K122888
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Attachment 3

APR 3 0 2013

CDR Systems

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Rocky View, AB Canada T1X 0K3
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September 11, 2012

Tab 5
Revised 01/10/13

510(k) Summary

Manufacturer's Name:	CDR Systems, Inc.
Address:	#33, 235105 Wrangler Drive S.W. Calgary, Alberta, Canada T1X OK3
Corresponding Official:	Carl Denis
Title:	CEO
Telephone:	403-850-7035
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Trade Name:	CDR Systems Precision Patient Positioning System
Common Name:	Radiation therapy patient positioning devices
Classification Name:	Accessory to Medical Linear Accelerator, 90IYE, and Accessory to Medical Charded Particle Radiation Therapy System, 90LHN, (per 21 CFR section 892.5050)
Predicates:	Bionix Development Corporation K100691: Omni V SBRT Positioning System K050701: Thigh and Foot Positioner, SuProne Plus K040773: Pelvis BellyBoard Plus Patient Positioning System, SecureFoam System, SecureFit Bar K030051: Versaboard Patient Positioning System Civco Medical Solutions K111340: MR Patient Positioning Devices

Device Description: The CDR Systems Precision Patient Positioning System consists of several options that may be purchased individually or as a complete system.

1. The CDR Systems Freedom SBRT Immobilization System is designed to provide an easy to use means to immobilize, position and reposition patients undergoing stereotactic radiation therapy. The SBRT Immobilization System is

manufactured from Vinyl skinned flexible polyurethane foam and carbon fiber/epoxy components.

1. The CDR Systems Couch Overlay and Couch Extension are manufactured from carbon fiber/epoxy over a foam core providing a rigid radio-translucent platform to immobilize and position the Head, Neck and Shoulders of a patient.

2. The CDR Systems Belly Board System has a generally rectangular contour with a firm base that provides patient support and locations for softer modules that provide additional support for a patient's pelvis and head. The indexing bars ensure secure fixation of the Belly Board to the treatment couch.

3. The CDR Systems Prone Breast Patient Positioning System is generally rectangular in shape with firm base and soft cushions with a specific location for, pelvis, head and breasts. An interchangeable left or right contra-lateral breast support provides support for the breast not requiring radiation treatment. The breast opposite to the contralateral breast is intentionally unsupported and is allowed to hang providing unobstructed treatment access.

4. The CDR Systems Prone Head and Neck Immobilization System is a headboard that attaches to a base plate that locates onto a couch tabletop, onto a Couch Overlay or Couch Extension and provides adjustable positive and negative tilt for patient's head. The Prone Head and Neck Immobilization System can be used for support of a patient's head in supine or prone position.

5. The CDR Systems InstaForm Foam is designed to provide an easy to use means to stabilize, position and reposition patients undergoing radiation therapy on a treatment couch. Shortly after the foam has completed expanding inside a plastic bag it becomes rigid, resulting in a customized mold of the patient's anatomy for accurate positioning and stabilization for subsequent patient setups requiring the same initial position.

6. The CDR Systems Vacuum Cushion is constructed from vinyl coated nylon material that is filled with small polystyrene beads to immobilize the patient. Once evacuated, the Vacuum Cushion holds a rigid shape over the course of a specific patients radiation therapy treatment.

7. The CDR Systems Indexing Bar is designed for the indexing of patient immobilization devices onto a treatment couchtop.

Intended Use: CDR Systems Precision Patient Positioning System is indicated to assist in the proper positioning of patients for radiation therapy and radiosurgery simulation and treatment including electron, photon and proton treatments.

Performance Testing – Bench (Tab 12) indicates that CDR devices attenuate a 6 MeV radiation beam by less than 3%.

Technological Characteristics: See the attached Predicate Comparison Table

Predicate Device Comparison Table

#	Feature	Predicate Device(s): Bionix Omni V SBRT Positioning System - Whole Body Stereotactic Immobilizer	Device(s): CDR Systems Freedom SBRT Immobilization System with Compression Bridge, Arms Down Module and Arms Up Module
1	Intended Use	For positioning and repositioning patients undergoing radiation therapy	For positioning and repositioning patients undergoing radiation therapy
2	Classification	Class II (K100691 – Bionix)	Class II
3	Features	Has several components designed to work together to provide an easy to use means of reproducing the position of a patient undergoing external beam Stereotactic radiation therapy. Locates onto an attachment bar for location on treatment couch. Integrated rails for attaching other components of the system including breath-suppression and fiducial arches.	Designed to be used to position and immobilize the patient's head, neck and shoulders. The immobilization system locates onto treatment couch using an indexing bar. The SBRT system has same head and neck features as the Overlay and Extension with the addition of molded-in attachment points to locate other components of the system, including a compression bridge. The system has various modules that are combined to easily setup patients for specific techniques of treatment including an arms up position, an arms down position using the Arms Up module or Arms Down Hand Positioning Module, and a contoured shape location of a vacuum cushion-type body immobilizing support. The SBRT system is designed to function with both the Knee/Leg Module and Foot positioning Module.
4	Material 1	Acrylic/PVC Carbon fiber/epoxy laminate material	Carbon fiber/epoxy laminate material with foam core
5	Material 2	Civco K111340 MR Kevlar	MR Safe – Kevlar/epoxy laminate material with foam core
6	Beam Attenuation	Low attenuation, radiolucent	Low attenuation, radiolucent

