.decimal, LLC
℅ Kevin Erhart, Ph.D.
President/CTO
121 Central Park Place
SANFORD FL 32771

July 1, 2021

Re: K211511
Trade/Device Name: decimal Bolus
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ, IXI
Dated: April 22, 2021
Received: May 14, 2021

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,

For

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211511

Device Name
decimal Bolus

Indications for Use *(Describe)*
The decimal Bolus product is a solid piece of material (rigid or rubber-like) that will be placed on the skin of a patient with the intended use and primary purpose of helping control the dose received by that patient when undergoing radiation therapy treatment. decimal Bolus devices are designed by radiation therapy professionals to a unique shape that is specific to each patient being treated. The device is intended to modify the dose delivered during a radiation therapy treatment. As this product is a simple general purpose bolus device, the intended patient population and indications for use are quite broad. The most common indications for use are for the treatment of patients receiving radiation therapy, which encompasses a wide range of potential disease types and locations. As such, these devices will be required to have a wide range of potential shapes, sizes, and material properties and each device must be tested and approved by the radiation therapy professional prior to use on a 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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.decimal®
The benchmark for custom radiation therapy

Section 5	510(k) Summary	K211511

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:

April 22, 2021

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:

decimal Bolus

Common Name:

Bolus / Custom Bolus

Classification Name:

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

Device Description:

The decimal Bolus product is a solid piece of material (rigid or rubber-like) that will be placed on the skin of a patient with the intended use and primary purpose of helping control the dose received by that patient when undergoing radiation therapy treatment. decimal Bolus devices will be manufactured according to the unique, patient-specific shape requested by a clinical customer. Trained radiation therapy professionals will create the bolus device design. In the most common use case, the devices are designed to increase the dose that will be delivered at the patient's skin surface for the treatment of superficial tumors. In this case the decimal Bolus operates as a "build-up" region, which is necessary as radiation dose is typically at its maximum strength slightly below the entrance surface. Such treatments may occur anywhere on a patient's body. As such, these devices will be required to have a wide range of potential shapes and sizes and material properties.

Predicate Device:

.decimal Bolus Compensator K091911

Intended Use:

The decimal Bolus product is placed on the skin of a patient with the intended use and primary purpose of helping control the dose received by that patient when undergoing radiation therapy treatment. decimal Bolus devices will be manufactured according to the unique, patient-specific shape requested by a clinical customer.

Indications for Use:

The decimal Bolus product is a solid piece of material that will be placed on the skin of a patient with the intended use and primary purpose of helping control the dose received by that patient when undergoing radiation therapy treatment. decimal Bolus devices are designed by radiation therapy professionals to a unique shape that is specific to each patient being treated. The device is intended to modify the dose delivered during a radiation therapy treatment. As this product is a simple general purpose bolus device, the intended patient population and indications for use are quite broad. The most common indications for use are for the treatment of patients receiving radiation therapy, which encompasses a wide range of potential disease types and locations. As such, these devices will be required to have a wide range of potential shapes, sizes, and material properties and each device must be tested and approved by a radiation therapy professional prior to use on a patient.

Summary of Technological Characteristics:

The decimal Bolus device is substantially equivalent to the listed predicate device as well as many other off-the-shelf generic bolus products. Much like the Bolus Compensator predicate, the decimal Bolus device is custom manufactured to the unique size and shape

of an individual patient to improve the fit and improve day-to-day reproducibility. Both devices rely on external software tools to aid clinicians in designing the devices, and both also require the clinical end users to test and approve the devices for their individual patients prior to use. The new device and the predicate both are constructed from skin-safe, homogeneous materials and are used to control the dose delivered to patients when undergoing radiation therapy treatments. Unlike the predicate, the decimal Bolus device may use flexible material, improving the fit and comfort for the patient and reducing the likelihood of undesirable air gaps between the bolus and patient skin. As the design, end use, and acceptance testing of the product is the same as the predicate, the changes in material and manufacturing approaches do not impact the safety or risk associated with use of the device.

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, safety, or 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. This testing showed that this design provides well-fitting bolus devices, with homogeneous material composition, performing as well or better than the predicate device in all areas tested, indicating the decimal Bolus device is safe for routine clinical use. These validation tests are documented in section 18 herein.