Portavision Medical LLC
% Daniel Kamm
Principal Engineer
Kamm and Associates
8870 Ravello Ct
NAPLES FL 34114

June 24, 2021

Re: K211191
Trade/Device Name: Virtual C DRF 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
Dated: April 17, 2021
Received: April 21, 2021

Dear Daniel 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); 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)*
K211191

Device Name
Virtual C DRF Digital Imaging System

Indications for Use *(Describe)*
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

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary, K211191

PortaVision Medical LLC
800 Central Avenue
Jefferson, Louisiana 70121
Phone: 866-783-4133
email: info@pvmed.net
www.portavisionmedical.com
Contact: Terry Ancar, President
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.