Imaging Engineering, LLC
℅ Mr. George Jachode
President
1318 NW 7th Ave
CAPE CORAL FL 33993

July 27, 2021

Re: K210469
Trade/Device Name: Insight Agile DRF
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: JAA, OXO, RCC, QHY
Dated: July 12, 2021
Received: July 19, 2021

Dear Mr. Jachode:

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)*
K210469

Device Name

Insight Agile DRF

Indications for Use *(Describe)*

The Insight Agile DRF is intended for use by a qualified/trained medical professionals, who have full understanding of the safety information and emergency procedures as well as the capabilities and functions of the device. The device provides fluoroscopic imaging and is used for guidance and visualization during routine fluoroscopic and image-guided procedures. The device is to be used in professional healthcare facilities, in a variety of image-guided procedures such as feeding tube and catheter insertion on pediatric patients and neonates (birth to one month). This device is not indicated for large/obese patients or interventional use. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. The system is not intendedfor mammography applications. (Rx Only)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Exhibit 5: 510(k) Summary

1. **Trade/proprietary name:** Insight Agile DRF

510(k) Clearance #:	**K210469**
Regulation Name:	Image-Intensified Fluoroscopic X-ray System
Regulation Number:	21 CFR 892.1650
Regulatory Class:	Class II
Product Code:	JAA, OXO, RCC and QHY
Common/Usual Name:	Mobile Fluoroscopic System

2. **Predicate Device: K191503**

Trade Name:	MobileRay Pulse SE Digital Imaging System
Manufacturer:	PortaVision Medical, LLC
Regulation Number:	21 CFR 892.1650
Regulatory Class:	Class II
Product Code:	OWB, JAA, QHY, OXO and RCC
Common/Usual Name:	Mobile Fluoroscopic System

3. **Reference Devices:** (Used with this device)

Trade Name:	Insight Enhanced DRF Digital Imaging System
510(k) Clearance #:	K200396
Clearance date:	03/06/2020
Classification Name:	Image Intensified Fluoroscopic X-ray System
Classification Panel:	Radiology
CFR Section:	21CFR 892.1650 (Produce Code: JAA)
Device Class:	Class Ⅱ

Trade Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
510(k) Clearance #:	K202722
Clearance date:	10/26/2020
Classification Name:	Image Intensified Fluoroscopic X-ray System
Classification Panel:	Radiology
CFR Section:	21CFR 892.1680 (Produce Code: MQB)
Device Class:	Class Ⅱ

4. **Device Description**

The **Insight Agile DRF** Digital Imaging System is a modification of Insight Enhanced DRF, a previously cleared (K200396) fluoroscopic imaging chain employing a flat-panel digital detector (Vieworks 1212G) to replace the image intensifier and video camera on GE R&F systems (P500, Legacy and Advantx). This system has now been modified in the following manner: 1) the digital interface board (DIB) that provides communications with the GE systems has been replaced with a software program that utilizes virtual serial ports.

2) Another software program has been added to allow the system to communicate with and control a Source-Ray x-ray generator. The generator interface provides for Automatic Brightness Stabilization (ABS) control and optional manual control through a graphical user interface on the Insight Agile image acquisition screen. 3) A second dynamic flat-panel detector (Rayence 1212FCA, K202722) has been integrated to provide an alternate digital detector. 4) the software risk assessment has been changed from minor to moderate. 5) the Indications for Use has been changed to that of the predicate device.

With these modifications, Insight Agile DRF is a fluoroscopic imaging chain that can acquire, process, and display fluoroscopic images when installed on any suitable positioning system in a fixed room, on a mobile or portable stand. Another purpose of this application is to expand the indications for use.

