510(K) Summary, K211191

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Date Prepared: June 18, 2021

1. **Identification of the Device:**
   Trade/Device Names: Virtual C DRF Digital Imaging System
   Regulation Number: 21 CFR 892.1650
   Regulation Name: Image intensified fluoroscopic x-ray system
   Regulatory Class: II
   Product Codes: OWB, JAA, OXO
   Common/Usual Name: Mobile Fluoroscopic System

2. **Equivalent legally marketed device: K191503**
   Trade/Device Name: MobileRay Pulse SE Digital Imaging System
   Manufacturer: PortaVision Medical
   Regulation Number: 21 CFR 892.1650
   Regulation Name: Image intensified fluoroscopic x-ray system
   Regulatory Class: II
   Product Code: OWB, JAA, OXO
   Common/Usual Name: Mobile Fluoroscopic System

3. **Reference Imaging Chain:**
   Trade/Device Name: Insight Agile DRF Digital Imaging System K200396, Vieworks Vivix-D 1212G, 1717G and DRTECH EVS4343WP, 4336WP Detectors customer picks one of the units)
   Manufcaturer: Imaging Engineering, LLC
   Regulation Number: 21 CFR 892.1650
   Regulation Name: Image Intensified Fluoroscopic X-ray System
   Regulatory Class: II; Product Code: JAA and LLZ

4. **Alternate Devices:**
   K193031, DRTECH Corporation
   Trade/Device Name: EVS 4343WP, EVS 3643WP Flat Panel Detector (customer picks one of the units) (with RADINFO Software used in our main predicate K191503.)
   Regulation Number: 21 CFR 892.1680
   Regulation Name: Stationary x-ray system
   Regulatory Class: II; Product Code: MQB

5. **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 radiographic, multiradiographic and 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, and extremities. The device may be used for other imaging applications on all patients except 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. (RX Only)**

6. **Description of the Device: The Virtual C DRF system is a mobile imaging system that acquire, process and display both static radiographic images and dynamic radiographic images such as multi-rad and fluoroscopy. Dynamic image acquisition is performed without the limitation of a mechanical linkage between the x-ray source and the x-ray detector. The mechanical linkage typical in existing dynamic imaging systems is either a c-arm or u-arm that ensures the alignment of the imaging components during image acquisition. The Virtual C DRF System features a novel collimator with built-in x-ray source to detector alignment software (Machine-Vision Collimator (MVC), combine they provide the technology for a "virtual c-arm" system. The novel MVC utilized four independent shutter to automatically position the radiation beam, so the area of exposure always remains within the confines of the active area of the detector. In addition, the angle and inclination of x-ray source is displayed to the operator. A visual display provides real time video images of the patient and a shaded area within the video images represent the location and size of the radiation beam with respect to the patient. As compared to our predicate device, there are three main changes: The digital receptor panel become a DRTECH brand panel, the generator changes from Sedecal to Source-ray, and and the collimator is changed from Colimar to a PortaVision "Machine Vision" collimator. An initial report was submitted for that collimator.**

7. **Safety and Effectiveness, comparison to predicate device. This device has similar indications for use and similar technological characteristics as the predicate device, and employs already 510(k) cleared digital panels. The chief differences are: The predicate uses a different falt panel detector and mobile cart Otherwise the two systems have the same functionality and uses.**

8. **Substantial Equivalence Chart: Please see the next page.**

Characteristics	Predicate Device MobileRay Pulse SE K191503	Proposed Device Virtual C DRF Digital Imaging System
Intended Use	Intended for use by a qualified/trained medical professionals on both adult and pediatric patients for diagnostic radiographic, surgery, and interventional procedures. The device is to be used in healthcare facilities both inside and outside of hospital, in sterile as well as nonsterile environments, and 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. 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.	Intended for use by a qualified/trained medical professionals on both adult and pediatric patients for diagnostic radiographic, surgery, and interventional procedures. The device is to be used in healthcare facilities both inside and outside of hospital, in sterile as well as nonsterile environments, and 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. 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. SAME
Energy Source	110V-120V, Single 50-60 Hz	110V-120V, Single 50-60Hz
System Weight and Size	136 lbs. 35.75” x 28” x 72.5”	121 lbs. 36” x 26” x 77”
Generator Type	High frequency Inverter type	High frequency Inverter type
Maximum Output Power	4KW	80 kVp x 2 ma = 160 watts for Source Ray Generator 4w for Sedecal Generator (alternate available generator)
Fluoroscopy		
Pulse	0.5 – 10 mA	N/A
Continuous	N/A	.1 – 2 mA
Radiography		
KV range	40 – 125 KV	35 – 80 KV Source Ray Generator 40 – 125 KV if Sedecal Generator is selected.
mA range	20 – 100 mA	n/a for Source Ray .1 – 2 mA if Sedecal Generator is selected.
mAs range	0.8 – 200 mAs	n/a for Source Ray 0.8 – 200 mAs if Sedecal Generator is selected.
Pulse width	10 ms	10 ms
Pulse rate	1 – 7.5 fps	1 – 15 fps DRTECH Detectors 1 – 30 fps Vieworks Detectors
X-ray Tube	Stationary anode	Stationary anode
Indicators	Display on workstation monitor	Same as predicate

