC	V17Ge	-	-
	F14 Clarity	-	F14C	-
	F14 HC	-	F14G	-
	W17 Clarity	-	-	V17Ce

Clinical				
Indications for Use	The Wireless(V14 CLARITY, V14 HC, V17 CLARITY, V17 HC, F14 CLARITY, F14 HC)/Wired(V14 CLARITY, V14 HC, V17 CLARITY, V17 HC, F14 CLARITY, F14 HC, W17 Clarity, W17 HC) PRORAD 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 PRORAD X-Ray Flat Panel Detector with DROC is not intended for mammography, fluoroscopy, tomography, and angiography ap-	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	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	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, fluoroscopy, tomography, and angiography applications. The use of this

	plications. The use of this product is not recommended for pregnant women and the risk of radioactivity must be evaluated by a physician.	DROC is not intended for mammography, fluoroscopy, tomography, and angiography applications.	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.	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 - European Medical Devices Directive (93/42/EEC) - EN ISO 13485 - ISO 14971 - ANSI/AAMI ES60601-1 - CAN/CSA C22.2 No. 60601-1:14	- 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		

	- 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	- ISO 10993-1 - ISO 10993-5 - ISO 10993-10 - ISO 15223-1		
Technical				
Dimensions (mm)	V14 HC: 460(W)×383(L)×15(H) V14 Clarity: 460(W)×383(L)×15(H) V17 HC: 460(W)×460(L)×15(H) V17 Clarity: 460(W)×460(L)×15(H) W17 HC: 460(W)×460(L)×15(H) F14 HC:	V14G: 460(W)×383(L)×15(H) V14C: 460(W)×383(L)×15(H) V17G: 460(W)×460(L)×15(H) V17C: 460(W)×460(L)×15(H) V17Ge: 460(W)×460(L)×15(H)	F14G: 460(W)×383(L)×15(H) F14C: 460(W)×383(L)×15(H)	V17Ce: 460(W)×460(L)×15(H)

	460(W)×383(L)×15(H) F14 Clarity: 460(W)×383(L)×15(H) W17 Clarity: 460(W)×460(L)×15(H)			
Weight (Kg)	V14 HC: 2.7 V14 Clarity: 2.7 V17 HC: 3.2 V17 Clarity: 3.2 W17 HC: 3.5 F14 HC: 2.3 F14 Clarity: 2.5 W17 Clarity: 3.6	V14G: 2.7 V14C: 2.7 V17G: 3.2 V17C: 3.2 V17Ge: 3.5	F14G: 2.3 F14C: 2.5	V17Ce: 3.6
Substrate	V14 HC: Glass V14 Clarity: Glass V17 HC: Glass V17 Clarity: Glass W17 HC: Glass F14 HC: Non-Glass F14 Clarity: Non-Glass	Glass	Non-Glass (polyethylene tereph- thalate laminate)	Glass

	W17 Clarity: Glass			
Scintillator	V14 HC: GOS V14 Clarity: CsI V17 HC: GOS V17 Clarity: CsI W17 HC: GOS F14 HC: GOS F14 Clarity: CsI W17 Clarity: CsI	V14G: GOS V14C: CsI V17G: GOS V17C: CsI V17Ge: GOS	F14G: GOS F14C: CsI	V17Ce: CsI
Pixel Pitch	140 µm	140 µm	140 µm	140 µm
DQE	GOS: at 1 lp/mm, RQA5 is 0.27 CsI: at 1 lp/mm, RQA5 is 0.50	GOS: at 1 lp/mm, RQA5 is 0.27 CsI: at 1 lp/mm, RQA5 is 0.48	GOS: at 1 lp/mm, RQA5 is 0.27 CsI: at 1 lp/mm, RQA5 is 0.50	CsI: at 1 lp/mm, RQA5 is 0.48
MTF	GOS: at 1 lp/mm, RQA5 is 0.52 CsI: at 1 lp/mm, RQA5 is 0.69	GOS: at 1 lp/mm, RQA5 is 0.52 CsI: at 1 lp/mm, RQA5 is 0.69	GOS: at 1 lp/mm, RQA5 is 0.52 CsI: at 1 lp/mm, RQA5 is 0.63	CsI: at 1 lp/mm, RQA5 is 0.69
Max.	GOS: 3.57 lp/mm	GOS: 3.57 lp/mm	GOS: 3.57 lp/mm	CsI: 3.57 lp/mm

