Acceletronics SM

K101038

AUG 17 2010

510(k) Summary

May 10, 2010, revised 7/03/10

The following submission is provided following the format of 21CFR 807.92 for the RAD II Simulator & RAD II KV Imager.

1. Submitter: ACCELETRONICS, INC.
   602 Gordon Drive
   Exton, PA. 19341 USA
   Contact: Stephen E. Haynes
   Phone: 510/867-5336
   Fax: 510/522-2635
   Email: shaynes@acceletronics.com

2. Name of the Device: RAD II Simulator & RAD II KV Imager
   Trade/Proprietary Name: RAD II Simulator & RAD II KV Imager
   Common or Usual Name: Therapy Attached Simulator/verification device
   Classification Name: System Simulator, Radiation Therapy
   21CFR 892.5840
   Class II
   Product Code: KPQ

3. Predicate Devices to claim substantial equivalence:

A) Varian Medical Systems On-Board Imager	K040192
B) Varian Medical Systems Portal Vision	K003636
C) Elekta Synergy	K032996
D) Oldelft Simulux-HP	K946128
E) Haynes Radiation Ltd., Inc. RAD II Simulator	K834281

4. Description of the device: The RAD II KV Imaging device is mounted directly to the head of a Linear Accelerator or Cobalt Therapy device. This "Therapy Attached" application has been in use as the RAD II Simulator since 1983 (510K # K834281). With the addition of an FDA approved Digital Imager and Patient Positioning Software, the RAD II KV Imager operates as an "On Board Imaging Device" for Image Guided Radiation Therapy (I.G.R.T.) Protocols.

   Substantial Equivalence = The RAD II is substantially equivalent in name to predicated devices A-E as a "Simulator" or "On Board Imager" device.

5. Intended Use Statement:
   A) The **RAD II KV Imager** device is used for verification of correct patient position in relation to the Radiation Therapy Machine Isocenter; and verification of the treatment fields in relation to anatomical and or fiducial landmarks prior to radiation therapy treatment.

   Substantial Equivalence: The **RAD II KV** Imager is substantially equivalent in usage as an "On Board Imager" when compared to the predicated devices A-C.

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B) The **RAD II Simulator** device is intended for use in developing and verifying patient treatment positioning protocols for radiation therapy treatment of cancer.

Substantial Equivalence: The **RAD II Simulator** is substantially equivalent in usage as a "Radiation Therapy Simulator" when compared to the predicated devices D&E.

6. Summary of the Technological Characteristics: The Substantial Equivalence Comparison Chart on Exhibit C-4 provides a comparison of the technological characteristics and componentry to those of the predicate devices. The RAD II Simulator and the RAD II KV Imager are detailed in this chart Exhibit C-4 showing substantial equivalence of componentry to the predicate devices listed.

A) The predicate devices use:	RAD II Simulator and KV Imager Use:
X-Ray Generator	X-Ray Generator
X-Ray Tube	X-ray Tube
Collimator & Bearing	Collimator & Bearing
Gantry	Mounted to a Gantry
Imaging Via X-ray Film	Imaging Via X-ray Film
Imaging Via Digital Imager	Imaging Via Digital Imager
Imaging Via Image intensifier	Imaging via X-ray film
Positioning Software	Positioning Software
Computer	Computer

- The **RAD II Simulator** & **RAD II KV Imager** are substantially equivalent to the predicate RAD II Simulator device in almost all of its predicate capabilities. The differences exist in the RAD II KV Imager which has no delineator, but has advanced digital imaging.

- The **RAD II Simulator** & **RAD II KV Imager** are substantially equivalent to the Oldelft Standalone Simulator in their ability to create relevant Patient positioning Images for Radiation Therapy Treatment protocols, while using the Therapy gantry they are mounted to, and the Therapy couch, which is part of the Therapy System assembly.

- The **RAD II KV Imager** is substantially equivalent to the predicate Varian On-Board Imager as a Therapy attached diagnostic device using digital imaging and Patient positioning software for required adjustments and verification for Radiation Therapy Treatment Protocols.

- The **RAD II KV Imager** is substantially equivalent to the predicate Portal Vision Devices as a Therapy attached digital imaging Device using Digital Imaging and patient positioning software for required adjustments and verification for Radiation Therapy Treatment Protocols.