Characteristics	Predicate Device MobileRay Pulse SE K191503	Proposed Device Virtual C DRF Digital Imaging System
Collimator	Multi-leaf adjustable motorized, Collimare Touch LED 	Machine Vision motorized made by PortaVision, model MVC Accession # 2010848-000 
Digital Panel Specification	PerkinElmer XRpad2 3025 4346 as cleared in K161942, K161966	Vivix-D1212G or D1717G previously cleared in K200396 OR: DRTECH EVS 4343WP or 4336WP previously cleared K193031
Pixel Pitch	100 µ	Vivix-D1212G 145 µ or Vivix-D1717G 140 µ OR: EVS 4343WP: 140 µ or EVS 3643WP: 140 µ
Pixel Matrix	2508 X 3004	Vivix-D1212G 2048x2048 or Vivix-D1717G 3072 x 3072 OR: EVS 4343WP: 3,072 x 3,072 EVS 3643WP: 2,560 x 3,072
AD Conversion	16 bits	16 bits (SAME)
DQE	60% (1 cy/mm),	Vivix-D1212G 56 % @ 1 lp/mm Vivix-D1717G 56 % @ 1 lp/mm OR: EVS 4343WP: 50.0 % at 1 lp/mm EVS 3643WP: 52.3 % at 1 lp/mm
MTF	40% (2 cy/mm)	Vivix-D1212G 30 % @ 2 lp/mm Vivix-D1717G 30 % @ 2 lp/mm OR EVS 4343WP: 52.3 % at 2.0 lp/mm EVS 3643WP: 46.8 % at 2.0 lp/mm
Image acquisition	Amorphous Silicon Direct deposition CsI:Tl	Amorphous Silicon Direct deposition CsI:Tl
Connection	Ethernet or Wi-Fi	Same as predicate
DICOM	Yes	Same as predicate
Performance Standard	21CFR 1020.30	Same as predicate

Characteristics	Predicate Device MobileRay Pulse SE K191503	Proposed Device Virtual C DRF Digital Imaging System
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	Same as predicate
Software features, human factors, user tools, analysis tools, capabilities, etc.	As described in user manual	Same as predicate (or same as alternate configuration described in K200396)
Photo		
Alternate Proposed Configuration	 This model is called Virtulal C DRF MBS. It employs the imaging chain cleared in K200396 (unmodified)	

The following table compares The MobileRay Pulse SE software to the predicate software.

Feature	Predicate Device MobilePulse SE K191503	Proposed Device Virtual C DRF
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

9. **Summary of non-clinical testing**: Bench testing was performed to assess the device safety and effectiveness. Electrical safety and EMC testing was performed on the unit. The standards employed were: EN 60601-1-2 (2015): Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests EN 301 489-1 V2.2.0 (2017): Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements & EN 301 489-17 V3.2.0 (2017): Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems AND: IEC 60601-1: 2005 + Corr.1: 2006 + A1: 2012 EN 60601-1: 2006 + A11: 2011 + A1: 2013 + AC:2014 + A12:2014 UNE-EN 60601-1: 2008 + Erratum 2008 + Corr.: 2010 + A11: 2012 + AC:2014 + A12:2015 POSE000_14 (General procedure of Safety Lab)
EMC and Electrical Safety performance for the digital receptor panels had previously been submitted to FDA in K193031. 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. **Summary of** clinical testing: No clinical data is necessary to evaluate safety or effectiveness for purposes of determining substantial equivalence of the proposed modification. The digital panels both received previous 510(k) clearances

Conclusion: After analyzing software integration validation, safety testing data, and bench test images, it is the conclusion of PortaVision Medical LLC that the Virtual C DRF Digital Imaging System is as safe and effective as the predicate device, has insignificant technological differences, and has identical indications for use, thus rendering it substantially equivalent to the predicate device.