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

May 15, 2015

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

Re: K150547
Trade/Device Name: .decimal Astroid Dosimetry App
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: March 9, 2015
Received: March 11, 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)*
K150547

Device Name
Astroid Dosimetry App

Indications for Use *(Describe)*
The .decimal astroid Dosimetry App device is used for planning and analysis of proton radiation therapy treatments. The Dosimetry App serves as a tool which provides tested and validated calculation and design functions for use in other end-user applications. The Dosimetry App provides access to the functions that make up what is considered much of the core components of a typical proton treatment planning system. Through the use of these functions in user generated scripts or programs, users will be able to design and/or analyze proton treatment plans for regular and irregular fields using custom designed blocks and range compensators. Additionally, the functions provided by this device can also allow users to generate programs and scripts capable of performing treatment preparation and plan analysis tasks, such as structure/contour modification, image data analysis, and secondary dose calculation checks. Users should be experienced computer programmers, researchers, and physicists that contain a strong working knowledge of proton radiation therapy and general treatment planning processes.

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.

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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:

February 25, 2015

Submitter's Name:

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121 Central Park PL
Sanford, Florida32771

Contact Person:

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Device Name:

Astroid Dosimetry App

Classification Name:

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

Device Description:

The .decimal Astroid Dosimetry App device is used for planning and analysis of proton radiation therapy treatments. The Dosimetry App device is not an interactive end user application. Users of the system will write scripts or fully interactive software programs that make calls to the functions provided by the Astroid Dosimetry App. In essence, this device serves a foundational proton dosimetry calculation library that greatly reduces the burden and time required to develop treatment planning and plan analysis software by making readily available much of the core functionality common to these types of applications. This core functionality includes various CT image processing tools, structure and contour modification operators, proton dose calculations, proton aperture and range compensator device design algorithms, and other low-level radiotherapy specific calculation functions.

Predicate Device(s):

Proton Vision 7.0 K002312
RayStation 3.5 K130617

Intended Use:

The intended use for the Astroid Dosimetry application is to aid software developers in accessing calculation functions necessary in developing, analyzing, and testing proton radiation therapy software programs and algorithms. This device serves a foundational proton dosimetry calculation library that greatly reduces the burden and time required to develop treatment planning and plan analysis software by making readily available much of the core functionality common to these types of applications. These core functions will allow users to perform image processing, proton dose calculation, proton device design, and other plan review and analysis tasks.

Indications for Use:

The .decimal Astroid Dosimetry App device is used for planning and analysis of proton radiation therapy treatments. The Dosimetry App serves as a tool which provides tested and validated calculation and design functions for use in other end-user applications. The Dosimetry App provides access to the functions that make up what is considered much of the core components of a typical proton treatment planning system. Through the use of these functions in user generated scripts or programs, users will be able to design and/or analyze proton treatment plans for regular and irregular fields using custom designed blocks and range compensators. Additionally, the functions provided by this device can also allow users to generate programs and scripts capable of performing treatment preparation and plan analysis tasks, such as structure/contour modification, image data analysis, and secondary dose calculation checks. Users should be experienced computer programmers, researchers, and physicists that contain a strong working knowledge of proton radiation therapy and general treatment planning processes.

Summary of Technological Characteristics:

The astroid Dosimetry App technology is substantially equivalent to both the listed predicate devices. The astroid Dosimetry App, ProtonVision 7.0, and RayStation 3.5 all provide tools to calculate, analyze, and otherwise compare potential treatment plans for proton radiation therapy courses. All three systems allow for estimation of proton energy ranges, design of patient-specific treatment devices, and provide proton dose calculations that rely on machine specific proton beam models. While the predicate devices do also include functionality for direct display of results, this does not detract from the point that the underlying functions contained within all three systems are substantially equivalent.

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. Clinically oriented validation test cases were written and executed by .decimal personnel and hospital-based testing partners. Validation tests comparing results of proton dose calculations, with the inclusion of all applicable treatment delivery devices, to experimental and analytical datasets were performed. Additional verification and validation tests were also performed for all other functions available for external use through the system. These tests show that the astroid Dosimetry App performed as well as the predicate devices and that the astroid Dosimetry App is deemed safe and effective for clinical use.