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Exhibit C-4	RAD II SIMULATOR & RAD II KV Imager Substantial Equivalency Chart									
RAD II Make, Model & Operational Prd.	X-Ray Tube Model & Make	X-Ray Generator Model & Make	Tube Mount Model & Make	X-Ray Film Model & Make	Film Cassette Model & Make	Imager Model & Make	Cassette & Imager Mount Model & Make	Patient Positioning software	Imager Comp Model & Make	Application Comp. Model & Make	510K Number
HRL RAD II MODEL Phantom-HF 2003-Present	Phantom Hd., Superior by Dynarad & Del Global 50-100kVp	Phantom Generator Dynarad & Dell Global, 12.5mA fixed	Variable Design by HRL for Clinac & Cobalt	Kodak T-Mat-H	Kodak Lannex Regular & Fast	None	Variable Design by HRL for Clinac & Cobalt	None	None	None	K834281
HRL RAD II Rad Only MODEL 2001-HF 1994-1999	Rad-74, Eureka 50-125kVp	Futurus 2001 Generator by Innerscan 50-500mA	Variable Design by HRL for Clinac & Cobalt	Kodak T-Mat-H	Kodak Lannex Regular	None	Variable Design by HRL for Clinac & Cobalt	None	None	None	K834281
HRL RAD II Rad Only MODEL 2001-HF 1999-Present	Rad-74, Varian 50-125kVp	SHF-320 Generator by SEDECAL 25-300mA	Variable Design by HRL for Clinac & Cobalt	Kodak T-Mat-H	Kodak Lannex Regular	None	Variable Design by HRL for Clinac & Cobalt	None	None	None	K834281
HRL Shut Down in 2006, purchased by Acceletronics in 2007, RAD II kV Imager product developed from 2008-2009											
Single Headed RAD II kV Imager MODEL 2001-HF 2009-Present	Qty. 1 Rad-60, Varian 50-150kVp	(1) SHF-320 Generator by SEDECAL 25-300mA	Fixed or Retractable Design by Acceletronics for	None	None	QTY. 1 NAOMI Imager by RF SYSTEMS LAB	Fixed or Retractable Arm Design by Acceletronics for	Theraview Software by Cablon	Mini Computer by Cablon	DELL PC Loaded with Theraview software	K101038
Dual Headed RAD II kV Imager MODEL 2001-HF 2009-Present	Qty. 2 Rad-60, Varian 50-150kVp	(2) SHF-320 Generator by SEDECAL 25-300mA	Retractable Design by Acceletronics for Accelerators	None	None	QTY. 2 NAOMI Imager by RF SYSTEMS LAB	Retractable Arm Design by Acceletronics for Accelerators	Theraview Software by Cablon	Mini Computer by Cablon	DELL PC Loaded with Theraview software	K101038
Varian O.B.I. 2004-Present	Qty. 1 Rad-60, Varian 50-150kVp	(1) CPI Indico 100 Generator by CPI 25-300mA	Retractable Head Design by Varian mounts to	None	None	Varian 4030 Amorph Silicone Imaging Panel	Retractable Arm Design by Varian mounts to middle of	Proprietary Software	Unknown?	PC at Therapist Console Area	K040192
Elekta Synergy Imager 2003 to present	Qty. 1 Rotating Anode Tube 50-125kVp	(1) Generator make/model unknown	Retractable Head Design mounts to mid-gantry of Clinac	None	None	Amorph Silicone Imaging Panel	Retractable Arm Design by Elekta mounts to middle of	Proprietary Software	Unknown?	PC at Therapist Console Area	K032996
Varian Portal Vision 2004-Present				None	None	Varian 4030 Amorph Silicone Imaging Panel	Retractable Arm Design by Varian mounts to Ctwt. Ass.	Proprietary Software	Unknown?	PC at Therapist Console Area	K003636
Theraview				None	None	CCD Camera Imaging Panel	Theraview Ret. Arm Design mounts to Gantry Ctwt. Assy.	Proprietary Software	Unknown?	PC at Therapist Console Area	K960510
Oldelft Simulux-HP	Qty. 1 R/F Rotating Anode Tube 50-150kVp	(1) R/F X-Ray Generator 25-500mA	Standalone Gantry Simulates an Accelerator	None	None	Glass Image Intensifier - Variable sizes	Variable Imager Arm Design by Oldelft mounts to lower Gantry	Proprietary Software	Unknown?	PC at Therapist Console Area	K945128
RAD II Simulator	Qty. 1 Fixed Anode Tube 50-125kVp	(1) Generator make by Porta Ray/Dynarad	Typically fixed Adapter mounts to Head of Accelerator	None	Kodak Lannex Fast Cassettes		Variable Design by HRL for Clinac & Cobalt				K834281

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Stephen Haynes
Project Design & Engineering
Acceletronics Digital Imaging, LLC
602 Gordon Drive
EXTON PA 19341

AUG 17 2010

Re: K101038
Trade/Device Name: Rad II KV Imager & RAD II Simulator
Regulation Number: 21 CFR 892.5840
Regulation Name: Radiation therapy simulator system
Regulatory Class: II
Product Code: KPQ
Dated: July 29, 2010
Received: July 30, 2010

Dear Mr. Haynes:

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.

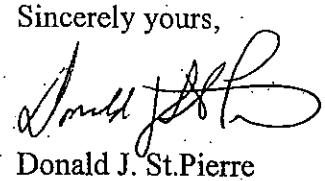
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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K101038

Indications for Use

Revised 7/03/10

510(k) Number (if known): K101038

Device Name: Rad II KV Imager & RAD II Simulator

Indications for use:

1. Both the RAD II KV Imager and RAD II Simulator are used in the field of Radiation Therapy as diagnostic imaging devices for patient positioning verification prior to radiation therapy treatments for cancer.

2. Both the RAD II KV Imager and RAD II Simulator are permanently mounted to the Therapy Head of Linear Accelerators and Cobalt Teletherapy devices.

3. The RAD II KV Imager is an "On Board Imager" intended for usage as a patient positioning verification device.

4. The RAD II KV Imager uses digital imaging to acquire its images, and positioning software to verify and/or adjust patient positioning prior to radiation therapy treatment via a Clinac as prescribed by a Radiation Oncologist.

5. The RAD II Simulator is a "Therapy Attached" Simulator intended for developing and or verifying patient treatment protocols as prescribed by Radiation Oncologist.

6. The RAD II Simulator device uses standard x-ray film to acquire its images, which are reviewed by the Therapist and or Oncologist to either verify or adjust patient positioning prior to radiation therapy treatment via a Clinac as prescribed by a Radiation Oncologist.

Prescription Use YES 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)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101038

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