5. Indications for Use

The Insight Agile DRF is intended for use by a qualified/trained medical professionals, who have full understanding of the safety information and emergency procedures as well as the capabilities and functions of the device. The device provides fluoroscopic imaging and is used for guidance and visualization during routine fluoroscopic and image-guided procedures. The device is to be used in professional healthcare facilities, in a variety of image-guided procedures such as feeding tube and catheter insertion on pediatric patients and neonates (birth to one month). This device is not indicated for large/obese patients or interventional use. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. The system is not intended for mammography applications. (Rx Only)

6. Summary of Design Control Risk Management

The Insight Agile DRF fluoroscopic imaging chain has been developed to provide OEMs and System Integrators a fluoroscopic imaging chain system that can be integrated with a suitable positioning system. It provides optimized workflow when imaging patients while meeting critical functional requirements and international safety standards. The risks and the hazardous impact of the device design were analyzed with FMEA method. The specific risk control and protective measures to mitigate the risks from the device design and production phase were reviewed and implemented in the new product design phase. The overall assessment concluded that all risks and hazardous conditions identified arising from the design and production were successfully mitigated and accepted.

7. Substantial Equivalence

The Insight Agile™ DRF fluoroscopic imaging chain conforms to the FDA recognized standards as like the predicate device. Based on the recognized standard conformity evidence related to the electro-, mechanical, software-, clinical-and risk management, it is the sponsor's opinion that the subject device is a safe and effective device.

Characteristic	MobileRay Pulse SE Digital Imaging System (K191503)	Insight Agile DRF Digital Imaging System
Power source	120 VAC 50/60 HZ 2.5 amps	120 VAC 50/60 HZ 3.5 amps
Generator Type	High frequency inverter type	SAME
Output Power	4 kW	80 W
Fluoroscopy	0.5 – 10 mA (pulsed) 40 – 25kV	0.1 – 5 mA (Cont.) 35 – 80 kV
Image acquisition	Up to up to 7.5 fps (fluoro)	Up to 30 fps (fluoro)
X-ray Tube	Stationary Anode	SAME
Indicators	Display on workstation monitor	SAME
Collimator	Multi-leaf adjustable motorized, Collimare Touch LED	Fixed Aperture with 0.1 mm Cu fixed filter
Digital Panel Specification	PerkinElmer XRpad2 3025 4346	Vieworks 1212G Rayence 1212FCA
Pixel Pitch	100 µm	Vw 1212G 145 µm Ray.1212FCA 194 µm
Matrix	2508 x 3004	Vx 2000 x 2000 Ray 1536 x 1536
A/D conversion	16 bits	SAME
Image Acquisition	Amorphous Si direct deposition CsI:Tl	Vw 1212G SAME Ray IZGO CsI:Tl
Performance Standard	21 CFR 1202.30	SAME
Electrical Safety	IEC60601-1:2005 + A1 (2012) IEC60601-1-2:2007 IEC60601-1-3:2008 IEC60601-2-28:2010 IEC60601-2-43:2010 IEC60601-2-54:2009	IEC60601-1-2:2014+ANSI+AAMI IEC60601-1-3:2008+A1:2013 IEC60601-2-54:2009 +AMD1:2015+AMD2:2018

The following table compares The MobileRay Pulse SE software (predicate device) to the subject device software.

Feature	Predicate Device MobileRay Pulse SE K191503	Subject Device
Acquiring image from detector	Yes	Yes
Viewing image	Yes	Yes
Change window/level	Yes	Yes
Invert	Yes	Yes
Lookup Table	Yes	Yes
Zoom	Yes	Yes
Pan	Yes	Yes
Noise Reduction	Yes	Yes
Patient Information	Yes	Yes
Annotation	Yes	Yes
Image rotation	Yes	Yes
X-Ray generator control	Yes	Yes
DICOM worklist and Send	Yes	Yes

8. Difference Discussion

The predicate device is a portable system that employs a more powerful generator than the subject device. The predicate device has an indication for use statement that includes radiography and interventional use. The subject device has a lower power generator but does have similar technological characteristics as it relates to fluoroscopic imaging as the predicate device. The indication for use statement of the subject device therefore does not include either radiography or interventional use and further restricts the patient population it is indicated for. Accordingly, the subject device is only substantially equivalent to the fluoroscopic imaging characteristics of the predicate device.