resolution	CsI: 3.57 lp/mm	CsI: 3.57 lp/mm	CsI: 3.57 lp/mm	
A/D Conversion	16 bit	16 bit	16 bit	16 bit
Pixels	V14 HC: 2500 x 3052 V14 Clarity: 2500 x 3052 V17 HC: 3072 x 3072 V17 Clarity: 3072 x 3072 W17 HC: 3072 x 3072 F14 HC: 2500 x 3052 F14 Clarity: 2500 x 3052 W17 Clarity: 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 (100BASE-TX or 10BASE-T) Wireless: IEEE802.11 ac /a/g/n * W17 HC, W17 Clarity are not applicable for wireless function.	Wired: Gigabit Ethernet (100BASE-TX or 10BASE-T) Wireless: IEEE802.11 ac /a/g/n * V17Ge is not applicable for wireless function.	Wired: Gigabit Ethernet (100BASE-TX or 10BASE-T) Wireless: IEEE802.11 ac /a/g/n	Wired: Gigabit Ethernet (100BASE-TX or 10BASE-T)

Power Source	Rechargeable Lithium Battery * W17 HC, W17 Clarity are not applicable	Rechargeable Lithium Battery * V17Ge is not applicable	Rechargeable Lithium Battery	No Battery
Biological				
Biological safety	All material contact with patients are in accordance with ISO 10993.	All material contact with patients are in accordance with ISO 10993.	All material contact with patients are in accordance with ISO 10993.	All material contact with patients are in accordance with ISO 10993.
Others				
Accessories	- Battery (Optional) * W17 HC, W17 Clarity are not applicable - Power supply (Adapter) - SE cable (Back-up cable) - Power Cord (Optional) - Charger (Optional) - Charger Adapter (Optional)	- 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 (Option-	- Power supply (Adapter) - SE cable (Back-up cable) - Power Cord

	- DROC Dongle (Optional)		al) - Charger Adapter (Optional) - DROC Dongle (Optional)	

VI. PERFORMANCE DATA

Non-clinical Performance Data: PRORAD X-Ray Flat Panel Detector with DROC 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 concern as basic; *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (issued on September 27, 2023)* 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: IEC60601-1-2 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 PRORAD X-Ray Flat Panel Detector with DROC 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, **V14 Clarity, V14 HC, V17 Clarity, V17 HC, W17 HC, F14 Clarity, F14 HC, W17 Clarity**, which are similar to the predicate devices 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.

Error! Reference source not found. Product Name/Model Name Difference

Manufacturer	InnoCare Optoelectronics Corp.		PROGNOSYS MEDICAL SYSTEMS PRIVATE LIMITED
Product Name	Yushan X-Ray Flat Panel Detector with DROC		PRORAD X-Ray Flat Panel Detector with DROC
Model Name	**FDA Cleared Device:** K201528	V14C	PRORAD V14 Clarity
		V14G	PRORAD V14 HC
		V17C	PRORAD V17 Clarity
		V17G	PRORAD V17 HC
		V17Ge	PRORAD W17 HC
	FDA Cleared Device: K210988	F14C	PRORAD F14 Clarity
		F14G	PRORAD F14 HC
	FDA Cleared Device: K220510	V17Ce	PRORAD W17 Clarity

VII. CONCLUSIONS

PRORAD X-Ray Flat Panel Detector with DROC 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.

PRORAD X-Ray Flat Panel Detector with DROC is 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.