#	Feature	Predicate Device(s): Bionix Thigh Bolster and Foot Positioner (Comfort Hold™)	CDR Device(s): CDR Systems Leg/Knee positioning module, Indexable foot positioning module, wedges supports and positioning aids
1	Intended Use	For positioning and repositioning patients undergoing radiation therapy in supine or prone position	For positioning and repositioning patients undergoing radiation therapy, in supine or prone position
2	Classification	Class II (K050701 – Bionix)	Class II
3	Features	Designed to be used together as a combined thigh and foot support or alone as a foot or thigh and calve support. Also will interface with Bionix secure bar allowing it to be secured to the treatment couch.	Designed to provide support and positioning of a patient's thigh, calves, knees and feet. Each can be used alone or in combination with each other (knee and foot positioner). A variety of shapes are offered to optimize patient setup and comfort. Regardless of shape used, the purpose for use identical. Can be used free on couchtop surface or indexed using indexing bar allowing it to be indexed on treatment couch.
4	Material	ABS Plastic	MR Safe - ABS plastic, foam with vinyl cover.
5	Beam Attenuation	Minimal beam attenuation	Minimal beam attenuation

#	Feature	Predicate Device(s): Bionix VersaBoard Patient Positioning System	CDR Device(s): CDR Systems Couch Overlay, Couch Extension with Shoulder Depression and Roll adjustment couch extension adapter
1	Intended Use	For positioning and repositioning patients undergoing radiation therapy in supine and prone position	For positioning and repositioning patients undergoing radiation therapy, in supine and prone position
2	Classification	Class II (K030051 – Bionix)	Class II
3	Features	Generally torso shaped in contour with an area specifically designed for head, shoulders and back. Allows for prone as well as supine positioning of patient. Simple interlock device to locate to couch tabletop and others to locate low-melt thermoplastic to be formed into a mask that contours the patient.	Generally torso shaped in contour and designed to position patient's head, neck and shoulders and a simple fixation device for patient specific low temperature thermoplastic mask that contours the patient and simple fixation device for Shoulder Depression. Positions onto treatment couch with the extension interface at end of treatment couch provides an integrated pitch adjustment knob allowing for correction for couch sag. Provides a platform for both prone and supine patient position. Roll adapter module provides Roll axis of adjustment.
5	Material 1	Carbon fiber/epoxy laminate material with foam core	Carbon fiber laminate material with foam core and aluminum base
6	Material 2	Civco K111340 MR Kevlar	Kevlar/epoxy laminate material with foam core and aluminum base
7	Beam Attenuation	Minimal beam attenuation	Minimal beam attenuation

#	Feature	Predicate Device(s): Bionix Pelvis BellyBoard Plus Patient Positioning System	CDR Device: CDR Systems Koilia-Mikros Belly Board and Prone Breast Patient Positioning System
1	Intended Use	For positioning and repositioning of patients receiving radiation therapy.	For positioning and repositioning of patients receiving radiation therapy.
2	Classification	Class II (K040773 - Bionix)	Class II
3	Features	A generally rectangular contour with rigid base and specific location for head abdominal and leg cushions	A generally rectangular contour with firm base and soft cushions with specific location for, pelvis, head and breast, a contra-lateral breast support with through opening to allow treatment side breast to hang unobstructed.
4	Material	Thermoplastic shell with foam core base with Velcro attachable cushions for head abdomen and legs	Thermoplastic shell with foam core base / Firm cushion base with Velcro attachable cushions for head abdomen and hips and legs.
5	Beam Attenuation	Minimal beam attenuation	Minimal beam attenuation

