

**510(k) Summary**

**510(k) Number K080847**

**AUG - 6 2008**

**Almana Medical Imaging  
P.O. Box 3568 Alkhobar 31952**

**Kingdom of Saudi Arabia**

**T: +966 3 8679400**

**F: +966 3 8962421**

**Date Prepared: May 11, 2008**

**Contact: Mohammed Irfanullah Farooqui, Sales and Marketing Manager**

**1. Identification of the Device:**

**Proprietary-Trade Name:** RFVision 9.9D Image Intensified Fluoroscopic System

**Classification Name:** Image intensified fluoroscopic system, Product Code 90 JAA

**Common/Usual Name:** Fluoroscopic X-Ray

2. Equivalent legally marketed device: K061173, Device Name: Cpivision Digital Imaging System, Communications & Power Industries Canada, Inc.
3. Indications for Use (intended use) The RFVision 9.9D is a high resolution, digital imaging system designed for digital videography. It is intended to replace conventional film techniques in multipurpose or dedicated applications when general fluoroscopy, interventional fluoroscopy or angiography or cardiac imaging procedures are performed. The RFVision 9.9D allows the operator to view and enhance digital fluoroscopic images. High resolution digital spot images may be acquired at single or rapid acquisition rates. Images may be viewed and enhanced enabling the operator to bring out diagnostic details.
4. Description of the Device: RFVision 9.9 D is an advanced remote controlled 90/90 Digital RF system with floating table top for radiographic and fluoroscopy procedures. Reliable, time tested generator. High quality image intensifier and digital imaging system improves diagnostic capabilities assures filmless operations and smooth integration in digital PACS environment.
5. Safety and Effectiveness, comparison to predicate device. The results of bench, test laboratory and clinical testing indicates that the new device is as safe and effective as the predicate devices.

## 6. Substantial Equivalence Chart

Characteristic	K061173, Device Name: CPIVision Digital Imaging System, Communications & Power Industries Canada, Inc.	Almana RFVision 9.9D Image Intensified Fluoroscopic System
Intended Use:	The CPIVision is a high resolution, digital imaging system designed for digital videography. It is intended to replace conventional film techniques in multipurpose or dedicated applications when general fluoroscopy, interventional fluoroscopy or angiography or cardiac imaging procedures are performed. The CPIVision allows the operator to view and enhance digital fluoroscopic images. High resolution digital spot images may be acquired at single or rapid acquisition rates. Images may be viewed and enhanced enabling the operator to bring out diagnostic details....	SAME
Performance Standard	21 CFR 1020.30	SAME
Generator	Communications & Power Industries Canada, Inc	SAME
Electrical safety	Electrical Safety per IEC-60601. UL listed	SAME, CSA listed

## 7. Conclusion

After analyzing both bench and user testing data as well as external laboratory testing to applicable standards, it is the conclusion of Almana Medical Imaging that the RFVision Fluoroscopic 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.



**AUG - 6 2008**

Almana Medical Imaging  
% Mr. Daniel Kamm, P.E.  
Regulatory Engineer, Submission Correspondent  
Kamm & Associates  
PO Box 7007  
DEERFIELD IL 60015

Re: K080847

Trade/Device Name: RFVision 9.9D Image Intensified Fluoroscopic System  
Regulation Number: 21 CFR 892.1650  
Regulation Name: Image intensified fluoroscopic x-ray system  
Regulatory Class: II  
Product Code: JAA  
Dated: July 21, 2008  
Received: July 23, 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.

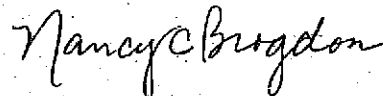
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to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

Indications for Use

510(k) Number (if known): K080847

Device Name: RFVision 9.9D Image Intensified Fluoroscopic System

Indications For Use:

The RFVision 9.9D is a high resolution, digital imaging system designed for digital videography. It is intended to replace conventional film techniques in multipurpose or dedicated applications when general fluoroscopy, interventional fluoroscopy or angiography or cardiac imaging procedures are performed.

The RFVision 9.9D allows the operator to view and enhance digital fluoroscopic images. High resolution digital spot images may be acquired at single or rapid acquisition rates. Images may be viewed and enhanced enabling the operator to bring out diagnostic details.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

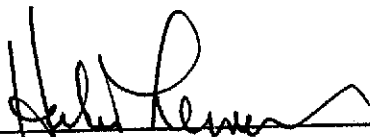
AND/OR

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal and  
Radiological Devices  
510(k) Number K080847

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