K083048

SECTION 5. 510(K) SUMMARY

Submission Correspondent:	PortaVision Medical, LLC Phone: 866-783-4133 Fax: 504-883-4133 Email: info@pvmed.net Contact: Terry L. Ancar President
Submission Sponsor:	PortaVision, LLC 5401 Cocos Plumosas Dr. Kenner, LA 70065 Phone: (866) 783-4133 Email: terry@pvmed.net Contact: Terry Ancar President
Date summary prepared:	October 1, 2008
Device trade name:	The NeoRay DDR 2520 Digital Imaging System
Device common name:	Mobile X-Ray System
Device classification name:	Mobile x-ray system IZL at 21 CFR Part 892.1720
Legally marketed devices to which the device is substantially equivalent:	K043062 Portable Digital X-Ray System Model SR-130-D SourceRay, Inc. K973833 NEO Mobile X-Ray System Dynarad Corp.
Description of the device:	The NeoRay DDR 2520 Digital Imaging System is a portable X-Ray system comprised of a portable digital radiographic imaging system, an X-Ray generator/collimator system, and a mobile stand.

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Intended use of the device:	The NeoRay DDR 2520 Digital Imaging System is intended for use in generating radiographic images of human anatomy. It is specifically optimized to operate within the Neonatal environment. 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:	There are no significant differences between the NeoRay DDR 2520 Digital Imaging System and the predicate devices and therefore, the NeoRay DDR 2520 Digital Imaging System does not raise any questions regarding safety and effectiveness. The NeoRay 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2008

Mr. Terry Ancar
President
PortaVision, LLC
5401 Cocos Plumosas Drive
KENNER LA 70065

Re: K083048
Trade/Device Name: NeoRay DDR 2520 Digital Imaging System
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: October 6, 2008
Received: October 14, 2008

Dear Mr. Ancar:

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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(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 Biometrics' (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,

Joyce M. Whang, Ph.D.
Acting 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: K083048

Device Name: NeoRay DDR 2520 Digital Imaging System

Indications for Use: The NeoRay DDR 2520 Digital Imaging System is intended for use in generating radiographic images of human anatomy, it is specifically optimized to operate within the Neonatal environment. This device is not intended for mammography applications. 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)

(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 K083048