#	Feature	Predicate Device(s): Bionix SuProne Plus	CDR Device: CDR Systems Prone Head and Neck Immobilization System
1	Intended Use	For positioning and repositioning of patients receiving radiation therapy.	For positioning and repositioning of patients receiving radiation therapy.
2	Classification	Class II (K050701 - Bionix)	Class II
3	Features	A headboard that affixes to a base plate that can be secured to a couch tabletop or VersaBoard (as shown in Bionix catalog) and provides an adjustable tilt for patient's head. Can be used for support of a patient's head in supine or prone position.	A headboard that attaches to a base plate that locates onto a couch tabletop, onto a CDR Couch Overlay or Couch Extension and provides adjustable positive and negative tilt for patient's head. Can be used for support of a patient's head in supine or prone position. A low temperature thermoplastic mask can be used for additional immobilization.
4	Material 1	Optional acrylic base, Carbon fiber/epoxy laminate material with foam core	Carbon fiber/epoxy laminate material with foam core
5	Material 2	Civco K111340 MR Kevlar	MR Safe – Kevlar/epoxy laminate material with foam core
6	Beam Attenuation	Minimal beam attenuation	Minimal beam attenuation

#	Feature	Predicate Device(s): Bionix SecureFoam	CDR Device: CDR Systems InstaForm Foam
1	Intended Use	For positioning and re-positioning of patients receiving radiation therapy.	For positioning and re-positioning of patients receiving radiation therapy.
2	Classification	Class II (K040773 -Bionix)	Class II
3	Method	Mix A part (diisocyanate) with B (polyol) to form water blown foam	Mix A part (diisocyanate) with B (polyol) to form water blown foam
4	Barrier	Plastic bag	Plastic bag or plastic Sheet
5	Common Name	2 part foaming agent	2 part foaming agent
6	Beam Attenuation	Air-equivalent radiolucency, minimal beam attenuation	Air-equivalent radiolucency, minimal beam attenuation

#	Feature	Predicate Device(s): Bionix SecureVac Immobilization System	CDR Device: CDR Systems Vacuum Cushion
1	Intended Use	Designed to be used for the positioning and repositioning of patients for receiving radiation therapy	Designed to be used for the positioning and repositioning of patients for receiving radiation therapy
2	Classification	Class II (K040773 - Bionix)	Class II
3	Method	SecureVac bags are constructed from strong, vinyl coated nylon material that is filled with small polystyrene spheres to immobilize the patient. Each bag is double sealed airtight and fitted with a self-closing valve for ease of use. It also features a pinch clamp system for more security. Once evacuated, the SecureVac cushion holds a rigid shape over the course of the radiation therapy treatment regimen	The CDR Systems Vacuum Cushion is constructed from vinyl coated nylon material that is filled with small polystyrene beads to immobilize the patient. Each bag is sealed airtight and fitted with a self-closing valve. Once evacuated, the Vacuum Cushion holds a rigid shape over the course of a specific patients radiation therapy treatment.
4	Material	Vinyl-coated nylon material that is filled with small polystyrene spheres	MR Safe - Vinyl-coated nylon material that is filled with small polystyrene spheres
5	Beam Attenuation	Air-equivalent radiolucency	Air-equivalent radiolucency

#	Feature	Predicate Device(s): Bionix SecureFit Bar	CDR Device: CDR Systems Indexing Bar
1	Intended Use	For the indexing of patient immobilization devices to treatment couchtop	For the indexing of patient immobilization devices to treatment couchtop
2	Classification	Class II (K040773 - Bionix)	Class II
3	Method	Located onto treatment couch using location pins on bottom of bar that interface with a treatment couches features designed to accept and with pins on the surface that interface with patient immobilization device such as a Belly Board	Located onto a treatment couch using location pins on the bottom of the Indexing Bar that interface with a treatment couch and also with pins on the surface that interface with patient immobilization device such as a Belly Board
4	Material 1	Aluminum or carbon fiber/epoxy laminate material	Aluminum or carbon fiber/epoxy laminate material
5	Material 2	Civco K111340 MR Kevlar	MR Safe – Kevlar/epoxy laminate material
6	Beam Attenuation		Aluminum is not intended to be in the beam while carbon fiber or Kevlar /epoxy laminate material is acceptable if required to be in the path of the beam.

The CDR Systems Precision Patient Positioning System has the same intended use and safety characteristics as the comparable predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 30, 2013

CDR Systems, Inc.
% Mr. Carl Denis
CEO
#33, 235105 Wrangler Drive S.W.
Calgary, Alberta, CANADA T1X OK3

Re: K122888
Trade/Device Name: CDR Systems Precision Patient Positioning System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: March 25, 2013
Received: April 2, 2013

Dear Mr. Denis:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122888

Device Name: CDR Systems Precision Patient Positioning System

Indications for Use:

CDR Systems Precision Patient Positioning System is indicated to assist in the proper positioning of patients for radiation therapy and radiosurgery simulation and treatment including electron, photon and proton treatments. Place a clean sheet over the device to ensure a clean device from patient to patient.

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 *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k)_____K122888_____