December 19, 2024

InnoCare Optoelectronics Corp.
% April Cheng
Regulatory Affairs
Rm. B, No. 2, Sec. 2, Huanxi Rd.,
Southern Taiwan Science Park, Xinshi Dist.
Tainan City, 741
TAIWAN

Re: K243171
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: September 26, 2024
Received: November 4, 2024

Dear April Cheng:

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)*
K243171

Device Name
Yushan x-ray flat panel detector

Indications for Use *(Describe)*

The Wireless (V14C, V14G, F14C, F14G, V17C, V17G)/Wired (V14C, V14G, F14C, F14G, V17C, V17G, V17Ge, V17Ce) 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.

510(k) Summary
K243171

I. SUBMITTER

InnoCare Optoelectronics Corp.
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TEL: +886-6-700-7238 # 22598
Email: yumei.cheng@innocare-x.com
Contact Person: Yumei Cheng / Regulatory affairs
Date Prepared: Feb 10, 2022

II. DEVICE

Trade name: **Yushan X-Ray Flat Panel Detector**
Model name: V14C, V14G, V17C, V17G, F14C, F14G, V17Ce, V17Ge
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 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

b.

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

c.

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

IV. INDICATIONS FOR USE

The Wireless (V14C, V14G, F14C, F14G, V17C, V17G)/Wired (V14C, V14G, F14C, F14G, V17C, V17G, V17Ge, V17Ce) 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.

V. DESCRIPTION OF THE DEVICE SUBJECT TO PREMERKET NOTIFICATION

The subject device Yushan X-Ray Flat Panel Detector, model V14C, V14G, V17C, V17G, F14C, F14G are portable(wireless/wired) detectors, while V17Ce, V17Ge are a non-portable(wired) detector. The Yushan X-Ray Flat Panel Detector 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. 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.

Yushan series is working by using Xresta and DR console.

The Xresta is a software running on a Windows PC as an 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 support the necessary DICOM Services to allow a smooth integration into the clinical network

The software level of concern is determined to be basic based on the “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

The cybersecurity risks 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).

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

Both software level of concern is determined to be basic based on the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; and the cybersecurity risks 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

Yushan X-Ray Flat Panel Detector (model: V14C, V14G, F14C, F14G, V17C, V17G, V17Ge, V17Ce) has the same Indications for Use, and very similar functional and technical requirements as the model V14C, V14G, V17C, V17G, V17Ge in K201528, F14C, F14G in K210988, V17Ce in K201528. The comparison of technological characteristics are listed in the following table. Yushan X-Ray Flat Panel Detector has been successfully tested and validated.

Product name	Yushan X-Ray Flat Panel Detector	Yushan X-Ray Flat Panel Detector with DROC	Yushan X-Ray Flat Panel Detector with DROC	Yushan X-Ray Flat Panel Detector with DROC
Model name	V14C	V14C	-	-
	V14G	V14G	-	-
	V17C	V17C	-	-
	V17G	V17G	-	-
	V17Ge	V17Ge	-	-
	F14C	-	F14C	-
	F14G	-	F14G	-
	V17Ce	-	-	V17Ce
Manufacturer	InnoCare Optoelectronics Corp.	InnoCare Optoelectronics Corp.	InnoCare Optoelectronics Corp.	InnoCare Optoelectronics Corp.
Qualified number	(Subject Device)	K201528	K210988	K220510
Clinical				

Indications for Use	The Wireless (V14C, V14G, F14C, F14G, V17C, V17G)/Wired (V14C, V14G, F14C, F14G, V17C, V17G, V17Ge, V17Ce) 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	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, fluoroscopy, tomography, and angiography applications.	The Wireless/Wired 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, fluoroscopy, tomography, and angiography applications.	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 product is not recommended for pregnant women and the risk of radioactivity must be evaluated by a physician.

	pregnant women and the risk of radioactivity must be evaluated by a physician.			
Technical				
Dimensions (mm)	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)	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)

Weight (Kg)	V14G: 2.7 V14C: 2.7 V17G: 3.2 V17C: 3.2 V17Ge: 3.5 F14G: 2.3 F14C: 2.5 V17Ce: 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	Glass: For V series Non-Glass (polyethylene terephthalate laminate): For F series	Glass	Non-Glass (polyethylene terephthalate laminate)	Glass
Scintillator	V14G: GOS V14C: CsI V17G: GOS V17C: CsI V17Ge: GOS F14G: GOS F14C: CsI V17Ce: 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	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	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	CsI: at 1 lp/mm, RQA5 is 0.64	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. resolution	GOS: 3.57 lp/mm CsI: 3.57 lp/mm	GOS: 3.57 lp/mm CsI: 3.57 lp/mm	GOS: 3.57 lp/mm CsI: 3.57 lp/mm	CsI: 3.57 lp/mm
A/D Conver-sion	16 bit	16 bit	16 bit	16 bit

Pixels	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	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 * V17Ge, V17Ce is 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	Not applicable

Power Source	Rechargeable Lithium Battery * V17Ge, V17Ce is not applicable for wireless function.	Rechargeable Lithium Battery *not applicable on model V17Ge	Rechargeable Lithium Battery	Rechargeable Lithium Battery *not applicable on model V17Ge
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) - Power supply (Adapter) - SE cable (Back-up cable) - Power Cord - Xresta Dongle (Optional) - DR Console (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 (Optional) - Charger Adapter (Optional) - DROC Dongle (Optional)	- Power supply (Adapter) - SE cable (Back-up cable) - Power Cord

VII. PERFORMANCE DATA

Non-clinical Performance Data: Yushan X-Ray Flat Panel Detector 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; *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 Yushan X-Ray Flat Panel Detector 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.

VIII. CONCLUSIONS

Based upon the supporting data provided, we concluded the 2 newly user interface applicable to Yushan X-Ray Flat Panel Detector is as safe and effective, which do not raise additional safety and effectiveness issues.

Yushan X-Ray Flat Panel Detector 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.

Yushan X-Ray Flat Panel Detector is designed to comply with applicable federal and

international safety and performance standards.

Based upon the supporting data summarized above, we concluded the 2 newly user interface applicable to Yushan X-Ray Flat Panel Detector is as safe and effective as the legally marketed device Yushan X-Ray Flat Panel Detector (K201528, K210988, K220510), and do not raise different questions of safety and effectiveness.