510(k) Summary
510(k) Number K080847

AUG - 6 2008

Almana Medical Imaging
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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 90WB
   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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FEB 19 2013

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: OWB and JAA
Dated: July 21, 2008
Received: July 23, 2008

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of August 6, 2008.

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
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_ 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 K080847