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

.decimal, LLC
% Kevin Erhart, Ph.D.
Senior Engineer
121 Central Park Place
SANFORD FL 32771

August 7, 2015

Re: K151369
Trade/Device Name: p.d 5.1
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: May 15, 2015
Received: May 21, 2015

Dear Dr. Erhart:

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.
Acting 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)*

K151369

Device Name
p.d 5.1

Indications for Use *(Describe)*

The p.d software is used by radiation therapy professionals to assist in the design, manufacturing, and quality assurance testing of various radiation therapy devices used for cancer patients. The p.d software performs three distinct, primary functions which each are described below.

1) The p.d software takes a design of a compensating filter from a Treatment Planning System and converts the Treatment Planning System compensator filter files into a .decimal file format. This file can then be electronically submitted to .decimal through the software, so that we can manufacture the device.
2) The p.d software can design a beam shaping and compensating filters based on Treatment Planning System and other user supplied data. The device designs for compensating filters will be transferred back into the Treatment Planning System for final dose verification before devices are ordered and used for patient treatment.
3) The p.d software can perform quality assurance testing of the physical characteristics of treatment devices using data from various types of scanned images, including computed tomography images.

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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Section 5	510(k) Summary

Section 807.87 (h) A 510(k) Summary as described in Section 807.92

Premarket Notification [510(k)] Summary as required by 21 CFR 807.92

Date summary was prepared:

May 15, 2015

Submitter's Name:

.decimal, LLC
121 Central Park PL
Sanford, Florida 32771

Contact Person:

Kevin Erhart
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Email:kerhart@dotdecimal.com

Device Name:

p.d 5.1

Classification Name and Code:

Class II, MUJ, 21 CFR 892.5050 Medical charged-particle radiation therapy systems

Device Description:

The .decimal p.d device is a software application that will enable users of various radiation treatment planning systems (TPS) to design, measure, and order beam shaping and modulating devices used in the delivery of various types of radiotherapy, including photon, electron, and particle therapy. The input from the treatment planning systems to the p.d product is generally received in DICOM file format, but other vendor specific or generic file formats are also utilized. p.d will also provide a simplified radiation dose calculator for the purpose of improving its ability to accurately create/modify patient-specific radiation beam modifying devices without the need for iteration with other treatment planning systems. However, all modulating devices will have final dose verification performed in a commissioned Treatment Planning System before devices are used for patient treatment. Additionally, the p.d software contains tools for analyzing

scanned image data that aids users in performing quality assurance measurement and testing of radiotherapy devices.

Predicate Device(s):

K083672 - p.d software (version 5.0) - .decimal, LLC (Primary Predicate Device)
K141283 - Eclipse Treatment Planning System - Varian Medical Systems, Inc. (Reference Predicate Device)

Intended Use:

The intended use of the p.d software is to aid radiation therapy professionals in the design, construction, and testing of radiotherapy beam modifying devices. The software is intended to interface with most major treatment planning systems and design devices that are compatible with most major radiotherapy linear accelerators and particle therapy delivery systems. And while the primary intent is for the software to design and measure devices that are manufactured by .decimal, this does not exclude, in some cases, the software being used with devices that are constructed on-site or by other vendors (with explicit permission from .decimal).

Indications for Use:

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1) The p.d software takes a design of a compensating filter from a Treatment Planning System and converts the Treatment Planning System compensator filter files into a .decimal file format. This file can then be electronically submitted to .decimal through the software, so that we can manufacture the device.
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3) The p.d software can perform quality assurance testing of the physical characteristics of treatment devices using data from various types of scanned images, including computed tomography images.

Summary of Technological Characteristics:

The device features of p.d are similar to the predicate device p.d (K083672) as both are software applications that design and order the same types of radiotherapy beam modifying devices, using nearly identical algorithms and processes. The new version however incorporates additional quality assurance measurement tools that are

substantially equivalent to functionality found in most all major treatment planning systems (TPS), including the Eclipse TPS from Varian Medical Systems (K141283), which is used here as the predicate device for comparison of this functionality of our p.d software. It should be noted that the p.d device contains are very small subset of the functionality present in the Eclipse TPS, so specifically, the quality assurance measurements performed in p.d use algorithms that are similar to those used to build Digitally Reconstructed Radiographs (DRRs), which is a tool present in the Eclipse TPS. In addition, the semi-automatic and automatic image contouring tools of Eclipse utilize similar image processing and recognition techniques as those employed within p.d.

Summary of Non-Clinical Testing:

Clinical testing was not performed as part of the development of this product. Clinical testing is not advantageous in demonstrating substantial equivalence or safety and effectiveness of the device since testing can be performed such that no human subjects are exposed to risk.

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

The software for this device was considered as a "Major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator. Clinically oriented validation tests were written and executed by .decimal personnel and hospital-based testing partners. Validation tests included comparing results to those of known predicate devices as well as performing quality assurance measurements on devices of known quality. In addition this device was evaluated and conforms to ISO 14971, IEC 62083, IEC 61217, IEC 62304 and IEC 62366 standards.

These tests show that the p.d software performed equivalently to the predicate device when appropriate and that the software is deemed safe and effective for clinical use.