July 22, 2025

InnoCare Optoelectronics Corp.
℅ Christy Huang
Quality Engineer
InnoCare Optoelectronics Corp.
Rm. B, No. 2, Sec. 2, Huanxi Rd., Southern Taiwan Science Park
Xinshi Dist., Tainan 741
TAIWAN

Re: K250211
Trade/Device Name: Yushan x-ray flat panel detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MQB
Dated: January 22, 2025
Received: June 23, 2025

Dear Christy Huang:

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,

Lu Jiang

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)*
K250211

Device Name
Yushan x-ray flat panel detector

Indications for Use *(Describe)*

The Wireless and 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 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
K250211

I. SUBMITTER

InnoCare Optoelectronics Corp.

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Email: regulatoryaffairs@innocare-x.com

Contact Person: Christy Huang/ Quality Engineer

Date Prepared: January 22, 2025

II. DEVICE

Trade name: Yushan X-Ray Flat Panel Detector

Model name: V14C PLUS, F14C PLUS, V17C PLUS, V17Ce PLUS

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:

a.

Trade/Device Name: Yushan X-Ray Flat Panel Detector

FDA 510(k) clearance number: K243171

Manufacturer: InnoCare Optoelectronics Corp.

Regulation description: Stationary x-ray system.

Review panel: Radiology

Product code: MQB

Regulation number: 21 CFR 892.1680

Device class: Class II

b.

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

FDA 510(k) clearance number: K201528

Manufacturer: InnoCare Optoelectronics Corp.

Regulation description: Stationary x-ray system.

Review panel: Radiology

Product code: MQB

Regulation number: 21 CFR 892.1680

Device class: Class II

c.

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

FDA 510(k) clearance number: K210988

Manufacturer: InnoCare Optoelectronics Corp.

Regulation description: Stationary x-ray system.

Review panel: Radiology

Product code: MQB

Regulation number: 21 CFR 892.1680

Device class: Class II

d.

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

FDA 510(k) clearance number: K220510

Manufacturer: InnoCare Optoelectronics Corp.

Regulation description: Stationary x-ray system.

Review panel: Radiology

Product code: MQB

Regulation number: 21 CFR 892.1680

Device class: Class II

IV. INDICATIONS FOR USE

The Wireless and Wired Yushan X-Ray Flat Panel Detector is intended to capture for display radio-

graphic 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 product is not recommended for pregnant women and the risk of radioactivity must be evaluated by a physician.

V. DESCRIPTION OF THE DEVICE SUBJECT TO PREMERKET NOTIFICATION

The Subject Device Yushan X-Ray Flat Panel Detector is static digital x-ray detector, model V14C PLUS, F14C PLUS, V17C PLUS are portable (wireless/ wired) detectors, while V17Ce PLUS is a non-portable (wired) detector. The Subject Device is equivalent to it's predicate device K243171, K201528, K210988, and K220510.

The Subject Device 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. The Subject Device has 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 Detector is currently indicated for general projection radiographic applications and the scintillator material is cesium iodide (Csl).

The Subject Device can automatically collect 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 fully-functional diagnostic system) is not part of the device. 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 Subject Device is working by using DROC (Digital Radiography Operating Console), Xresta or DR console, which are unchanged from the predicate device, cleared under K201528 for DROC and K243171 for Xresta and DR console. The DROC or Xresta is a software running on a Windows PC/Laptop as a user interface for radiologist to perform a general radiography exam. The function includes:

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 or Xresta supports the necessary DICOM Services to allow a smooth integration into the clinical network

The DR Console is a software/app-based device, which is a software itself. When this app is operating the OTS can be considered as the iOS system (iOS 16 or above), the safety and effectiveness of this OTS has been assessed and evaluated through the software testing (compatibility) action and also the usability test (summative evaluation). All the functions operate normally and successfully under this OTS framework. The function includes:

1. Imaging procedure review
2. Worklist settings
3. Detector connection settings
4. Calibration
5. Image processing

The software level of concern for the Yushan X-Ray Flat Panel Detector with DROC, Xresta, or DR Console has been determined to be basic based on the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"; and the cybersecurity risks of the Yushan X-Ray Flat Panel Detector with DROC, Xresta, or DR Console have also 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).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Compare to the predicate device, The Subject Device only made changes in the CsI scintillator thickness, DQE, MTF, and Sensitivity. Other portion, such as the software DROC, Xresta, DR Console are unchanged compare to the predicate device (K243171, K201528), the circuit design, operating principle, mechanism design...etc. are also unchanged compare to the predicate device (K243171). Change in the thickness of Scintillator trigger differences in image quality metrics (DQE, MTF, Sensitivity) in the Subject Device as compared to the Predicate Device (K243171, K201528). The details of changes to The Subject Device include:

DQE (Detective Quantum Efficiency)

- 0.60 @ 1 lp/mm (Typical)
- 0.45 @ 2 lp/mm (Typical)

MTF (Modulation Transfer Function)

- 0.64 @ 1 lp/mm (Typical)
- 0.34 @ 2 lp/mm (Typical)

Sensitivity

- 715 lsb/uGy

Thickness of Scintillator

- Thickness of Scintillator: 600um

The Subject Device has the higher DQE ratio than the predicate device, that means the better SNR (signal to noise ration) and reflect to the image quality. The Subject Device has the slightly less MTF than the CsI model of predicate device but the significantly higher MTF than the GOS model of predicate device. These changes on The Subject Device would not change the intended use, indications for use, and there are no new safety and effectiveness issues being raised, compared to the predicate device.

