DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 1, 2017

RadiaDyne, LLC
% Mr. Stuart Goldman
Senior Consultant
Emergo Group
2500 Bee Cave Road, Bldg. 1, Suite 300
AUSTIN TX 78746

Re: K162954
Trade/Device Name: OARtrac® System with Patient Specific Reusable PSD Sensors
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: NZT
Dated: May 3, 2017
Received: May 8, 2017

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,

For

Robert Ochs, Ph.D.
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)*
K162954

Device Name
OARtrac® System with Patient Specific Reusable PSD Sensors

Indications for Use *(Describe)*
The OARtrac® System with patient specific, reusable, pre-calibrated PSD sensors are intended for use during cancer treatments to measure photon radiation therapy as an adjunct to treatment planning permitting measurement and validation of radiation dose received by the patient to the targeted area of their body, and indicated for use when adhered to the skin with a bolus, or inserted into the rectum to measure the rectal prostatic interface via a specifically designed endorectal balloon device.

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.

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Section 5 – 510(k) Summary

OARtrac® System with Patient Specific Reusable PSD Sensors

K162954

1. Submission Sponsor

RadiaDyne, LLC

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USA

Phone number: (281) 759-9600

Contact: John Isham

Title: President & CEO

2. Submission Correspondent

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Austin, TX 78746

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Contact: Stuart R. Goldman, Senior Consultant, RA

Email: project.management@emergogroup.com

3. Date Prepared

May 29, 2017

4. Device Identification

Trade/Proprietary Name: OARtrac® System with Patient Specific Reusable PSD Sensors

Common/Usual Name: Radiation Dose Verification System

Classification Name: Medical charged-particle radiation therapy system

Regulation Number: 892.5050

Product Code: NZT (dosimeter, ionizing radiation, implanted)

Device Class: Class II

Classification Panel: Radiology

5. Legally Marketed Predicate Devices

OARtrac® System with Skin Sensors (K150719)

OARtrac® System (K141154)

6. Device Description

The *OARtrac® System* with patient specific, reusable, pre-calibrated PSD sensors is intended for use in photon radiation therapy to monitor and validate radiation dose during External Beam Therapy and HDR Brachytherapy to the surface of the skin or the rectal prostatic interface. This dose verification information obtained during the treatment is then used to compare with the planned dose that the Radiation Oncologists expect to provide to their patient. The OARtrac® System itself does not stop the radiation treatment to the patient, or change the radiation delivery, but only provides dose data which a trained Radiation Oncologist can decipher and use to adjust a patient's treatment plan accordingly.

7. Indication for Use Statement

The *OARtrac® System* with patient specific, reusable, pre-calibrated PSD sensors are intended for use during cancer treatments to measure photon radiation therapy as an adjunct to treatment planning permitting measurement and validation of radiation dose received by the patient to the targeted area of their body, and indicated for use when adhered to the skin with a bolus, or inserted into the rectum to measure the rectal prostatic interface via a specifically designed endorectal balloon device.

8. Substantial Equivalence Discussion

RadiaDyne has chosen its *OARtrac® System* (K141154) that was cleared for use at the prostatic rectal interface, and their *OARtrac® System with Skin Sensors* (K150719) that was cleared for use on the surface of the patient's skin as the predicate devices for its *OARtrac® System with Patient Specific Reusable PSD Sensors* that is the subject of this 510(k) submission. The following table compares the subject device against the two referenced predicate devices with respect to intended use, indications for use, technology and performance testing between them, thus demonstrating the basis for determination of substantial equivalence between these three devices.

