KA Imaging Inc.
℅ Amol Karnick
QA/RA Representative
560 Parkside Dr #3
Waterloo, Ontario N2L 5Z4
CANADA

September 3, 2020

Re: K201591
Trade/Device Name: Flat Panel Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: June 10, 2020
Received: June 12, 2020

Dear Amol Karnick:

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)*

K201591

Device Name
Flat Panel Detector

Indications for Use *(Describe)*

The flat panel detector when used with a radiographic imaging system is intended to generate radiographic images of human anatomy wherever a conventional screen-film, digital radiography (DR) or computed radiography (CR) detector is used for general purposes.

When the dual energy subtraction function is enabled, it is intended to assist the physician through the visualization of anomalies by reducing the visibility of underlying or overlying anatomical structures.

This device is not intended for use in mammography 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

I. SUBMITTER

KA Imaging Inc.
560 Parkside Dr #3, Waterloo, ON Canada N2L 5Z4
Phone: +1 (226)-215-9897
Email: sto@kaimaging.com
Contact Person: Samuel To
Position: QA/RA Representative
Date of Submission: June 10, 2020

II. DEVICE

Common name: Flat Panel Detector
Model name: Reveal 35C
Device Classification Name: Solid State X-Ray Imager (Flat Panel/Digital Imager)
Review Panel: Radiology
Product code: MQB
Regulation number: 21 CFR 892.1680
Device class: Class 2

III. PREDICATE DEVICE

Substantial equivalence to the following predicate devices is as follow:

510(k) #	Product	Company	Reference
K191939	Yushan X-Ray Flat Panel Detector	InnoCare Optoelectronics Corp.	Primary Predicate Device
K150766	Carestream DRX-1 System	Carestream Health, Inc.	Reference Predicate Device
K122454	FUJIFILM DUAL ENERGY SUBTRACTION (DES) SOFTWARE OPTION	FUJIFILM MEDICAL SYSTEM U.S.A., INC.	Reference Predicate Device
K013481	DUAL ENERGY AND TISSUE EQUALIZATION SOFTWARE OPTION	GE MEDICAL SYSTEMS	Reference Predicate Device

IV. DEVICE DESCRIPTION

The Reveal 35C Flat Panel Detector is similar to the FDA cleared Yushan X-ray Flat Panel Detector. The detectors consist of amorphous silicon flat panel image sensors with cesium iodide scintillators. The light is captured by an amorphous silicon photodetector and the resulting signal is transferred via amorphous silicon thin film transistor (TFT) switches to external readout electronics to obtain X-ray images. The Reveal 35C Flat Panel Detector is a portable digital detector that can be integrated with a PC workstation and an X-ray source to acquire digital X-

Ray images for general radiography. The detector supports wireless and wired data communication and can be used wherever a conventional screen-film, digital radiography, or computed radiography detector is used for general purposes.

The Reveal 35C Flat Panel Detector synchronize their image capture cycle with the X-Ray exposure in either of the two modes:

1. Wired Mode
2. Wireless Mode

The subject device, Reveal 35C Flat Panel Detector includes an optional Dual-Energy subtraction function. When the Dual-Energy Subtraction function is enabled, it will provide additional dual energy subtracted X-ray images. The images are intended to assist the physician through the visualization of anomalies by reducing the visibility of underlying or overlying anatomical structures.

V. INDICATIONS FOR USE

The flat panel detector when used with a radiographic imaging system is intended to generate radiographic images of human anatomy wherever a conventional screen-film, digital radiography (DR) or computed radiography (CR) detector is used for general purposes.

When the dual energy subtraction function is enabled, it is intended to assist the physician through the visualization of anomalies by reducing the visibility of underlying or overlying anatomical structures.

