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

June 24, 2016

Accuray Incorporated
% Ms. Elizabeth Osuna
Regulatory Affairs Project Manager
1310 Chesapeake Terrace
SUNNYVALE CA 94089

Re: K161144
Trade/Device Name: iDMS™ Data Management System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: April 23, 2016
Received: April 26, 2016

Dear Ms. Osuna:

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,

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)*
K161144

Device Name
iDMS™ Data Management System

Indications for Use *(Describe)*
The iDMS™ Data Management System is indicated for the storage, retrieval, and processing of data utilized in the practice of radiotherapy, stereotactic radiotherapy and stereotactic radiosurgery.

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)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Precise, innovative tumor treatments™

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Name, Address, Phone and Fax number of the Applicant

Accuray Incorporated
1310 Chesapeake Terrace
Sunnyvale, California 94089
Ph: (408) 716-4600
Fax: (408) 789-4249

Contact Person

Elizabeth Osuna
Regulatory Affairs Project Manager

Date Prepared

April 21, 2016

Device Name

Trade Name:	iDMS™ Data Management System
Common Name:	Radiosurgery/radiotherapy data management system
Classification Name:	Medical charged particle radiotherapy device
Regulatory Class:	Class II
Product Code:	IYE

Predicate Device

CyberKnife® Robotic Radiosurgery System (last cleared K150873)

Device Description

The subject device, iDMS™ Data Management System, is essentially the CyberKnife® Data Management System (CDMS) cleared in the predicate device, the CyberKnife® Robotic Radiosurgery System. This submission simply establishes the iDMS™ System as a stand-alone data management system and reflects its integration with Accuray's

robotic radiosurgery and ring gantry systems, including but not limited to the CyberKnife® System and Radixact™ Treatment Delivery System which is a next generation TomoTherapy® Treatment System. As such, modifications are limited to those required to integrate the iDMS™ System with the Radixact™ System which is a next generation TomoTherapy® Treatment System.

The iDMS™ System is a data management system that provides storage, applications and interfaces to access, add, modify, export, delete, and validate patient, user and system data for Accuray's radiotherapy, stereotactic radiotherapy, and stereotactic radiosurgery delivery systems, including but not limited to the CyberKnife® System and Radixact™ Treatment Delivery System which is a next generation TomoTherapy® Treatment System, as well as treatment planning systems, including the Precision™ Treatment Planning System. The IDMS™ System can store and retrieve treatment plans and delivery data for multiple systems.

Indications for Use

The iDMS™ Data Management System is indicated for the storage, retrieval, and processing of data utilized in the practice of radiotherapy, stereotactic radiotherapy and stereotactic radiosurgery.

Intended Use

The iDMS™ Data Management System is intended to provide secure data server operations for radiation oncology facilities. Data services provided include support for multiple treatment delivery and planning systems, connectivity to radiation oncology information systems, access to remote network access services; local database access to add, modify, export, delete, review, validate, archive, and restore patient, user and system data; import, export, review, and archive patient medical images and records, provide access to administrative tools used to approve, discontinue, or disallow delivery of treatment plans; automated generation of digitally reconstructed radiographs (DRRs); import, retrieve, and export measured beam data, and access report generation tools to view, print, sign, and save patient, utilization, and worklist reports.

Intended users include physicians, radiation oncologists, dosimetrists, medical physicists, radiation therapists and administrative personnel of a radiation oncology facility. Secondary users include installation, maintenance and service engineers.
The iDMS™ Data Management System is intended for use in a clinic or hospital environment.

Substantial Equivalence

The subject device, the iDMS™ System is substantially equivalent to the data management features in the predicate system, the CyberKnife® System, in intended use, principles of operation, technological characteristics and labeling.

The energy source, design, materials and other physical properties are the same or equivalent to the predicate systems. Testing included in the premarket notification demonstrates that the performance characteristics of the device are equivalent to the data management performance of the predicate CDMS.

Testing was completed to verify that all hardware and software perform as designed, as well as regression testing to verify the integrity of existing features. Testing demonstrated that the IDMS™ System performance is equivalent to the predicate, the CDMS features.