Table 5-1 – Comparison of Characteristics

Device	RadiaDyne			Similarities/Differences
Trade Name:	OARtrac® System with Patient Specific Reusable PSD Sensors	OARtrac® System with Skin Sensors	OARtrac® System	-
510(k):	Pending	K150719	K141154	-
Product Code:	NZT	NZT	NZT PCT	Same
Regulation:	§892.5050	§892.5050	§892.5050 §892.5720	Same
Class:	II	II	II	Same
Intended Use:	The *OARtrac® System* with patient specific, reusable, pre-calibrated PSD sensors is intended for use in photon radiation therapy to monitor and validate radiation dose during External Beam Therapy and HDR Brachytherapy to the surface of the skin or the rectal prostatic interface.	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 prostatic rectal interface, during prostate external beam radiation treatment.	The subject and predicate devices act as a radiation dose verification system, to the prostatic rectal interface, and the skin of the patient, that have been exposed to radiation treatment.
Indications for Use:	The *OARtrac® System* with patient specific, reusable, pre-calibrated PSD sensors are intended for use during cancer treatments to measure photon radiation therapy as an adjunct to treatment planning permitting measurement and validation of radiation dose received by the patient to the targeted area of their body, and indicated for use when adhered to the skin with a bolus, or inserted into	The OARtrac® System pre-calibrated skin sensors are specifically indicated for use during cancer treatments to measure	The OARtrac® System is specifically indicated for male prostate cancer treatment to measure	The subject device has expanded indications where the OARtrac® System PSD sensors are now reusable up to five times in total on the same patient.

	the rectum to measure the rectal prostatic interface via a specifically designed endorectal balloon device.	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.	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.	
Material:	Plastic scintillation detectors (PSD) are made from polyurethane.	Plastic scintillation detectors (PSD) are made from polyurethane.	Plastic scintillation detectors (PSD) are made from polyurethane.	Same
Implantable:	No	No	No	Same
Body Location:	Prostatic rectal interface and the skin of the patient.	Skin contacting.	Placed in rectum; inserted inside prostate Endorectal balloon.	Same
Sterile:	No	No	No	Same
Single Use:	No	Yes	Yes	The PSD sensors used with the subject device can be reused up to five

				times.
PSD Sensors Cleaned and Disinfected	Yes	No	No	The PSD sensors used with the subject device have been validated (cleaning and disinfecting) for up to five times.
Key Performance Specifications/ Characteristics of the Device	<table><tr><th></th><th>Photon Energy Based Therapies</th></tr><tr><td>Energy Range</td><td>.37-18 MeV</td></tr><tr><td>Dose Rate Range</td><td>1.3-17.3 cGy/s</td></tr><tr><td>Dose Range</td><td>27-1200 cGy</td></tr><tr><td>Dose Accuracy</td><td>+/- 6% , 2σ</td></tr></table>	Same	Same	Same
Biocompatibility Testing per ISO 10993-1	Yes	Yes	Yes	Same
Electrical Safety Testing per IEC 60601-1	Yes	Yes	Yes	Same
EMC Testing per IEC 60601-1-2	Yes	Yes	Yes	Same

9. Non-Clinical Performance Data

As part of demonstrating the safety and effectiveness of the *OARtrac® System with Patient Specific Reusable PSD Sensors* and in showing substantial equivalence to the predicate devices that are the subject of this 510(k) submission, RadiaDyne completed a number of tests. The subject device meets all the requirements for overall design, biocompatibility, package shelf-life, electrical safety, EMC, cleaning and disinfection, which confirms that the output meets the design inputs and specifications for the device, and 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
- Cleaning validation to demonstrate reusability per AAMI 12 and 30
- Disinfection validation to demonstrate reusability per AAMI 12 and 30

10. Clinical Performance Data

There was no human clinical testing required to support the *OARtrac® System with Patient Specific Reusable PSD Sensors* as the original OARtrac® System predicate devices cleared under K141154 and K150719 were not subjected to any human clinical studies. The purpose of the testing presented in this 510(k) submission by RadiaDyne was to demonstrate that its PSD sensors can be effectively cleaned and disinfected so that they can be used up to five times on the same patient. The non-clinical testing detailed in this submission supports the substantial equivalence of the subject device to the predicate devices.

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 predicate device. Or the device has the same intended use and different technological characteristics, and that can be demonstrated that the subject device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device. The *OARtrac® System with Patient Specific Reusable PSD Sensors*, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices, the *OARtrac® System* (K141154), and the *OARtrac® System with Skin Sensors* (K150719).