This device is not intended for use in mammography applications.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

KA Reveal 35C device is an X-ray flat panel detector (FPD) equivalent to its indicated predicate devices. Like the predicate devices, Reveal 35C is able to capture radiographic images in a medical diagnostic setting thanks to its amorphous silicon active matrix array with an overlying cesium iodide scintillator layer. It also contains a graphical user interface software that allows for FPD operation, image processing and image display, similar to that of the identified predicate devices. Reveal 35C is therefore equivalent to its predicate devices with respect to form-factor and operation.

Unlike its predicate devices, Reveal 35C is composed of three (3) stacked active matrix arrays. Each array has its own substrate, TFT/photo-diode layer and scintillator layer. These arrays are simultaneously read and are then additively combined to generate a single image. This additive image is always digitally stored and transferred for viewing. This single image is equivalent to the single image obtained by any of the listed predicate devices, thus making Reveal 35C's image output equivalent to those devices.

Additionally, Reveal 35C's three-layer design allows for a Dual-Energy software option to be included with this submission. When this option is used, this software option is able to compute tissue-subtracted Dual-Energy images, thanks to the spectral differences between the different layer images. The Dual-Energy images obtained by this software option are equivalent to those of reference predicate devices (K122454 and K013481). See Table 1 below for a summary.

SE Table 1

Description	**Proposed Device:** KA Imaging Reveal 35C Flat Panel Detector	**Primary Predicate Device:** InnoCare Optoelectronics Yushan X-Ray Flat Panel Detector (K191939)	**Reference Predicate Device:** Carestream DRX-1 System (K150766)
Indication for Use	The flat panel detector when used with a radiographic imaging system is intended to generate radiographic images of human anatomy wherever a conventional	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	The device is intended to capture for display radiographic images of human anatomy including both pediatric and adult patients. The device is intended for use in general

	screen-film, digital radiography (DR) or computed radiography (CR) detector is used for general purposes. When the dual energy function is enabled, it is intended to assist the physician through the visualization of anomalies by reducing the visibility of underlying or overlying anatomical structures. This device is not intended for use in mammography applications.	radiographic applications wherever conventional 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.	projection radiographic applications wherever conventional screen-film systems or CR systems may be used. Excluded from the indications for use are mammography, fluoroscopy, and angiography applications.
Detector Type	Flat Panel detector with scintillator	Flat Panel detector with scintillator	Flat Panel detector with scintillator
Image Capture Area	35cm x 43 cm	35cm x 43 cm	35cm x 43 cm
Detector Device Material	Amorphous Silicon Sensor Array with Cesium Iodide scintillator	Amorphous Silicon Sensor Array with Cesium Iodide or Gadolinium Oxisulfide scintillator	Amorphous Silicon Sensor Array with Cesium Iodide or Gadolinium Oxisulfide scintillator
Pixel Pitch	140 microns	140 microns	139 microns
Detector Element Matrix	2500 x 3052	2500 x 3052	2544 x 3056 (3543 GOS), 2520 x 3032 (3543 CsI)
Dynamic Range	16 bits	16 bits	16 bits
Operating System	Windows PC	Windows PC	Windows PC
Operating Console	Graphical User Interface Based	Graphical User Interface Based	Graphical User Interface Based
Image Transmission	Image is electronically	Image is electronically	Image is electronically

	transmitted in digital form through tether (cable) or wireless connection to a computer monitor for display	transmitted in digital form through tether (cable) or wireless connection to a computer monitor for display	transmitted in digital form through tether (cable) or wireless connection to a computer monitor for display
Detector Dimensions	38 x 46 x 1.5 cm	38.3 x 46 x 1.5 cm	38 x 46 x 1.6 cm
Detector Weight	3.2 kg	2.7 Kg	4 kg
Power Source	Battery powered	Battery powered	Battery powered
Communication	Wireless/ Wired	Wireless/ Wired	Wireless/ Wired

The KA Imaging Reveal 35C Flat Panel Detector also includes a dual energy subtraction software option, which can be used to optionally generate three types of radiographic images from a single X-Ray exposure. The first is a (1) standard projection radiography image, equivalent to the primary and reference predicate device (K150766). The second and third images are a (2) soft-tissue image with the bone information removed, and a (3) bone image with the soft tissue information removed. The second image and third image allow the radiologist to subtract specific materials (e.g. bone, soft tissue) and focus on the tissue-type of choice, thus increasing the visualization of the objects of interest.

