

SECTION 5. 510(K) SUMMARY

K072766

**Submission
Correspondent:**

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Contact: Ian Gordon
Sr. Vice President

DEC 11 2007

Submission Sponsor:

PortaVision, LLC
5401 Cocos Plumosas Dr.
Kenner, LA 70065

Phone: (504) 883-4133
Email: tancar@angiovision.com
Contact: Terry Ancar
President

Date summary prepared:

April 10, 2007

Device trade name:

The PortaVision Medical Digital Imaging System

Device common name:

Solid State X-ray Imager (Flat Panel/Digital Imager)

Device classification name:

Electrostatic x-ray imaging system (solid-state x-ray imaging system x-ray system).
IXK at 21 CFR Part 892.1630

**Legally marketed devices
to which the device is
substantially equivalent:**

K024147
Paxscan 4030 Medical Digital Imaging Systems
Varian Medical Systems, Inc.

Description of the device:

K904519A
ADC-70
Agfa Medical Systems
The PortaVision PVMed DDR 2520 Digital Imaging System consists of two components, an amorphous silicon digital x-ray imager and software for viewing the captured images on a Windows-based computer.
The digital imager is composed of an amorphous silicon flat panel imager which uses a large-area amorphous silicon sensor array with a gadolinium oxysulfide scintillator. The PVMed DDR 2520 Digital Imaging System will display high quality images in less than 5 seconds over a wide range of X-Ray dose settings. The System is not intended to be used for mammography.

Intended use of the device:	The PortaVision PVMed DDR 2520 Digital Imaging System is intended for use in generating radiographic images of human anatomy. The system is not intended to be used for mammography. It is intended to replace film/screen or computed radiography in extremity and general-purpose procedures appropriate to the input field of view. This imager is intended for incorporation into a complete x-ray system by a qualified equipment manufacturer. This device is intended for use by qualified medical personnel and is contraindicated when, in the judgment of the physician, procedures would be contrary to the best interest of the patient
Technological characteristics:	The technological characteristics between the predicate and proposed devices are identical. There is no difference in fundamental scientific technology. The only difference is the size. The proposed device is smaller than the predicate device.
Conclusions:	<p>By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device.</p> <p>There are no significant differences between the PortaVision PVMed DDR 2520 Digital Imaging System the predicate devices and therefore, the PortaVision PVMed DDR 2520 Digital Imaging System does not raise any questions regarding safety and effectiveness.</p> <p>The PortaVision PVMed DDR 2520 Digital Imaging System, as designed, is as safe and effective as the predicate device, and the device is determined to be substantially equivalent to the referenced predicate device currently on the market.</p>



DEC 11 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

PortaVision Medical
% Mr. Daniel W. Lehtonen
Senior Staff Engineer-Medical Devices
Intertek Testing Services
2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K072766

Trade/Device Name: PortaVision PVMed DDR 2520 Digital Imaging System

Regulation Number: 21 CFR 892.1630

Regulation Name: Electrostatic x-ray imaging system

Regulatory Class: II

Product Code: IXK

Dated: November 21, 2007

Received: November 26, 2007

Dear Mr. Lehtonen:

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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number:

Device Name:

Indications for Use:

PortaVision PVMed DDR 2520 Digital Imaging System

The PortaVision PVMed DDR 2520 Digital Imaging System is intended for use in generating radiographic images of human anatomy. (The system is not intended to be use for mammography). It is intended to replace film/screen or computed radiography in extremity and general-purpose procedures appropriate to the input field of view. This imager is intended for incorporation into a complete x-ray system by a qualified equipment manufacturer. This device is intended for use by qualified medical personnel and is contraindicated when, in the judgment of the physician, procedures would be contrary to the best interest of the patient.

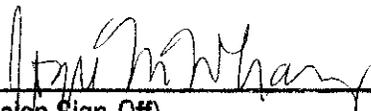
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K1092766