Communications & Power Industries
communications & medical products division

Section 5

510(k) Summary of Safety and Effectiveness

Date Prepared: October 27, 2008

Name of Contact Person: Norm Morikawa

Address: Communications & Power Industries Canada Inc.
Communications & Medical Products Division
45 River Drive, Georgetown, Ontario, L7G 2J4, Canada
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Device Trade Name: **CPI RAD VISION**

Common Name: Digital Radiography

Classification Name: Solid State x-ray Imager (flat panel/digital imager)

Device Description:

The CPI RAD VISION is a component of a complete radiographic x-ray system. The CPI RAD VISION provides a single user interface for control of the x-ray generator and all digital imaging functions required by a radiographic acquisition modality (acquisition, processing, storage, display, and distribution of images).

The CPI RAD VISION consists of Flat Panel Detector, ISO-BOX (Medical Grade Isolation Transformer), LCD Monitor, and a workstation (computer) with x-ray generator interface, image receptor interface, and network port for communications with supported DICOM devices.

Intended Use:

The CPI RAD VISION is a full featured Radiographic Flat Panel Digital Imaging System for X-ray Generator and Acquisition of digital radiography. The CPI RAD VISION is configurable to any high resolution (3K x 3K) Solid State X-Ray Imager (SSXI) presently in the market. It is intended to replace conventional film screen systems.

The CPI RAD VISION allows a qualified operator to perform digital radiographic examinations of various anatomic regions on both adult and pediatric patients. Anatomic

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regions of interest for diagnostic radiographic exposure include: skull, spinal column, chest, shoulder girdle, abdomen, pelvic girdle and extremities.

The CPI RAD VISION enables a qualified operator to acquire, process, and display images with for the benefit of obtaining an optimal diagnostic product. The CPI RAD VISION system enables the qualified operator to store, hardcopy images with a laser printer or send images over a network.

This device is not intended for mammographic, fluoroscopic and or angiographic applications. The CPI RAD VISION system will not include the X-Ray system itself.

Conclusion drawn from comparison:

The CPI RAD VISION can be considered to be substantially equivalent to:

CMT MEDICAL TECHNOLOGIES LTD.
SMART RAD 510 (k) – K003438

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2009

Mr. Norm Morikawa
QA Manager/Regulatory Affairs
Communications & Power Industries Canada, Inc.
45 River Drive
Georgetown, Ontario, L7G 2J4
CANADA

Re: K083224
Trade/Device Name: CPI RAD VISION
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: February 24, 2009
Received: February 25, 2009

Dear Mr. Morikawa:

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): Not known at this time K083224

Device Name: CPI RAD VISION

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 K083224