November 5, 2021

IMAGExRAY, LLC
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

Re: K212523
Trade/Device Name: VFSS Pro Mobile Digital Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA, OXO, RCC, QHY
Dated: August 9, 2021
Received: August 11, 2021

Dear Mr. Kamm:

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 and Part 809); 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212523

Device Name
VFSS Pro Mobile Digital Imaging System

Indications for Use *(Describe)*

The VFSS Pro Mobile system is intended for use by a qualified/trained medical professionals, who have full understanding of the safety information and emergency procedures as well of capabilities and function of the device. The device provides fluoroscopic imaging and is used for guidance and visualization during diagnostic radiographic, surgery, and interventional procedures. The device is to be used in healthcare facilities both inside and outside of hospital, in a variety of procedures of the skull, spinal column, chest, abdomen, extremities, and at the discretion of the medical professional the device may be used for other imaging applications on all patients except neonates (birth to one month) within the limits of the device. 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

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 K212523

IMAGExRAY, LLC
160 Park Avenue
Nutley, NJ 07110 USA

Date Prepared: September 15, 2021

Prepared by: Gary Korkola
Tel. 973-235-0606 Fax. 973-235-0132

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

1. Trade/proprietary name: VFSS Pro Mobile Digital Imaging System
Regulation Name: Image-Intensified Fluoroscopic X-ray System
Regulation Number: 21 CFR 892.1650
Regulatory Class: Class II
Product Code: OWB, JAA, OXO, RCC and QHY
Common/Usual Name: Mobile Fluoroscopic System

2. Predicate Device: K211191
Trade Name: Virtual C DRF Digital Imaging System
Manufacturer: PortaVision Medical, LLC
Regulation Number: 21 CFR 892.1650
Regulatory Class: Class II
Product Code: OWB, JAA and OXO
Common/Usual Name: Mobile Fluoroscopic System

3. Reference Devices: (Used with this device)
Imaging Chain:
Trade Name: Insight Agile DRF Digital Imaging System
Manufacturer Imaging Engineering, LLC
510(k) Clearance #: K210469
Classification Name: Image Intensified Fluoroscopic X-ray System
Classification Panel: Radiology
CFR Section: 21CFR 892.1650
Product Codes: JAA, OXO, RCC and QHY
Device Class: Class II

Digital Panel(s) (Customer picks one)
Manufacturer: Vieworks Co. LTD
Trade Name: FXDD-1212G
510(k) Clearance #: K200396
Classification Name: Stationary x-ray system
Classification Panel: Radiology
CFR Section: 21CFR 892.1680 (Product Code: JAA)
Device Class: Class II
OR
Manufacturer: Rayence Co. LTD
Trade Name: 1212FCA
510(k) Clearance #: K202722
Classification Name: Stationary x-ray system
Classification Panel: Radiology

CFR Section:	21CFR 892.1680 (Product Code: MQB)
Device Class:	Class II

4. Device Description

The **VFSS Pro Mobile** system is a mobile imaging system that can acquire, process, and display fluoroscopic images. It can be easily positioned within a room and moved from room to room within a facility. To provide the ability to perform fluoroscopic examinations as needed within a facility. The system employs a low-powered mono-block generator and a dynamic flat-panel detector so that it can be powered through a single-phase 120VAC power outlet. The imaging chain is powered by the Insight Agile DRF Digital Imaging System which allows the operator to view and enhance high-definition fluoroscopy images up to 30 fps. Images may be viewed and enhanced enabling the operator to bring out diagnostic details difficult or impossible to see using conventional imaging techniques. Images can be stored locally for short term storage. The Insight Agile DRF Digital Imaging System enables the operator to produce hardcopy images with a laser printer or send images over a network for longer-term storage. The major system components include: a dynamic flat panel detector, monitors, and an image processor PC. This device employs either the Vieworks FXDD-1212G or the Rayence 1212FCA digital x-ray receptor panels (previously cleared, see Reference devices). The device software employed is from the Reference device Insight Agile DRF.

5. Indications for Use

The VFSS Pro™ Mobile system 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 except 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.

