InnoCare Optoelectronics Corp.
℅ Yumei Cheng
Senior Engineer
Rm. B, No. 2, Sec. 2, Huanxi Rd., Xinshi Dist.,
Tainan City, Taiwan 744
REPUBLIC OF CHINA

October 11, 2020

Re: K201528
Trade/Device Name: Yushan 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: June 2, 2020
Received: August 31, 2020

Dear Yumei 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 (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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201528

Device Name
Yushan X-Ray Flat Panel Detector with DROC

Indications for Use *(Describe)*
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.

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 K201528

I. SUBMITTER

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Contact Person: Yumei Cheng / Senior Engineer
Date Prepared: Jun 02, 2020

II. DEVICE

Trade name: Yushan X-Ray Flat Panel Detector with DROC
Model name: V14C, V14G, V17C, V17G, 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:
Trade/Device Name: Yushan X-Ray Flat Panel Detector
FDA 510(k) clearance number: K191939
Manufacturer: InnoCare Optoelectronics Corp.
Decision Date: 08/29/2019
Regulation description: Stationary x-ray system.
Review panel: Radiology
Product code: MQB
Regulation number: 21 CFR 892.1680
Device class: Class II

IV. DESCRIPTION OF THE DEVICE SUBJECT TO PREMERKET NOTIFICATION

InnoCare's Yushan X-Ray Flat Panel Detector with DROC, model V14C, V14G, V17C, V17G are portable digital detector system, while V17Ge is a non-protable digital detector. The Yushan X-Ray Flat Panel Detector with DROC is designed to be used in any environment that would typically use a radiographic cassette for examinations. Model V14C, V14G, V17C, V17G support both wireless and wired/tethered data communication between the detector and the system, while model V17Ge is only applicable for wired use. 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. Every model 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 Yushan X-Ray Flat Panel Detector with DROC is currently indicated for general projection radiographic applications and offers two different detector types in terms of scintillator materials (gadolinium oxysulfide (GOS) and cesium iodide (Csl)).

The Yushan 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 sensor does not have an x-ray source, which is provided and controlled by independent system manufacturers. 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.

Yushan series is working due to the combination of SDK(software development kit) and DROC(Digital Radiography Operating Console).

The SDK provides the interface for DROC to control the Yushan X-Ray Flat Panel Detector. SDK initiates the taking of X-ray images from the Yushan X-Ray Flat Panel Detector, through the Sensor Driver application. Once an X-ray is taken, Sensor Driver reads it from the flat panel and transfers it to SDK. Then the DROC will take

the image data from SDK for further image process and display.

The DROC 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 level of concern for the Yushan X-Ray Flat Panel Detector with DROC 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 of the Yushan 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).

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Yushan X-Ray Flat Panel Detector with DROC (V14C, V14G, V17C, V17G) and its predicate device, Yushan X-Ray Flat Panel Detector (V14C, V14G) are portable digital detector systems, while the model V17Ge is a non-portable type, that are used to acquire x-ray exposures. Yushan X-Ray Flat Panel Detector with DROC has the same Indications for Use, and very similar functional and technical requirements as the predicate device, K191939. The comparison of technological characteristics are listed in the following table. Yushan X-Ray Flat Panel Detector with DROC has been successfully tested and validated, there are 5 models in this submission, V14C, V14G, V17C, V17G, V17Ge, and V14C, V14G are exactly the same device in K191939 named V14C and V14G, except for the modification of the user interface which has

been changed into DROC version, and V17C, V17G, V17Ge are the serial models using the same user interface, DROC. Please refer to the following table for more detailed information.

Product name	Yushan X-Ray Flat Panel Detector with DROC	Yushan X-Ray Flat Panel Detector
Model name	V14G V14C V17G V17C V17Ge	V14G V14C
Manufacturer	InnoCare Optoelectronics Corp.	InnoCare Optoelectronics Corp.
Qualified number	-	K191939
Clinical		
Indications for use	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 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.

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 - 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	- 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
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)	V14G: 460(W)×383(L)×15(H) V14C: 460(W)×383(L)×15(H)
Weight (Kg)	V14G: 2.7	V14G: 2.7

	V14C: 2.7 V17G: 3.2 V17C: 3.2 V17Ge: 3.5	V14C: 2.7
Scintillator	V14G: GOS V14C: CsI V17G: GOS V17C: CsI V17Ge: GOS	V14G: GOS V14C: CsI
Pixel Pitch	140 μm	140 μm
DQE	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 0.48
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
Max. resolution	GOS: 3.57 lp/mm CsI: 3.57 lp/mm	GOS: 3.57 lp/mm CsI: 3.57 lp/mm
A/D Conver-sion	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	V14G: 2500 x 3052 V14C: 2500 x 3052
Interface	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
Power Source	Rechargeable Lithium Battery * V17Ge is not applicable	Rechargeable Lithium 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.
Others		
Accessories	- 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

VI. PERFORMANCE DATA

Non-clinical Performance Data: Yushan X-Ray Flat Panel Detector with DROC (V14C, V14G, V17C, V17G, V17Ge) 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; *Radio Frequency Wireless Technology in Medical Devices (issued on August 14, 2013)*, FCC 47 CFR PART 15 SUBPART C, FCC 47 CFR PART 15 SUBPART E and FCC SAR were followed to test the wireless features, which V17Ge is not applicable for this test; *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 2, 2014)* was also followed to consider issues related to cybersecurity in the design and development process of this device. Additionaly, 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, FCC 47 CFR PART 15 SUBPART B, ETSI EN 301 489-

17 V3.1.1:2017 and ETSI EN 301 489-1 V2.1.1:2017, 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 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.

VII. CONCLUSIONS

Yushan 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.

Yushan 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, we concluded the Yushan X-Ray Flat Panel Detector with DROC (V14C, V14G, V17C, V17G, V17Ge) is as safe and effective as the legally marketed device Yushan X-Ray Flat Panel Detector (Yushan V14C, Yushan V14G) (K191939), and do not raise different questions of safety and effectiveness than K191939.