December 13, 2019

.decimal, LLC
% Kevin Erhart, Ph.D.
President/Chief Technology Officer
121 Central Park Place
SANFORD FL 32771

Re: K192554
Trade/Device Name: decimal3D
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: October 14, 2019
Received: October 15, 2019

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*
K192554

Device Name
decimal3D

Indications for Use *(Describe)*
The primary purpose and intended use of this device is to improve the efficiency of designing patient specific radiation therapy beam-shaping block devices through the use of optical scanning technology. This device will serve as a direct replacement to the current processes for designing such radiotherapy devices in cases where a "clinical patient set up" is used (i.e. cases where the treatment field is determined by direct physician examination, not by internal imaging technology).

This product is not intended to replace CT imaging or other internal imaging modalities and should be used only in cases where a qualified radiation oncologist has made appropriate determination of the acceptability of a "clinical patient set up" approach, independent of any information provided by this application. In other words, the role of this product is to simply ensure efficient and accurate ordering of a patient-specific beam-shaping block device from our company, in cases where a licensed radiation oncologist has predetermined that such a device and treatment approach is appropriate for the patient at hand. Thus this device's indications for use include patients with a variety of cancer and disease conditions, which will be treated under the direct supervision and guidance of a radiation oncologist that has prescribed a desired dose of radiation to be delivered to the patient.

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.

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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:

November 21, 2019

Submitter's Name:

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

Contact Person:

Kevin Erhart, PhD
President/Chief Technology Officer
Phone: 407-330-3300
Fax: 407-322-7546
Email:kerhart@dotdecimal.com

Device Name:

decimal3D (K192554)

Classification Name:

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

Device Description:

This device is a software product with the primary purpose to improve the efficiency of designing patient specific radiotherapy treatment devices. It uses proven off-the-shelf optical scanning technology to replace portions of the current clinical treatment device design workflow to achieve this goal. Specifically, this device uses an off-the-shelf depth sensing scanner to accurately capture and construct a full color, 3D model of a patient's treatment area. This scanner captures dimensionally accurate depth information in real-time using a combination of a structured light field infrared projector and infrared camera, and is coupled with a color camera to provide precise, full color, 3D models of patients without exposing them to any harmful radiation.

Our decimal3D software is an iPad application that guides users through the process of capturing a scan of a patient. It then provides tools that allow users to digitize the treatment area, which is pre-drawn on the patient's skin by the radiation oncologist, on the 3D model. Users also specify other device parameters, such as their treatment machine type, applicator size, and treatment direction, which allows the decimal3D software to complete the design of their treatment device. Finally, our software allows them to view and order the device for fabrication by our company. This process is directly analogous to the current digitization process in the existing clinical workflow except the predicate software device requires the user to use a clear plastic template placed in the head of the actual treatment delivery machine to project the device shape to the patient's skin surface using a light field. This acrylic template is then scanned using a flatbed document scanner and the shape is digitized in 2D using the predicate software.

Predicate Device(s):

.decimal p.d K151369

Intended Use:

The primary purpose and intended use of this device is to improve the efficiency of designing patient specific radiotherapy devices. This device will serve as a direct replacement to the current processes for designing such patient-specific radiotherapy devices. One such common current process is for electron therapy clinical setups, which involves hand drawing of the patient-specific aperture shape onto a semi-transparent "template" block, using the treatment light field to verify accuracy against the treatment area that has been outlined directly on a patient by the treating physician. This now flattened and projected aperture shape can then be scanned and digitized allowing for computer controlled fabrication. This decimal3D device will replace this process by providing a means to accurately scan and digitize the treatment area. This device also provides a means for designing and ordering the required devices.

Indications for Use:

The primary purpose and intended use of this device is to improve the efficiency of designing patient specific radiation therapy beam-shaping block devices through the use of optical scanning technology. This device will serve as a direct replacement to the current processes for designing such radiotherapy devices in cases where a "clinical patient set up" is used (i.e. cases where the treatment field is determined by direct physician examination, not by internal imaging technology).

This product is not intended to replace CT imaging or other internal imaging modalities and should be used only in cases where a qualified radiation oncologist has made appropriate determination of the acceptability of a "clinical patient set up" approach, independent of any information provided by this application. In other words, the role of this product is to simply ensure efficient and accurate ordering of a patient-specific beam-shaping block device from our company, in cases where a licensed radiation oncologist has predetermined that such a device and treatment approach is appropriate for the patient at hand. Thus this device's indications for use include patients with a variety of cancer and disease conditions, which will be treated under the direct supervision and guidance of a radiation oncologist that has prescribed a desired dose of radiation to be delivered to the patient.

Summary of Technological Characteristics:

decimal3D technology is substantially equivalent to the listed predicate device p.d (K151369). decimal3D and p.d both provide tools to digitize physician outlined treatment fields into patient-specific devices to be used in radiotherapy treatment delivery. Both p.d and decimal3D include displays for visualizing the physician drawn shape and tools for digitizing this image into a two dimensional contour. Unlike p.d, decimal3D provides a mechanism to directly capture the physician drawn treatment area rather than importing this image from a separate system. However, this does not detract from the point that the features included in both software for creating the patient device are substantially equivalent in terms of technology, intended uses, and end user profiles.

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 where this device was deemed safe and effective for clinical use. The tests show that this device performed as well as the predicate device and demonstrated that the quality of the resulting surface scans is sufficient to provide the accuracy needed to design patient specific beam shaping devices.