InnoCare Optoelectronics Corp.
Yumei Cheng
Senior Engineer
Rm. B, No. 2, Sec. 2, Huanxi Rd., Xinshi Dist
Tainan City 744, TAIWAN

August 29, 2019

Re: K191939
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: July 15, 2019
Received: July 19, 2019

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 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)*
K191939

Device Name
Yushan X-Ray Flat Panel Detector

Indications for Use *(Describe)*
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.

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 K191939

I. SUBMITTER

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TEL: +886-6-505-1889 # 22598
Email: Yumei.cheng@innolux.com
Contact Person: Yumei Cheng / Senior Engineer
Date Prepared: Aug 09, 2019

II. DEVICE

Trade name: Yushan X-Ray Flat Panel Detector
Model name: Yushan V14C, Yushan V14G
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: FDR D-EVO II Flat Panel Detector System
FDA 510(k) clearance number: K142003
Manufacturer: FUJIFILM Medical Systems U.S.A., Inc.
Decision Date:10/21/2014
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 (Yushan V14C, Yushan V14G) is a portable digital detector system. The Yushan X-Ray Flat Panel Detector is designed to be used in any environment that would typically use a radiographic cassette for examinations of adults. The detector models support both wireless and wired/tethered data communication between the detector and the system. 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 Yushan X-Ray Flat Panel Detector 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 sensor can automatically collects x-ray images from an x-ray source. The Yushan X-Ray Flat Panel Detector sensor 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.

The SDK(software development kit) software library runs on a PC workstation and provides the interface for system manufacturer 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 user interface which designed by the system manufacture will take the image data from SDK for further image process and display. Please be noted that the software is not based on the predicate device.

The software level of concern for the Yushan X-Ray Flat Panel Detector 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 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

Both Yushan X-Ray Flat Panel Detector and FDR D-EVO II (DR-ID1200) are portable digital detector systems that are used to acquire x-ray exposures. Yushan X-Ray Flat Panel Detector has the same Indications for Use, and very similar functional and technical requirements as the predicate device, K142003. The comparison of technological characteristics are listed in the following table. Yushan X-Ray Flat Panel Detector has been successfully tested and validated, please refer to the next section for more detailed information.

Product name	InnoCare Yushan X-Ray Flat Panel Detector	FDR D-EVO II (DR-ID 1200) flat panel sensor system
Model name	V14G V14C	DR-ID 1201SE DR-ID 1211SE
Manufacturer	InnoCare Optoelectronics Corp.	FUJIFILM Medical Systems U.S.A., Inc.
Qualified number	-	CE0123/K142003
Clinical		
Indications for use	The Wireless/Wired InnoCare 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	The Wired/Wireless FDR D-EVO II flat panel sensor system is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications including pediatric and

	film/screen or CR systems may be used. The InnoCare Yushan X-Ray Flat Panel Detector is not intended for mammography, fluoroscopy, tomography, and angiography applications.	neonatal exams wherever conventional film/screen or CR systems may be used. The FDR D-EVO II 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	- AAMI/ANSI ES60601-1 - IEC 60601-1 - IEC 60601-1-2 - IEC 62304 - IEC 62366
Technical		
Dimensions (mm)	V14G: 460(W)×383(L)×15(H) V14C: 460(W)×383(L)×15(H)	DR-ID 1201SE: 460(W)×384(L)×15(H) DR-ID 1211SE: 460(W)×384(L)×15(H)
Weight (Kg)	V14G: 2.7	DR-ID 1201SE: 2.6

	V14C: 2.7	DR-ID 1211SE: 2.6
Scintillator	V14G: GOS V14C: CsI	DR-ID 1201SE: GOS DR-ID 1211SE: CsI
Pixel Pitch	140 μm	150 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 0.30 CsI: at 1 lp/mm, RQA5 is 0.54
	Although the results show small differences. We, InnoCare has the Yu-shan image compared with the predicate device's image, and the image quality do not show significant difference.	
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 0.60 CsI: at 1 lp/mm, RQA5 is 0.80
	Although the results show small differences. We, InnoCare has the Yu-shan image compared with the predicate device's image, and the image quality do not show significant difference.	
Max. resolution	GOS: 3.57 lp/mm CsI: 3.57 lp/mm	GOS: 3.33 lp/mm CsI: 3.33 lp/mm
A/D Conver-sion	16 bit	16 bit
Pixels	2500 x 3052	2336 x 2836
Interface	Wired: Gigabit Ethernet (100BASE-TX or 10BASE-T) Wireless: IEEE802.11 ac /a/g/n	Wired: Gigabit Ethernet (100BASE-TX or 10BASE-T) Wireless: IEEE802.11 n
Power Source	Rechargeable Lithium Battery	Rechargeable Lithium Battery
Technical		
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) - Power supply (Adapter) - SE cable (Back-up cable) - Power Cord	- Battery Charger (Optional) - Power supply - SE cable

VI. PERFORMANCE DATA

Non-clinical Performance Data: Yushan X-Ray Flat Panel Detector (Yushan V14C, Yushan V14G) 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; *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; *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 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 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 Yushan X-Ray Flat Panel Detector (Yushan V14C, Yushan V14G) is as safe and effective as the legally marketed device FDR D-EVO II (DR-ID 1200) flat panel sensor system (K142003), and do not raise different questions of safety and effectiveness than K142003.