510(K) Summary, K212557

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1. Identification of the Device:
Trade/Device Names: Virtual C DRF-NEO 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: K211191
Trade/Device Name: Virtual C DRF 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 Device: DRTECH FLAT PANEL DETECTOR EVS 2430W
510(K) Number K171137
Regulation Number: 21 CFR 892.1650
Regulation Name: Image intensified fluoroscopic x-ray system
Regulatory Class: II Product Code: MQB

4. 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, multi-radiographic 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, extremities, and at the discretion of the medical professional the device may be used for other imaging applications on all pediatric patients (birth to 21 years) 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).

5. Description of the Device: The Virtual C DRF-NEO system is a mobile imaging system that acquire, process and display both static radiographic images and dynamic radiographic images such as photo-spot 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-NEO 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.

6. 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 flat panel detector and mobile cart. Otherwise, the two systems have the same functionality and uses.

7. Substantial Equivalence Chart:

Characteristics	**Predicate Device** **Virtual C DRF Digital Imaging System** **K211191**	**Proposed Device** **Virtual C DRF-NEO Digital Imaging System**
Intended 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, 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 (Rx Only)	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, multi-radiographic 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, extremities, and at the discretion of the medical professional the device may be used for other imaging applications on all pediatric patients (birth to 21 years) 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) Comment: The new smaller panel is better suited to smaller patients.
Energy Source	110V-120V, Single 50-60 Hz	110V-120V, Single 50-60Hz

Characteristics	Predicate Device Virtual C DRF Digital Imaging System K211191	Proposed Device Virtual C DRF-NEO Digital Imaging System
System Weight and Size	121 lbs. 36” x 26” x 77”	121 lbs. 36” x 26” x 77”
Generator Type	High frequency Inverter type	High frequency Inverter type
Maximum Output Power	80 KV x 2 mA = 160 watts	80 KV x 2 mA = 160 watts
Fluoroscopy		
Continuous	.1 – 2 mA	.1 – 2 mA
Radiography		
KV range	30 – 80 KV	30 – 80 KV
mA range	0.1 – 2 mA	0.1 – 2 mA
Pulse width	10 ms	10 ms
Pulse rate	1 – 15 fps	1 – 15 fps
X-ray Tube	Stationary anode	Stationary anode
Indicators	Display on workstation monitor	Same as predicate
Collimator	Machine Vision motorized made by PortaVision, model MVC Accession # 2010848-000 	Machine Vision motorized made by PortaVision, model MVC Accession # 2010848-000 SAME 
Digital Panel Specification	DRTECH EVS 4343WP & 4336WP previously cleared K193031	DRTECH EVS 2430W 10 x 12 DRTECH cleared K171137
Pixel Pitch	EVS 4343WP: 140 µ EVS 3643WP: 140 µ	EVS 2430W 76 µ
Resolution	EVS 4343WP: 3,072 x 3,072 EVS 3643WP: 2,560 x 3,072	EVS 2430W 2,298 x 2882
AD Conversion	16 bits	16 bits (SAME)
DQE	EVS 4343WP: 50.0 % at 1.0 lp/mm EVS 3643WP: 52.3 % at 1.0 lp/mm	EVS 2430W 45% at 1.0 lp/mm
MTF	EVS 4343WP: 52.3 % at 2.0 lp/mm EVS 3643WP: 46.8 % at 2.0 lp/mm	EVS 2430W 35% at 2.0 lp/mm
Frame Rate (Panel)	15fps (1x1, Full resolution.	20fps (1×1, Full resolution) 40fps (2×2, Full resolution)
Image acquisition	Amorphous Silicon Direct deposition CsI:Tl	Amorphous Silicon Direct deposition CsI:Tl

Characteristics	Predicate Device Virtual C DRF Digital Imaging System K211191	Proposed Device Virtual C DRF-NEO Digital Imaging System
Connection	Ethernet or Wi-Fi	Same as predicate
DICOM	Yes	Same as predicate
Energy used and/or delivered	Power Requirements described above. No energy is delivered to the patient.	Same as predicate
Performance Standard	21CFR 1020.30	Same as predicate
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
Photo		

The following table compares The Virtual C DRF-NEO software to the predicate software.

Feature	Predicate Device Virtual C DRF K211191	Proposed Device Virtual C DRF-NEO
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. **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).*

9. **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 panel received previous 510(k) clearance

10. **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-NEO 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.