The reference predicate devices Fujifilm Dual Energy Subtraction (DES) Software Option (K122454) and GE Dual Energy And Tissue Equalization Software Option (K013481) are both software options to provide Dual Energy subtracted images. For both K122454 and K013481, two spectral source images are obtained using two X-ray exposures (the first exposure at a lower kV (typically 60kV) and the second exposure at a higher kV (typically 120kV)). For Reveal 35C, the spectral source images are generated from only a single kV(typically 120kV) exposure because of the use of three active matrix arrays in the Reveal 35C design. Since only a single exposure is utilized for Reveal 35C, there is no additional software required to correct for the involuntary motion artifacts described in K122454. Please see the summary in Table 2 below:

SE Table 2

Description	**Proposed Device:** KA Imaging Reveal 35C Flat Panel Detector	**Reference Predicate Device:** Fujifilm Dual Energy Subtraction (DES) Software Option (K122454)	**Reference Predicate Device:** GE Dual Energy And Tissue Equalization Software Option (K013481)
Indication for Use	The flat panel detector when used with a radiographic imaging system is intended to generate radiographic images of human anatomy wherever a conventional screen-film, digital radiography (DR) or computed radiography (CR) detector is used for general purposes. When the dual energy function is enabled, it is intended to assist the physician through the visualization of anomalies by reducing the visibility of underlying or overlying anatomical structures.	Fujifilm's FDR Dual Energy Subtraction (DES) Option may be used with Fujifilm's DR X-ray systems and is intended to be used by a qualified/trained doctor or technologist for acquiring dual energy subtraction images of human anatomy DES is intended to assist the physician through the visualization of anomalies by reducing the visibility of underlying/overlying anatomical structures The device is not intended for mammographic applications	Dual Energy and Tissue Equalization software options are intended for use in generating digital radiographic images of human anatomy. This device is not intended for mammographic applications.

	This device is not intended for use in mammography applications.		
Number of x-ray exposures	1	2	2
Active imager matrix arrays	3	1	1
X-ray beam energies	120kVp	60 kVp/120kVp	60 kVp/120kVp
Automatic Image Subtraction	Yes	Yes	Yes
Involuntary patient motion reduction	Not required	Yes	Yes
Images sent to destination	3 Images (Standard, Bone and Soft Tissue)	3 Images (Standard, Bone and Soft Tissue)	3 Images (Standard, Bone and Soft Tissue)

VII. PERFORMANCE DATA

Non-clinical Performance Data

The Reveal 35C Flat Panel Detector conforms to the voluntary standards including IEC 60601-1 and IEC 60601-1-2. Non-clinical bench testing has determined that the device hardware and software requirements conform to its specification.

FDA's Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices (issued on September 1, 2016), Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Guidance for Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, were followed to demonstrated that the performance of Reveal 35C Flat Panel Detector is substantially equivalent to the predicate devices.

Furthermore, the image quality validation confirmed that the image quality of KA Imaging Reveal 35C Flat Panel Detector is substantially equivalent to that of the predicate device.

VIII. CONCLUSIONS

The Reveal 35C Flat Panel Detector is substantially equivalent to the predicate devices in technical characteristics, design features, operating principles, functional and performance characteristics, and for the intended uses.

The Reveal 35C Flat Panel Detector is designed to comply with applicable federal and international safety and performance standards.

Based upon the supporting data summarized above, we can conclude the subject device is substantially equivalent in safety and effectiveness as the legally marketed devices. The verification and validation activities performed on the subject device did not raise any issues related to safety and effectiveness.