K141154
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510(k) Summary
for
OARtrac® System

JUL 2 2 2014

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3. Date Prepared

May 2, 2014

4. Device Identification

Trade/Proprietary Name:	OARtrac® System
Common/Usual Name:	Dose radiation verification and prostate immobilizer system
Classification Name:	Dosimeter, ionizing radiation, implanted
Classification Regulation:	892.5050
Product Code:	NZT and PCT
Device Class:	Class II
Classification Panel:	Radiology

5. Legally Marketed Predicate Device(s)

Sicel Technologies, Inc., Dose Verification System (DVS) (K083055)
RadiaDyne, LLC, Prostate Immobilizer Rectal Balloon (PIRB) (K132194)

6. Device Description

The OARtrac® System provides radiation oncologists with near real- time, in-vivo, multi-point radiation-dose information obtained from two (2) Radiatrac® Plastic Scintillating Detectors (PSD) sensors located on the anterior surface of a modified clinically accepted OARtrac® prostate Endorectal Balloon (ERB) to monitor dose photon based radiation

therapy for prostate cancer treatment. This information allows the physician to monitor the dose at the rectal prostatic interface, compare the actual dose relative to the planned dose, and provides graphs and dose information for both the current treatment as well as a log of dose from five previous treatments. The OARtrac® System also provides dose rate during actual treatment.

The function of the OARtrac® prostate ERB is to immobilize the prostate while at the same time positioning the Radiatrac® PSD sensors so that measurement of in-vivo radiation received on the anterior surface of the balloon can be monitored to verify the radiation dose to surrounding organs at risk, specifically the protatic rectal interface. The actual verification of the dose radiation is accomplished by the other main components of the OARtrac® System, those being the Clinical Detector Unit (CDU) with its Charged Coupled Device (CCD) camera and the system's own proprietary dose management software that are further addressed in the remainder of this section.

7. Indication for Use Statement

The OARtrac® System is specifically indicated for male prostate cancer treatment to measure photon beam therapy as an adjunct to treatment planning permitting measurement of in-vivo radiation dose received on the anterior surface of a modified Prostate Immobilization Endorectal Balloon (ERB) device to monitor and verify the surrounding organs at risk, specifically the protatic rectal interface.

8. Substantial Equivalence Discussion

RadiaDyne has chosen two predicate devices in the 510(k) submission for its OARtrac® System, the Sicel Dose Verification System (K083035) manufactured by Sicel Technologies and cleared under Product Code NZT and §892.5050, and its own Prostate Immobilizer Rectal Balloon (PIRB) approved by the FDA through a de novo application (K132194) under Product Code PCT and §892.5720.

The following table compares the OARtrac® System to the predicate devices with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5-1
OARtrac® System vs. Predicate Devices - Similarities and Differences

Device	Sicel Technologies	RadiaDyne	RadiaDyne	Differences
Trade Name:	Dose Verification System	Prostate Immobilizer Rectal Balloon (PIRB)	OARtrac® System	-
510(k):	K083035	K132194	Pending	-
Product Code:	NZT	PCT	NZT + PCT	The OARtrac® System's technology is based on elements of both predicate device

				product codes in that it acts as a radiation dose verification system and as a prostate immobilization device.
Regulation:	§892.5050	§892.5720	§892.5050 + §892.5720	The OARtrac® System's technology is based on elements of both predicate device regulation numbers in that it acts as a radiation dose verification system and as a prostate immobilization device.
Class:	II	II	II	-
Intended Use:	The Dose Verification System (DVS) is intended for use in radiation therapy to verify treatment planning and radiation dose to tissue and organs in or near the irradiated areas of a patient.	The RadiaDyne Prostate Immobilizer Rectal Balloon (PIRB) is intended to be used for the temporary positioning of the rectal wall and adjacent structure in the male human anatomies.	The OARtrac® System is intended for use in photon beam radiation therapy to monitor and verify radiation treatment dose to the surrounding organs at risk tissue during prostate external beam radiation treatment.	The OARtrac® System shares technical elements of the DVS and PIRB in that it functions as both a radiation does verification system and a prostate immobilizer and positioning device.
Indications for Use:	The DVS system is specifically indicated for breast and prostate cancer to measure photon beam therapy and as an adjunct to treatment planning to permit measurement of the *in vivo* radiation dose received at the tumor periphery, tumor bed and/or surrounding normal tissues for validation of the prescribed dose.	The RadiaDyne Prostate Immobilizer Rectal Balloon is a single-use disposable, inflatable, non-powered positioning device intended to be used for the temporary positioning of the rectal wall and adjacent structure in the male human anatomies. The purpose of the device is to stabilize the prostate during Computed Tomography (CT) exam, X-ray, or Radiation Therapy (RT) treatments. The placement of the balloon requires a Physician or a Physician directed healthcare professional, and is performed as a separate procedure outside of the standard CT exam and RT treatment.	The OARtrac® System is specifically indicated for male prostate cancer treatment to measure photon beam therapy as an adjunct to treatment planning permitting measurement of in-vivo radiation dose received on the anterior surface of a modified Prostate Immobilization Endorectal Balloon (ERB) device to monitor and verify the	The OARtrac® System and PIRB are indicated for the treatment of the prostate only, while the Sicel DVS is indicated for use on the breast and prostate.

