



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

June 16, 2015

Re: K150719
Trade/Device Name: OARtrac[®] System with Skin Sensors
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged Particle Radiation Therapy System
Regulatory Class: II
Product Code: NZT
Dated: March 18, 2015
Received: March 19, 2015

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” (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 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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned over a faint, large watermark of the FDA logo.

For

Robert Ochs, Ph.D.
Acting 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)

K150719

Device Name

OARtrac® System with Skin Sensors

Indications for Use (Describe)

The OARtrac® System pre-calibrated skin sensors are specifically indicated for use during cancer treatments to measure photon beam therapy as an adjunct to treatment planning permitting measurement of radiation dose received on the surface of the skin. OARtrac® System pre-calibrated skin sensors are indicated for use when adhered to the surface of the skin using medical grade adhesive and with a medical grade bolus buildup placed directly on top of the sensor.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
for
OARtrac® System with Skin Sensors

1. Submission Sponsor

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Contact: John Isham, President & CEO

2. Submission Correspondent

Emergo Group
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Austin, TX 78701, USA
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Contact: Stuart R. Goldman, Senior Consultant, RA/QA
Email: project.management@emergogroup.com

3. Date Prepared

March 18, 2015

4. Device Identification

Trade/Proprietary Name: OARtrac® System with Skin Sensors
Common/Usual Name: Dose radiation verification
Classification Name: dosimeter, ionizing radiation, implanted
Classification Regulation: 892.5050
Product Code: NZT
Device Class: Class II
Classification Panel: Radiology

5. Legally Marketed Predicate Device

RadiaDyne, LLC
OARtrac® System (K141154)

6. Device Description

The OARtrac® System with Skin Sensors provides Radiation Oncologists with near real-time, multi-point radiation-dose information obtained from two (2) Radiatrac® Plastic Scintillating Detectors (PSD) located on the surface of the patient's skin to monitor dose photon based radiation therapy for cancer treatment. This information allows the physician to monitor the dose at the skin surface, compare the actual dose relative to the planned dose, and provides

graphs and dose information for the current treatment as well as a log of the dose from five previous treatments. 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.

7. Indication for Use Statement

The OARtrac® System pre-calibrated skin sensors are specifically indicated for use during cancer treatments to measure photon beam therapy as an adjunct to treatment planning permitting measurement of radiation dose received on the surface of the skin. OARtrac® System pre-calibrated skin sensors are indicated for use when adhered to the surface of the skin using medical grade adhesive and with a medical grade bolus buildup placed directly on top of the sensor.

8. Substantial Equivalence Discussion

RadiaDyne has chosen its own OARtrac® System as the predicate device which was previously cleared under K141154, and 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 at the protatic rectal interface. The following table compares the OARtrac® System with Skin Sensors to the original OARtrac® System with respect to intended use, indications for use, and performance testing between the subject and predicate device, thus demonstrating the basis for determination of substantial equivalence between the two devices.

Table 1 - OARtrac® System with Skin Sensors vs. OARtrac® System

Device	RadiaDyne		Similarities/Differences
Trade Name:	OARtrac® System with Skin Sensors	OARtrac® System	-
510(k):	Pending	K141154	-
Product Code:	NZT	NZT + PCT	The OARtrac® System with Skin Sensors is based on the same technology of the original OARtrac® System.
Regulation:	§892.5050	§892.5050 §892.5720	The subject and predicate device act as a radiation dose verification system.
Class:	II	II	Same
Intended Use:	The OARtrac® System with Skin Sensors is intended for use in photon beam radiation therapy to monitor and verify radiation treatment dose at the entrance to the skin.	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, specifically the protatic	The subject and predicate device act as a radiation dose verification system.

		rectal interface, during prostate external beam radiation treatment.	
Indications for Use:	The OARtrac® System pre-calibrated skin sensors are specifically indicated for use during cancer treatments to measure photon beam therapy as an adjunct to treatment planning permitting measurement of radiation dose received on the surface of the skin. OARtrac® System pre-calibrated skin sensors are indicated for use when adhered to the surface of the skin using medical grade adhesive and with a medical grade bolus buildup placed directly on top of the sensor.	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 Endorectal Balloon (ERB) device to monitor and verify the surrounding organs at risk, specifically the prostatic rectal interface.	The OARtrac® System with Skin Sensors is indicated for placement on the surface of the skin, while the OARtrac® System is specifically indicated for placement near the prostate.
Material:	Plastic scintillation detectors (PSD) are made from polyurethane.	Plastic scintillation detectors (PSD) are made from polyurethane.	Same
Implantable:	No	No	Same
Body Location:	Skin contacting	Placed in rectum	The OARtrac® System with Skin Sensors makes skin contact, while the OARtrac® System makes contact with the prostatic rectal interface.
Sterile:	No	No	Same
Single Use:	Yes	Yes	Same
Biocompatibility Testing per ISO 10993-1	Yes	Yes	Same
Electrical Safety Testing per IEC 60601-1	Yes	Yes	Same
EMC Testing per IEC 60601-1-2	Yes	Yes	Same

9. Non-Clinical Performance Data

As part of demonstrating the safety and effectiveness of the OARtrac® System with Skin Sensors and in showing substantial equivalence to the predicate device that is the subject of this 510(k) submission, RadiDyne completed a number of tests. The OARtrac® System with Skin Sensors meets all the requirements for overall design, 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 with Skin Sensors passed all the testing in accordance with national and international standards shown below to support substantial equivalence of the subject device to the predicate device 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
- Package Shelf-Life per ASTM F1980-07
- Device Risk Analysis per ISO 14971
- Dose Range Verification Testing
- Ship Testing Calibration

10. Clinical Performance Data

There was no human clinical testing required to support the OARtrac® System with Skin Sensors as the original OARtrac® System was not subjected to any human clinical studies. The non-clinical testing detailed in this submission supports the substantial equivalence of the OARtrac® System with Skin Sensors to the predicate device. The purpose of this testing was to verify that the OARtrac® System skin sensors with Radiatrac® PSD detectors provide results that are acceptable to current clinical standards when simulating treatments from a standard LINAC machine and the Accuray CyberKnife system. RadiaDyne showed that using the Radiatrac® PSD to take measurements at the surface of the skin is accurate to that within the established accuracy of the original OARtrac® System cleared under K141154.

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 with Skin Sensors functions as a radiation dose verification system when the patient receives their radiation treatment to the targeted area of their body applied at the surface of their skin. Therefore, based on the substantial equivalence analysis described above, the OARtrac® System with Skin Sensors, as designed, developed and manufactured for RadiaDyne, is determined to be substantially equivalent to the company's original OARtrac® System (K141154).