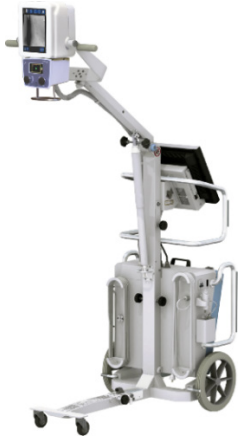
6. Summary of Design Control Risk Management

The VFSS Pro Mobile DRF Digital Imaging System has been developed to provide medical professionals 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 VFSS Pro Mobile Digital Imaging System 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's the sponsor's opinion that the subject device is a safe and effective device. Equivalence is evaluated in the comparison table below:

Characteristic	PortaVision Medical, LLC Virtual C DRF Digital Imaging System (K211191)	VFSS Pro Mobile DRF Digital Imaging System
Indications for Use:	Intended for use by a qualified/trained medical professionals, who have full understanding of the safety information and emergency procedures as well of capabilities and function of the device. The device provides fluoroscopic imaging and is used for guidance and visualization during diagnostic radiographic, surgery, and interventional procedures. The device is to be used in healthcare facilities both inside and outside of hospital, in a variety of procedures of the skull, spinal column, chest, abdomen, extremities, and at the discretion of the medical professional the device may be used for other imaging applications on all patients except neonates (birth to one month) within the limits of the device. 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.	The VFSS Pro™ Mobile system 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 except 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. Comparison note: This indication is a specialized subset of the capabilities of the predicate and excludes interventional procedures.
Power source	120 VAC 50/60 HZ 2.5 amps	120 VAC 50/60 HZ 2.5 amps
System Weight and Size	121 lbs. 36” x 26” x 77”	410 lbs. 78.4” x 40” x 84.85”
Generator Type	High frequency inverter type Source Ray	SAME
Output Power	80 kVp x 2 ma = 160 watts for Source Ray Generator	80 kVp x 1 ma = 80 watts Similar power level. Different model of the SAME generator
Fluoroscopy	.001 – 2 mA, 35 – 80 kV	0.001 – 1 mA (Cont.) 35 – 80 kV
Image acquisition	1 – 15 fps DRTECH Detectors 1 – 30 fps Vieworks Detectors	Up to 30 fps
X-ray Tube	Stationary Anode	SAME
Indicators	Display on workstation monitor	SAME
Collimator	Machine Vision motorized made by PortaVision, model MVC	Fixed Aperture with 0.1 mm Cu fixed filter
Digital Panel Specification	Vivix-D1212G, Vivix-D1717G or EVS 4343WP or EVS 3643WP	Vieworks 1212G or Rayence 1212FCA
Pixel Pitch	140 or 145 µm	Vieworks 1212G 145 µm Rayence.1212FCA 194 µm

Characteristic	PortaVision Medical, LLC Virtual C DRF Digital Imaging System (K211191)	VFSS Pro Mobile DRF Digital Imaging System
Pixel Matrix	2048 x 2048	Vieworks 2000 x 2000 Rayence 1536 x 1536 (K210469)
Panel Sizes	17 x 17, 14 x 17, 12 x 12	12 x 12
A/D conversion	16 bits	SAME
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 NEMA PS 3.1-3.20	IEC60601-1:2005 + A1 (2012) IEC60601-1-2:2014+ANSI+AAMI IEC60601-1-3:2008+A1:2013 IEC60601-2-54:2009 +AMD1:2015 +AMD2:2018 NEMA PS 3.1-3.20
Photo		

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

Feature	**Virtual C DRF Digital Imaging System (K211191)**	**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

Feature	Virtual C DRF Digital Imaging System (K211191)	Subject Device
X-Ray generator control	Yes	Yes
DICOM worklist and Send	Yes	Yes

Difference Discussion

The subject device has similar indications for use and similar technological characteristics as the predicate device. The software application and the Vieworks and Rayence flat panel detectors have already been cleared as fluoroscopic imaging chain components (K210469). The primary differences are that a lower powered x-ray generator is used (80 vs 160 watts) and that the predicate device is a portable system whereas the subject device is a mobile system. The subject device represents a subset of the capabilities of the predicate for the purpose of specialization of the particular procedures that can be performed, namely Video Fluoroscopic Swallow Studies and similar studies.

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

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) and uses the same manufacturing technology (amorphous Si) as the dFPD on the predicate device. 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 with Insight Agile DRF (K210469).

9. Description of non-clinical tests.

Bench testing was performed on the subject device with the Rayence 1212FCA on the system to assess substantial equivalence compared to the predicate device. 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 VFSS Pro Mobile system to determine if the system complies with IEC 60601-1, IEC 60601-1-3, IEC60601-2-54 and 21 CFR 1020.32. 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.

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).*

10. 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.

11. Conclusion as to Substantial Equivalence.

The VFSS Pro Mobile Digital Imaging System, the subject device is substantially equivalent to the predicate (K211191). The intended use, the design principle, and the applicable standards for the subject device are similar to those of the predicate 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.