			surrounding organs at risk, specifically the protatic rectal interface.	
Mode of Operation:	Metal oxide semiconductor field-effect transistor (MOSFET) is implanted in patient to allow for dose verification of their radiation treatment procedure. The dosimeter is powered telemetrically and measures radiation using two MOSFETs. The MOSFETs are hermetically sealed in a biocompatible glass capsule.	Polyurethane balloon is designed as an immobilizer to assist in positioning the prostate during CT exams, and during radiation treatment therapy procedures.	Plastic scintillation detectors (PSD) have been imbedded in the center of the previously cleared RadiaDyne PIRB device to allow for dose verification of the patient's radiation treatment procedures.	The OARtrac® System's dose verification technology is based on fiber optics and PSD sensor technology, while the DVS device uses MOSFET technology to achieve its dose verification function.
Material:	Glass capsule	Polyurethane	Polyurethane	Same as above.
Implantable:	Yes, 3-12 cm maximum depth from any skin surface.	No	No	The OARtrac® System's ERB component is not implanted in the body while the DVS's MOSFET dosimeter is.
Body Location:	Implanted under skin in the target area.	Placed in rectum	Placed in rectum	The OARtrac® System's ERB and PIRB are indicated for placement in the rectum while the DVS's MOSFET dosimeter is indicate for placement under the skin.
Target Area:	Breast and Prostate	Prostate	Prostate	The OARtrac® System and PIRB are indicated for treatment of the prostate while the DVS is indicated for treatment of the prostate and breast.
Fiducial Marker:	Yes	Yes	Yes	All three devices have a fiducial marker that is used as an aid for device position and location in the patient.
Sterile:	EtO	No	No	The OARtrac® System's ERB component and PIRB are provided non-sterile and not

				intended to be sterilized, while the DVS's implantable MOSFET dosimeter is provided EtO sterilized.
Single Use:	Yes	Yes	Yes	All three devices are for single use.
Hard Wired:	No, powered telemetrically.	NA	Yes, fiber optic cable.	The OARtrac® System's ERB component is hard wired to the robust cable that is wired to the clinical detector unit, while the DVS employs no hard wiring and operates telemetrically.
Pre-Calibrated:	Yes (Cobalt-60)	NA	Yes (Cobalt-60)	Both the OARtrac® System and DVS are pre-calibrated using Cobalt-60.
System Software:	Yes	NA	Yes	Both the OARtrac® System and DVS run on their own custom software platforms.
Energy Range:	6-18 MV Photon Dose	NA	1-20 MV Photon Dose	Both the OARtrac® System and DVS have the ability to measure the energy range of the radiation photon dose administered to the patient, but use different technologies to accomplish this. PSD fibers measure light output in the OARtrac® System, while the DVS uses MOSFET technology.
Dose Range:	80 Gy maximum	NA	90 Gy maximum	The capability of the OARtrac® System to measure a dose range to the patient 10 Gy higher than the DVS is purely a function of the higher cumulative dose regimes used in current prostate radiation treatment plans compared to when the predicate device was cleared in 2008, and was specified by

