Portavision Medical LLC
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Court
NAPLES, FL 34114

Re: K191503
Trade/Device Name: MobileRay Pulse SE 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: May 29, 2019
Received: June 6, 2019

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,

Laurel M. Burk, Ph.D.
Assistant 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)*
K191503

Device Name
MobileRay Pulse SE 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, 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. The device may be used for other imaging applications on all patients except pediatrics 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)

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, K191503

PortaVision Medical LLC
800 Central Avenue
Jefferson, Louisiana 70121
Phone: 866-783-4133
email: info@pvmed.net
www.portavisionmedical.com
Contact: Terry Ancar, Predsident
Date Prepared: August 3, 2019

1. **Identification of the Device:**
   Trade/Device Names: MobileRay Pulse SE 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**: K160279
   Trade/Device Name: AnyView 500R Fluoroscopic Mobile X-ray System
   Manufacturer: EcoTron
   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 Devices**: (Used with this device, customer picks one of the units below. They differ only in size)
   K161942
   Trade/Device Name: XRpad2 3025 HWC-M Flat Panel Detector
   Regulation Number: 21 CFR 892.1680
   Regulation Name: Stationary x-ray system
   Regulatory Class: II
   Product Code: MQB
   K161966
   Trade/Device Name: XRpad2 4336 HWC-M Flat Panel Detector
   Regulation Number: 21 CFR 892.1680
   Regulation Name: Stationary 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, 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 pediatrics 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)

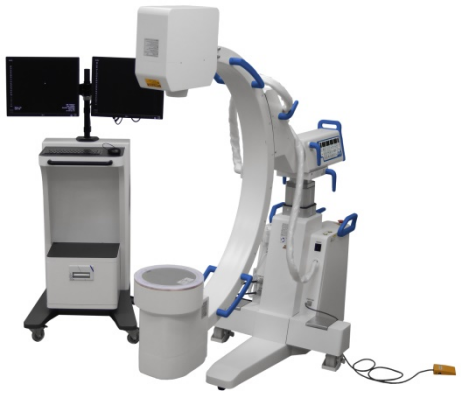
5. **Description of the** Device: The MobileRay Pulse SE system is a radiographic multi-rad, and fluoroscopic digital mobile X-Ray system that is designed for all pediatric and adult patients during diagnostic, surgery, and interventional procedures. The systems include (1) an x-ray source consisting of a X-Ray generator, X-Ray tube, and x-ray collimator, (2) a portable digital imaging system consisting of a wired and/or wireless flat panel digital detector, workstation software to acquire and process digital images in radiographic, multi-rad, and fluoroscopic modes, a laser SSD measuring system to accurately measure the distance between the X-ray tube focal spot and the patient, software which calculate radiation skin dose for KVp, mAs and SSD selected for the patient weight and body part being examined, a computer, mouse, keyboard, and image display monitor, or a laptop computer and (3) a mobile cart. The device does not incorporate a mechanically C-Arm or other mechanically device to ensure the x-ray source and flat panel detector are aligned. The device incorporates an electronic X-ray source and flat panel detector alignment system to comply with FDA regulation 21 CFR 1020.31 (g) (1). The system incorporates an automatic X-ray beam limited device to comply with FDA regulation 21 CFR 1020.32 (i) (ii). There are several advance motion sensing technologies available to accurately determine if the X-ray source is aligned to the flat panel detector. The device incorporates a radiation inhibit safety circuit to prevent the emission of radiation if the

   X-ray source is not aligned to the detector and to immediately shut down emission of radiation if for whatever reason the X-ray source is no longer aligned to the detector within the predetermine tolerance of FDA regulation 21 CFR 1020.31 (g) (1). The portable x-ray generator employed is a slightly modified version of the one cleared in K121410.

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 fixed Source to Image distance dictated by a "C-Arm," and uses image intensifier technology whereas the proposed new device uses a unique source to image receptor location technology and the image receptor is a digital panel. Otherwise the two systems have the same functionality and uses.

7. **Substantial Equivalence Chart: (Next Page)**

Characteristic	EcoTron Anyview 500R K160279	MobileRay Pulse SE Digital Imaging System
Indications for Use:	Anyview-500R mobile C arm, fluoroscopic x-ray system, is radiation medical equipment only used by professional radiologists. This product is designed to provide fluoroscopic and spot film images of the patient during diagnostic and interventional procedures. This system can be applied in emergency room, operation room, cast room or etc. of hospital	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 pediatrics 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
Energy Source	220V-230V, Single 50-60 Hz	110V-120V, Single 50-60Hz (4 kW) or 220-230V Single 50-60Hz (8 kW)
System Weight and Size	200 lbs. 35.75” x 28” x 72.5”	136 lbs. 65” x 26” x 87”
Generator Type	High frequency Inverter type	High frequency Inverter type
Output Power	5KW	4 kW (120v) or 8KW (220v)
Fluoroscopy		
Pulse	0.5 – 20 mA	0.5 – 16mA
Boost	0.5 – 30 mA	N/A
Radiography		
KV range	40 – 125 KV	40 – 125 KV
mA range	20 – 100 mA	20 – 100 mA
mAs range	0.8 – 200 mAs	0.8 – 200mAs
Pulse width	N/A	10 ms
Pulse rate	8, 15, 30	1 – 7.5 fps but see key advantage immediately below:
Weight	552 lbs (Fairly heavy)	139 lbs. Much lighter and easier to maneuver.
X-ray Tube	Rotating anode	Stationary anode

Characteristic	EcoTron Anyview 500R K160279	MobileRay Pulse SE Digital Imaging System
Indicators	Display on workstation monitor	Same as predicate
Collimator	Multi-leaf adjustable motorized	Multi-leaf adjustable motorized
Digital Panel Specification	N/A, not digital	XRpad2 3025 100 µ, 3004 x 2508 pixels XRpad2 4336 100 µ, 4288 x 3524 pixels
Pixel Pitch	N/A not digital	100 µ
Pixel Matrix	N/A not digital	3004 x 2508 or 4288 × 3524
AD Conversion	N/A not digital	16 bits
DQE	N/A	75% (@ 0 lp/mm)
MTF	N/A	70% (1 lp/mm)
Image acquisition	Image Intensifier 9/6/4.5 in E5830SD-P4A (TOSHIBA)	Amorphous Silicon Direct deposition CsI:Tl
Connection	Ethernet or Wi-Fi	Same as predicate
DICOM	Yes	Same as predicate
Electrical Safety	IEC60601-1:2005 + A1 (2012) IEC60601-1-2:2007	Same as predicate, See bench test information below.
Photo		

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

Feature	Predicate Device EcoTron Anyview K160279	Proposed Device MobileRay Pulse SE
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

Feature	Predicate Device EcoTron Anyview K160279	Proposed Device MobileRay Pulse SE
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 K161942 and in K161966. 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).* In order to be able to perform fluoroscopic exposures the x-ray generator (cleared in K121410) was modified to include cooling fans and to allow for repetitive exposures, i.e. fluoro/pulsed mode. The internal temperature rise in the generator was measured during operation and found to be acceptable.

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 panels both received previous 510(k) clearances

10. **Conclusion:** After analyzing software integration validation, safety testing data, and bench test images, it is the conclusion of PortaVision Medical LLC that the MobileRay Pulse SE 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.