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

Feature	Subject Device	Predicate Device	Predicate Device
510(K)	K250211	K243171	K201528 K210988 K220510
Product name	Yushan X-Ray Flat Panel Detector with **DROC, Xresta, DR Console**	Yushan X-Ray Flat Panel Detector with **Xresta, DR Console**	Yushan X-Ray Flat Panel Detector with **DROC**
Model Name	V14C PLUS	V14C	V14C(K201528)
	-	V14G	V14G(K201528)
	V17C PLUS	V17C	V17C(K201528)
	-	V17G	V17G(K201528)
	-	V17Ge	V17Ge(K201528)
	F14C PLUS	F14C	F14C(K210988)
	-	F14G	F14G(K210988)
	V17Ce PLUS	V17Ce	V17Ce(K220510)
Manufacturer	InnoCare Optoelectronics Corp.	InnoCare Optoelectronics Corp.	InnoCare Optoelectronics Corp.
Feature	Subject Device	Predicate Device	Predicate Device
Indications for Use	The Wireless and 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	The Wireless (V14C, V14G, F14C, F14G, V17C, V17G)/Wired (V14C, V14G, F14C, F14G, V17C, V17G, V17Ge, V17Ce) Yushan X-Ray Flat Panel Detector is in-tended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications	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 in-tended for use in general projection radiographic applications wherever

	be used. The Yushan X-Ray Flat Panel Detector 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.	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 product is not recommended for pregnant women and the risk of radioactivity must be evaluated by a physician.	conventional film/screen or CR systems may be used. The Yushan X-Ray Flat Panel Detector with DROC is not intended for mammography, fluoroscopy, tomography, and angiography applications.
Dimensions (mm)	V14C PLUS:460(W)×383(L)×15(H) V17C PLUS:460(W)×460(L)×15(H) F14C PLUS: 460(W)×383(L)×15(H) V17Ce PLUS:460(W)×460(L)×15(H)	V14C:460(W)×383(L)×15(H) V14G:460(W)×383(L)×15(H) V17C:460(W)×460(L)×15(H) V17G:460(W)×460(L)×15(H) V17Ge:460(W)×460(L)×15(H) F14C:460(W)×383(L)×15(H) F14G:460(W)×383(L)×15(H) V17Ce:460(W)×460(L)×15(H)	V14C:460(W)×383(L)×15(H) V14G:460(W)×383(L)×15(H) V17C:460(W)×460(L)×15(H) V17G:460(W)×460(L)×15(H) V17Ge:460(W)×460(L)×15(H) F14C:460(W)×383(L)×15(H) F14G:460(W)×383(L)×15(H) V17Ce:460(W)×460(L)×15(H)
Weight (Kg)	V14C PLUS: 2.9 V17C PLUS: 3.55 F14C PLUS: 2.9 V17Ce PLUS: 3.9	V14C: 2.7 V14G: 2.7 V17C: 3.2 V17G: 3.2 V17Ge: 3.5 F14C: 2.3 F14G: 2.5 V17Ce: 3.6	V14C: 2.7 V14G: 2.7 V17C: 3.2 V17G: 3.2 V17Ge: 3.5 F14C: 2.3 F14G: 2.5 V17Ce: 3.6
Substrate	Glass: For V series Non-Glass (polyethylene terephthalate laminate): For F series	Glass: For V series Non-Glass (polyethylene terephthalate laminate): For F series	Glass: For V series Non-Glass (polyethylene terephthalate laminate): For F series
Scintillator	CsI	V14C: CsI V14G: GOS V17C: CsI V17G: GOS	V14C: CsI V14G: GOS V17C: CsI V17G: GOS

