April 14, 2022

InnoCare Optoelectronics Corp.
℅ Yumei Cheng
Principal Engineer
Rm. B, No. 2, Sec. 2, Huanxi Rd.,
Southern Taiwan Science Park, Xinshi Dist.
Tainan City, 741
TAIWAN

Re: K220510
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: February 15, 2022
Received: February 22, 2022

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
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)*
K220510

Device Name
Yushan X-Ray Flat Panel Detector with DROC

Indications for Use *(Describe)*
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.

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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Section 5 510(k) Summary
K220510

I. SUBMITTER

InnoCare Optoelectronics Corp.

Rm. B, No. 2, Sec. 2, Huanxi Rd., Southern Taiwan Science Park, Xinshi Dist., Tainan City 741, Taiwan, R.O.C.

TEL: +886-6-700-7238 # 22598

Email: yumei.cheng@innocare-x.com

Contact Person: Yumei Cheng / Principal Engineer

Date Prepared: Feb 10, 2022

II. DEVICE

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

Model name: V17Ce

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 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

Trade/Device Name: FDR D-EVO FLAT PANEL DETECTOR SYSTEM
FDA 510(k) clearance number: K132509
Manufacturer: FUJIFILM MEDICAL SYSTEMS USA, INC.
Decision Date: 11/25/2013
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

InnoCare's Yushan X-Ray Flat Panel Detector with DROC, model V17Ce is a non-protable(wired) 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. 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. V17Ce 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 the scintillator material is 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 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.

Yushan series is working by using DROC(Digital Radiography Operating Console). 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 Pre-market 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). The device software is being used unchanged from the predicate system.

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Yushan X-Ray Flat Panel Detector with DROC(model: V17Ce) has the same Indications for Use, and very similar functional and technical requirements as the model V17Ge in K201528. 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 is one models in this submission, **V17Ce**, which is the exact same model of **V17Ge** in K201528, except for the Scintillator, C stands for CsI, and G stands for GOS.

Product name	Yushan X-Ray Flat Panel Detector with DROC	Yushan X-Ray Flat Panel Detector with DROC
Model name	V17Ce	V17Ge
Manufacturer	InnoCare Optoelectronics Corp.	InnoCare Optoelectronics Corp.
Qualified number	-	K201528
Clinical		
Intended use	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.	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)	- 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	- 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)	V17Ce: 460(W)×460(L)×15(H)	V17Ge: 460(W)×460(L)×15(H)
Weight (Kg)	V17Ce: 3.6	V17Ge: 3.5
Scintillator	V17Ce: CsI	V17Ge: GOS
Pixel Pitch	140 μm	140 μm
DQE	CsI: at 1 lp/mm, RQA5 is 0.48	GOS: at 1 lp/mm, RQA5 is 0.27
MTF	CsI: at 1 lp/mm, RQA5 is 0.69	GOS: at 1 lp/mm, RQA5 is 0.52
Max. resolution	CsI: 3.57 lp/mm	GOS: 3.57 lp/mm
A/D Conver-sion	16 bit	16 bit
Pixels	V17Ce: 3072 x 3072	V17Ge: 3072 x 3072
Interface	Wired: Gigabit Ethernet	Wired: Gigabit Ethernet

	(100BASE-TX or 10BASE-T)	(100BASE-TX or 10BASE-T)
Power Source	Not applicable	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.
Others		
Accessories	- Power supply (Adapter) - SE cable (Back-up cable) - Power Cord	- Battery (Optional)* V17Ge is not applicable - 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 (V17Ce) 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 18, 2018)* 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 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 (V17Ce) is as safe and effective as the legally marketed device Yushan X-Ray Flat Panel Detector (Yushan V17Ge) (K201528), and do not raise different questions of safety and effectiveness than K201528.