JAN 22 2009

510(k) Summary
510(k) Number K083725

Virtual Imaging, Inc.
720 S. Powerline Road, Suite E
Deerfield Beach, FL 33442
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Contact: Chris Duca, Chief Operating Officer
Date Prepared: November 6, 2008

1 **Identification of the Device:**
Proprietary-Trade Name: RadPro ION Mobile Fluoroscopy Systems (Multiple Models)
Classification Name/Product Codes: Image Intensified Fluoroscopic System, JAA, Mobile X-Ray, IZL
Common/Usual Name: Mobile Fluoroscopic X-Ray System

2 **Equivalent legally marketed device** K073543 OEC 9900 Elite, GE Healthcare

3 **Indications for Use (intended use)** The RadPro ION Mobile Fluoroscopy Systems are designed to provide fluoroscopic and spot-film images of the patient during diagnostic, surgical and interventional procedures Examples of clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, critical care and emergency room procedures The system may be used for other imaging applications at the physician's discretion

4 **Description of the Device** The RadPro ION Mobile Fluoroscopy Systems (Multiple Models) are mobile x-ray units which employ image intensifier units and have various options for image display and storage The units are used to equip a radiological room of general surgery, orthopedic, traumatology and cardiology The CCD camera is characterized by high contrast and sensitivity and no persistence of image The camera head include a image rotation and image reversal system The automatic dose control, which acts either on KV and mA values, allows the user to reduce step by step the x-ray radiation to the minimum value, in accordance with the thickness and the density of the screened part All the configurations can accept connection to a digital memory, which allows to store and display in real time the image on the monitor only with a very little x-ray dose The new control panel with an alphanumerical display permits a fast and easy use by a rational and simple symbology, this console by an extension cable, could be located on the patient support to enable the c-arm control by the operator itself The system employs a Dose Area Product (DAP) meter for compliance with the US performance standard requirements

5 **Safety and Effectiveness, comparison to predicate device** The results of bench and test laboratory testing indicate that the new device is as safe and effective as the predicate devices

6. Substantial Equivalence Chart

Characteristic	K073543 OEC 9900 Elite, GE Healthcare	RadPro ION Mobile Fluoroscopy Systems
Intended Use	The OEC 9900 Elite Mobile Fluoroscopy Systems are designed to provide fluoroscopic and spot-film images of the patient during diagnostic, surgical and interventional procedures Examples of clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, critical care and emergency room procedures The system may be used for other imaging applications at the physician's discretion	SAME
Configuration	Mobile C-Arm	SAME
Performance Standard	21 CFR 1020 30	SAME
Generator	15 kW	18 kW
Power Source	120 VAC 1 phase 20 amp	SAME
Image Intensifiers	9" or 12"	9" or 13"
Electrical safety	Electrical Safety per IEC-60601 UL listed	SAME

7. Conclusion

After analyzing bench and external laboratory testing to applicable standards, as well as clinical images, it is the conclusion of Virtual Imaging, Inc that the RadPro ION Mobile Fluoroscopy Systems are as safe and effective as the predicate device, have few technological differences, and has no new indications for use, thus rendering them substantially equivalent to the predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 2009

Virtual Imaging, Inc
% Daniel Kamm, P E
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

Re K083725
Trade/Device Name RadPro ION Mobile Fluoroscopy Systems (Multiple Models)
Regulation Number 21 CFR 892 1650
Regulation Name Image-intensified fluoroscopic x-ray system
Regulatory Class II
Product Code JAA
Dated December 12, 2008
Received December 16, 2008

Dear Mr 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 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 os 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 892 xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Manufactures, 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 suppot/index html

Sincerely yours,

Janine M Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K083725

Device Name RadPro ION Mobile Fluoroscopy Systems (Multiple Models)

Indications For Use

The RadPro ION Mobile Fluoroscopy Systems are designed to provide fluoroscopic and spot-film images of the patient during diagnostic, surgical and interventional procedures Examples of clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, critical care and emergency room procedures The system may be used for other imaging applications at the physician's discretion

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083725