		V17Ge: GOS F14C: CsI F14G: GOS V17Ce: CsI	V17Ge: GOS F14C: CsI F14G: GOS V17Ce: CsI
Pixel Pitch	140 µm	140 µm	140 µm
DQE	CsI: at 1 lp/mm, RQA5 is 0.60	V series: GOS: at 1 lp/mm, RQA5 is 0.27 CsI: at 1 lp/mm, RQA5 is 0.48 F series: GOS: at 1 lp/mm, RQA5 is 0.27 CsI: at 1 lp/mm, RQA5 is 0.50	V series: GOS: at 1 lp/mm, RQA5 is 0.27 CsI: at 1 lp/mm, RQA5 is 0.48 F series: GOS: at 1 lp/mm, RQA5 is 0.27 CsI: at 1 lp/mm, RQA5 is 0.50
MTF	CsI: at 1 lp/mm, RQA5 is 0.64	V series: GOS: at 1 lp/mm, RQA5 is 0.52 CsI: at 1 lp/mm, RQA5 is 0.69 F series: GOS: at 1 lp/mm, RQA5 is 0.27 CsI: at 1 lp/mm, RQA5 is 0.63	V series: GOS: at 1 lp/mm, RQA5 is 0.52 CsI: at 1 lp/mm, RQA5 is 0.69 F series: GOS: at 1 lp/mm, RQA5 is 0.27 CsI: at 1 lp/mm, RQA5 is 0.63
Max. resolution	3.57 lp/mm	3.57 lp/mm	3.57 lp/mm
A/D Conversion	16 bit	16 bit	16 bit
Pixels	V14C PLUS:2500 x 3052 V17C PLUS:3072 x 3072 F14C PLUS:2500 x 3052	V14C: 2500 x 3052 V14G: 2500 x 3052 V17C: 3072 x 3072 V17G: 3072 x 3072 V17Ge: 3072 x 3072 F14C: 2500 x 3052 F14G: 2500 x 3052	V14C: 2500 x 3052 V14G: 2500 x 3052 V17C: 3072 x 3072 V17G: 3072 x 3072 V17Ge: 3072 x 3072 F14C: 2500 x 3052 F14G: 2500 x 3052

	V17Ce PLUS:3072 x 3072	V17Ce: 3072 x 3072	V17Ce: 3072 x 3072
Interface	Wired: Gigabit Ethernet (100BASE-TX or 10BASE-T) Wireless: IEEE802.11 ac /a/g/n * V17Ce PLUS is not applicable for wireless function.	Wired: Gigabit Ethernet (100BASE-TX or 10BASE-T) Wireless: IEEE802.11 ac /a/g/n * V17Ge, V17Ce is not applicable for wireless function.	Wired: Gigabit Ethernet (100BASE-TX or 10BASE-T) Wireless: IEEE802.11 ac /a/g/n * V17Ge, V17Ce is not applicable for wireless function.
Power Source	Rechargeable Lithium Battery *not applicable on model V17Ce PLUS	Rechargeable Lithium Battery *not applicable on model V17Ge, V17Ce	Rechargeable Lithium Battery *not applicable on model V17Ge, V17Ce
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.
Accessories	- Battery (Not applicable to V17Ce PLUS) - Power supply (Adapter) - SE cable (Back-up cable) - Power Cord - Charger (Not applicable to V17Ce PLUS) - Charger Adapter (Not applicable to V17Ce PLUS) - DROC Dongle (Optional) - Xresta Dongle (Optional) - DR Console (Optional)	- Battery (Not applicable to V17Ge, V17Ce) - Power supply (Adapter) - SE cable (Back-up cable) - Power Cord - Charger (Not applicable to V17Ge, V17Ce) - Charger Adapter (Not applicable to 17Ge, V17Ce) - Xresta Dongle (Optional) - DR Console (Optional)	- Battery (Not applicable to V17Ge, V17Ce) - Power supply (Adapter) - SE cable (Back-up cable) - Power Cord - Charger (Not applicable to V17Ge, V17Ce) - Charger Adapter (Not applicable to 17Ge, V17Ce) - DROC Dongle (Optional)

VII. PERFORMANCE DATA

Yushan X-Ray Flat Panel Detector **(V14C PLUS, F14C PLUS, V17C PLUS, V17Ce PLUS)** conforms 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 the device. 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. Additionally, the risk analysis, necessary verification and validation activities were performed.

In the Substantial Equivalence Comparison, the evaluation of the impact of different scintillator thicknesses on the image quality of FPDs shows the Subject Device provides lower noise performance and a smoother image compared to that of the predicate device. The comparisons of technological characteristics show the thicker CsI scintillator only change in DQE, MTF, Sensitivity and due to this change there are no new safety and effectiveness issues being raised. These testing result and image quality evaluation support the claims of substantial equivalence to that of the predicate device.

VII. CONCLUSIONS

The modification of the 600μm CsI scintillator has been thoroughly evaluated and is deemed accepta-ble, as it does not significantly impact the safety, effectiveness, or intended use of the cleared model. **Yushan X-Ray Flat Panel Detector (V14C PLUS, F14C PLUS, V17C PLUS, V17Ce PLUS)** is de-signed to comply with applicable federal and international safety and performance standards. Experi-mental results also confirm that the 600μm CsI provides superior noise performance and smoother im-age quality compared to the 400μm CsI, without clinically significant degradation of details or edges. Based upon the supporting data summarized above, we concluded the **Yushan X-Ray Flat Panel Detec-tor (V14C PLUS, F14C PLUS, V17C PLUS, V17Ce PLUS)** is as safe and effective as the legally mar-keted device Yushan X-Ray Flat Panel Detector (K243171, K201528, K210988, K220510), and do not

raise different questions of safety and effectiveness.