



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

Accuray Incorporated
% Ms. Erin Daly
Senior Regulatory Affairs Associate
1209 Deming Way
MADISON WI 53717

March 12, 2016

Re: K152488

Trade/Device Name: Onrad™ Treatment System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: September 1, 2015
Received: September 4, 2015

Dear Ms. Daly:

This letter corrects our substantially equivalent letter of September 28, 2015.

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 black ink that reads "Robert Ochs". The signature is written in a cursive, slightly slanted style.

Robert Ochs, Ph.D.
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)

K152488

Device Name

Onrad™ Treatment System

Indications for Use (Describe)

The Onrad™ Treatment System is intended to be used as an integrated system for the planning and precise delivery of radiation therapy, stereotactic radiotherapy, or stereotactic radiosurgery to tumors or other targeted tissues while minimizing the delivery of radiation to vital healthy tissue. The megavoltage x-ray radiation is delivered in a non-rotational, modulated (IMRT), or non-modulated (non-IMRT/three dimensional conformal) format in accordance with the physician approved plan.

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

Applicant:

Accuray Incorporated
1240 Deming Way
Madison, WI 53717-1954
Phone: 608.824.2800
Fax: 608.824.2981

Contact: Erin E. Daly
Date Prepared: August 15, 2015

Device Identification:

Device Name: Onrad™ Treatment System
Trade & Brand Names: Onrad™ Treatment System
Common Name: Radiation Therapy System
Classification: System, Planning, Radiation Therapy Treatment
Product Code: MUJ
Regulation Number: 21 CFR 892.5050
Regulation Description: Medical charged particle radiation therapy system

Predicate Device:

TomoTherapy Treatment System (K121934)

Description:

The Onrad™ Treatment System is a radiation therapy system that integrates planning, dose calculation, megavoltage CT imaging for IGRT functionality, and fixed beam (non-rotational) radiation therapy treatment capabilities into a single comprehensive system.

The Onrad™ Treatment System is a prescription device. It delivers radiation in accordance with a physician approved plan. The device does not diagnose disease, recommend treatment regimens, or quantify treatment effectiveness. The megavoltage CT imaging functionality is not intended for diagnostic use.

Intended Use:

The Onrad™ Treatment System is intended to be used as an integrated system for the planning and precise delivery of radiation therapy, stereotactic radiotherapy, or stereotactic radiosurgery to tumors or other targeted tissues while minimizing the delivery of radiation to vital healthy tissue. The megavoltage x-ray radiation is delivered in a non-rotational, modulated (IMRT), or non-modulated (non-IMRT/three dimensional conformal) format in accordance with the physician approved plan.

Technological Characteristics:

The technological characteristics of the Onrad™ Treatment System are substantially equivalent to the predicate. The physical properties of the device are cosmetic ONLY and do not impact the form, fit or function. The most significant change is the release of a new software version to support the removal of the “helical” treatment.

Performance Data:

The Onrad™ Treatment System was tested and shown to be in compliance with the requirements of applicable recognized consensus safety standards for medical devices. Results of verification and validation testing confirm the Onrad™ Treatment System conforms to design specifications and meets the needs of the intended users. No clinical tests were required to establish substantial equivalence. The performance data demonstrate the Onrad Treatment System is as safe, as effective, and performs as well as the predicate device.

Summary:

The Onrad™ Treatment System is substantially equivalent to the predicate device. The intended use, major technological characteristics, and the principles of operation of the Onrad™ Treatment System are substantially equivalent to those of the predicate device. Minor modifications do not raise new types of safety or effectiveness questions. Performance data demonstrate the Onrad™ Treatment System is as safe, as effective, and performs as well as the predicate device.

DECLARATION OF CONFORMITY WITH DESIGN CONTROLS