				RadiaDyne in the design and development of their device.
Dose Per Fraction:	150-250 cGY	NA	1-2000 cGy At dose rates of 1 cGy/s and above	Both the OARtrac® System and DVS have the ability to measure the radiation dose per fraction administered to the patient, but use different technologies (PSD fibers vs. MOSFET technology) to accomplish this, which accounts for the differences in the range of the values shown.
Time to Read Dosimeter:	Up to 10 minutes following radiation therapy. Optimal read time is 2 to 3 minutes following irradiation.	NA	20 seconds	Both the OARtrac® System and DVS have the ability to read and store the radiation dose administered to the patient, but use different technologies (PSD fibers vs. MOSFET technology) to accomplish this which accounts for the differences in the range of the values shown. Since the OARtrac® System uses PSD fibers that are hardwired to the CDU and its camera, readings are updating every 20 seconds during the treatment. This compares to the DVS where the radiation exposure time values are first stored in the implanted dosimeter. Once the radiation is delivered to the patient, the dose information can then be retrieved with the aid of the hand-held reader

				wand.
Dose Accuracy:	<5.5% (2σ) up to 20 Gy <6.5% (2σ) up to 74 Gy* Dosimeter axis is placed roughly parallel to the body axis. Actual lot accuracy is specified in the Lot Calibration Certificate. *Accuracy decreases slightly above 74 Gy.	NA	+- 6% at 95% confidence interval	The radiation dose accuracy for the OARtrac® System was obtained using controlled phantom data, and is similar to accuracy reported for the DVS.

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the OARtrac® System and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, RadiaDyne completed a number of tests. The OARtrac® System meets all the requirements for overall design, sterilization, biocompatibility, package shelf-life, electrical safety and EMC, which confirms that the output meets the design inputs and specifications for the device.

The OARtrac® System passed all the testing in accordance with national and international standards shown below to support substantial equivalence of the subject device to the predicates for which substantial equivalence is being claimed.

- Biocompatibility Testing per ISO 10993-1 (Parts 5, 10 and 11)
- Electrical Safety per IEC 60601-1
- EMC per IEC 60601-1-2
- Software Verifications and Validation per IEC 62304
- Bioburden per ISO 11137-1
- Package Shelf-Life per ASTM F1090-07
- Device Risk Analysis per ISO 14971
- Dose Range Verification Testing
- Ship Testing Calibration Testing
- Balloon Leak Test
- Balloon Tensile Strength Test
- Balloon Burst Strength Test
- Balloon Stopper Resistance Test

10. Clinical Performance Data

There was no human clinical testing required to support the OARtrac® System as the indications for use is equivalent to the predicate devices. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the OARtrac® System.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared device, or has the same intended use and different technological characteristics, but it can be demonstrated that the new device is substantially equivalent to the predicate device, and that the new device does not raise any questions regarding its safety and effectiveness when compared to the predicate device.

The OARtrac® System functions as both a radiation does verification system and as a prostate immobilizer and positioning device in one complete system, whereas the predicate devices would have to be used in combination to have the same intended use on a male subject. In addition, the OARtrac® System's ERB component is not implanted, thus reducing the risk of complications such as infection, implant migration, implant placement, and adverse reactions to implants by the patient, etc.

Therefore, based on the substantial equivalence analysis described above, the OARtrac® System, as designed, developed and manufactured for RadiaDyne, is determined to be substantially equivalent to the Dose Verification System (K083035) manufactured by Sicel Technologies, and to the Prostate Immobilizer Rectal Balloon (K132194) designed, developed and manufactured for RadiaDyne.

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

July 22, 2014

RadiaDyne, LLC
% Mr. Stuart Goldman
Senior Consultant
Emergo Group
816 Congress Avenue, Suite 1400
AUSTIN TX 78701

Re: K141154
Trade/Device Name: OARtrac® System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: NZT and PCT
Dated: May 2, 2014
Received: May 5, 2014

Dear Mr. Goldman:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
Not Assigned K141154

Device Name
OARtrac® System

Indications for Use *(Describe)*
The OARtrac® System is specifically indicated for male prostate cancer treatment to measure photon beam therapy as an adjunct to treatment planning permitting measurement of in-vivo radiation dose received on the anterior surface of a modified Prostate Immobilization Endorectal Balloon (ERB) device to monitor and verify the surrounding organs at risk, specifically the protatic rectal interface.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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