RadiaDyne, LLC
% Ms. Carmelina Allis
Attorney
The Allis Law Firm, PLLC
2437 Bay Area Blvd., #30
HOUSTON TX 77058

March 22, 2019

Re: K182395
Trade/Device Name: OARtrac® System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: NZT
Dated: February 21, 2019
Received: February 25, 2019

Dear Ms. Allis:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia Mills, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182395

Device Name
OARtrac® System

Indications for Use *(Describe)*
The OARtrac® System with patient specific, reusable up to five times, pre-calibrated PSD sensors are intended for use during cancer treatments to measure photon and electron 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. The system is indicated for use with electron energy when adhered to the skin with or without a bolus, and for photon energy when adhered to the skin with a minimum 3mm bolus or inserted into the rectum for measurements at the rectal wall during cancer treatment via a specifically designed OARtrac® 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.

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

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510(k) Summary of Safety and Effectiveness

OARtrac® System K182395

1. **Submission Sponsor**

RadiaDyne, LLC
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Phone: 281.759.9600
Fax: 281.759.9609
Contact: John Isham, Founder & CEO

2. **Submission Correspondent**

Carmelina G. Allis
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2437 Bay Area Blvd., #30
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Phone: 281-819-0216
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3. **Date Prepared**

August 22, 2018

4. **Device Identification**

Trade/Proprietary Name:	OARtrac® System
Common/Usual Name:	Radiation dose verification system
Regulation Name:	Medical charged-particle radiation therapy system
Regulation Number:	21 C.F.R. § 892.5050
Product Code:	NZT
Regulatory Class:	II
Classification Panel:	Radiology

5. **Legally Marketed Predicate Device(s)**

Radiadyne OARtrac® System with Patient Specific Reusable PSD Sensors, K162954

6. **Device Description**

The OARtrac® System with patient specific, reusable up to five times, pre-calibrated PSD sensors is intended for use in photon and electron radiation therapy to monitor and validate radiation dose during External Beam Therapy and HDR Brachytherapy to the surface of the skin or the rectal wall. 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 the 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 up to five times, pre-calibrated PSD sensors are intended for use during cancer treatments to measure photon and electron 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. The system is indicated for use with electron energy when adhered to the skin with or without a bolus, and for photon energy when adhered to the skin with a minimum 3mm bolus or inserted into the rectum for measurements at the rectal wall during cancer treatment via a specifically designed OARtrac® endorectal balloon device.

8. Substantial Equivalence Discussion

RadiaDyne has chosen its own OARtrac® System with Patient Specific Reusable PSD Sensors (K162954), cleared under Product Code NZT and 21 C.F.R. § 892.5050 as the predicate device for its OARtrac® System.

The following table compares the OARtrac® System to the predicate device. As shown below, the subject device is substantially equivalent to the predicate device with respect to intended use, technological characteristics and principles of operation.

Table 1

Device Trade Names:	**OARtrac® System**	**OARtrac® System with Patient Specific Reusable PSD Sensors**
510(k):	Pending	K162954
Product Code:	NZT	NZT
Regulation:	§892.5050	§892.5050
Class:	II	II
Indications for Use:	The OARtrac® System with patient specific, reusable up to five times, pre-calibrated PSD sensors are intended for use during cancer treatments to measure photon and electron 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. The system is indicated for use with electron energy when adhered to the skin with or without a bolus, and for photon energy when	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

	adhered to the skin with a minimum 3mm bolus or inserted into the rectum for measurements at the rectal wall during cancer treatment via a specifically designed OARtrac® endorectal balloon device.	prostatic interface via a specifically designed endorectal balloon device.
Mode of Operation:	Plastic scintillation detectors (PSD) allow for dose verification of the patient's radiation treatment procedures at the point of location.	Plastic scintillation detectors (PSD) allow for dose verification of the patient's radiation treatment procedures at the point of location.
PSD Sensors:	Simplex 0.5mm PSD Simplex 1mm PSD	Simplex Sensor Cable Duplex Unbundled Sensors Duplex Bundled Sensors
Material:	PSD sensors are made from polystyrene	PSD sensors are made from polystyrene
Scintillating Fiber:	1, 1	1, 2, 2
Fiducial Marker:	1, 1	1, 2, 1
Implantable:	No	No
Body Location:	The surface of the skin or inside of a Radiadyne OARtrac rectal balloon.	The surface of the skin or inside of a Radiadyne OARtrac rectal balloon.
Sterile:	No	No
Single Use:	No, reusable up to five times	No, reusable up to five times
Hard Wired:	Yes, fiber optic cable	Yes, fiber optic cable
Pre-Calibrated:	Yes (Linac)	Yes (Cobalt-60)
System Software:	Yes	Yes
Energy Range:	6-18 MV Photon Dose 12 MeV Electron Dose	1-20 MV Photon Dose
Dose Range:	2 cGy – 1 kGy (Assumes minimum dose rate of 2 cGy/s)	90 Gy maximum
Dose Per Fraction:	200 Gy/use (up to 5 uses) 1 kGy (single use) (Assumes minimum dose rate of 2 cGy/s)	1-2000 cGy @ dose rates of 1 cGy/s and above
Time to Read Dosimeter:	1 millisecond	20 seconds
Dose Accuracy:	Photon and Electron based therapies: ±5% (2 sigma) HDR based therapies: ±6 (2 sigma)	±6% @95% confidence interval.

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the OARtrac® System and in showing substantial equivalence to the predicate device, RadiaDyne completed several tests. Like the predicate device, the OARtrac® System meets all the

requirements for overall design, sterilization, biocompatibility, packaging, shelf-life, electrical safety and EMC, which confirms that the output meets the design inputs and specifications for the device. The proposed device was subjected to the same test protocols and standard validation studies as the predicate device, which were previously accepted by FDA under K162954.

The OARtrac® System meets criteria under the same national and international test standards as the predicate device. Performance data submitted in support of the OARtrac® System demonstrate that the device is substantially equivalent to the predicate device in performance and fundamental technology and is as safe and effective as the predicate device.

- 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
- Cleaning and disinfection per AAMI TIR 12 and AAMI TIR 30
- Package Shelf-Life per ASTM F1090-07
- Device Risk Analysis per ISO 14971
- Dose Range Verification Testing
- Electron-based Radiation Testing
- Endorectal Balloon Verification Testing

10. Clinical and Animal Performance Data – Not Conducted

The OARtrac System does not introduce new intended uses, modes, features, or technologies relative to the predicate device that would require evaluation through clinical or animal testing. These types of devices, including the predicate device, have been on the market for many years with proven safety and effectiveness for their intended use. The non-clinical testing detailed in this submission is sufficient to demonstrate that the OARtrac® System is as safe and effective as the predicate device in support of a substantial equivalence determination.

11. Statement of Substantial Equivalence

In conclusion, the tests conducted, as well as all verification and validation activities, demonstrate that the design specifications and technological characteristics of the OARtrac® System meet applicable requirements and standards for the safety and effectiveness of the device for its intended use. The intended use and fundamental technology are the same between the subject and predicate devices. There are some differences in the indications for use and technological characteristics between the predicate and subject devices, but those differences allow for the subject device to have additional use capabilities during electron-based radiation treatments. The testing and validation activities conducted demonstrate that any differences between the devices do not raise new or different questions of safety or effectiveness as compared to the predicate device. Therefore, the OARtrac® System is substantially equivalent to the predicate device.