The predicate device is a portable fluoroscopic and radiographic system. Insight Agile DRF is a fluoroscopic imaging chain that can be installed on any suitable positioning system including the predicate device. Insight Enhanced DRF and the Vieworks flat panel detector have already been cleared as a fluoroscopic imaging chain component (K200396) to upgrade the image intensifier and video camera on GE R&F systems. The Rayence 1212FCA detector has been previously cleared for MQB (K202722).

9. Summary of the technological characteristics of the device compared to the predicate device.

The predicate device employs a different fluoroscopic imaging chain consisting of a Sedecal x-ray generator, Collimare collimator, Perkin Elmer digital x-ray detector and console software provided by RADinfo Systems, Inc. Insight Agile DRF employs a Source-Ray x-ray generator, a manual collimator, a Vieworks or Rayence digital x-ray detector and the Insight Agile DRF console software.

Two dFPD detectors are being applied for clearance in this application. One of the dFPDs is manufactured by Vieworks and was cleared previously with Insight Enhanced (K200396). The second dFPD is manufactured by Rayence (1212FCA), this detector is based on 3rd generation flat panel television technology (Indium Zinc Gallium Oxide or IZGO). This technology provides a lower noise floor and much longer detector lifetime compared with a-Si based dFPDs due to its ten-fold increase in radiation damage resistance.

The Rayence 1212FCA was recently cleared for MQB (K202722). A complete SSXI data report for the Rayence 1212FCA detector is provided along with bench test data to establish substantial equivalency.

10. Description of non-clinical tests.

Bench testing was performed on the subject device with the Rayence 1212FCA on the system to assess substantial equivalence of the device and with the Vieworks detector in terms of image quality. Both detectors were integrated with the Source-Ray generator. Phantom images were acquired with the subject device and compared to the predicate device. These images and the doses used to acquire them were analyzed and compared. In conclusion, the tests obtained demonstrated substantial equivalence to the predicate device in terms of imaging performance.

Additional bench testing was performed by Imaging Engineering on the Insight Agile DRF system to determine if the system complies with IEC 60601-1-3, IEC60601-2-54 and 21 CFR 1020.32. The test results are provided in Exhibit 18. The system passed all electrical, mechanical and radiation safety testing. EMC and Electrical Safety performance for the Rayence digital receptor panel had previously been submitted to FDA in K202722.

A radiologist was provided a series of fluoroscopic patient exam images to evaluate the image quality produced by the subject device compared to 2 OEC (9800 and 9900) mobile c arms. A report of their findings is included in Exhibit 16. This report includes the following statement "**I found the Imaging Engineering images to be of high quality, high resolution, and clinically acceptable for the intended use and fully comparable to the OEC images."**

Software has been written and validated according to the FDA Software Guidance: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005.* Cybersecurity concerns have been addressed in accordance with: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff (October 2, 2014).*

11. Description of clinical tests.

No clinical data is necessary to evaluate safety or effectiveness for purposes of determining substantial equivalence of the proposed modification. Bench testing was performed to assess the device safety and effectiveness.

12. Conclusion as to Substantial Equivalence.

The Insight Agile DRF Digital Imaging System, the subject device is substantially equivalent to the fluoroscopic imaging properties of the predicate (K191503). The design principle and the applicable standards for the subject device are similar to those of the predicate device. The statement for use of the predicate device has been modified to remove radiographic and interventional use and to restrict the population demographics to reflect the limitations of the subject device. The performance test and non-clinical consideration result demonstrate that these differences do not raise any new questions of safety and effectiveness. Therefore, it is the sponsor's opinion that the subject device appears to be as safe and effective as the predicate device for fluoroscopic use.