.decimal®
The benchmark for custom radiation therapy

K132236
Page 1 of 3

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:

July 17, 2013

Submitter's Name:

.decimal, Inc.
121 Central Park Pl
Sanford, Florida 32771

OCT 16 2013

Contact Person:

Kimberly Rupp
Quality and Regulatory Affairs Manager
Phone: 407-330-3300
Fax: 407-322-7546
Email: krupp@dotdecimal.com

Device Name:

.decimal Proton Aperture

Classification Name:

IXI
21 CFR 892.5710 "Radiation Therapy Beam Shaping Block"
Class II

Device Description:

The .decimal Proton Aperture is a Brass Core encased in a reusable steel ring (or material with similar attenuating properties) with a 2D hole cut from it, which defines the area that is to be treated with a proton beam. The design for a .decimal Proton Aperture is generated out of a customer's treatment planning system (TPS) or physician's specifications and is unique to each patient. The device functions as a beam shaping

block. The apertures are inserted into the gantry's snout to shape and focus the beam as it exits the gantry en route to the targeted area. As radiation is passed through the gantry, the beam passes through aperture and it will be blocked. The opening of the aperture where there is no brass, the radiation will pass through targeted area defined by the radiation therapy professional. The operating principles are explained in section 12 of this submittal.

Predicate Device(s):

.decimal Proton Aperture (K121657), .decimal Inc., .decimal, Inc.

Intended Use:

.decimal's Aperture manufacturing service manufactures the ring and solid core apertures for intensity modulation of external beam proton radiation therapy. The apertures are designed by the customer's treatment planning system to block radiation from hitting critical structures and healthy tissue while guiding the radiation to the targeted area.

Indications for Use:

.decimal's Aperture manufacturing service manufactures the ring and solid core apertures for intensity modulation of external beam proton radiation therapy. The apertures are designed by the customer's treatment planning system to block radiation from hitting critical structures and healthy tissue while guiding the radiation to the targeted area.

Summary of Technological Characteristics:

The device features of .decimal's Apertures are similar to the predicate device .decimal Proton Aperture. They both are used for external beam radiation therapy treatments, they both are used to block radiation and guide it to affected areas. The target population is identical and the use parameters are also very similar.

A detailed comparison can be found in section 10 of this submittal.

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 in house by .decimal personnel where Proton Apertures were deemed safe and effective for clinical use. The tests show that .decimal Proton Apertures performed as well as the

predicate device. A declaration of conformity to this requirement can be found in section 18 of this document.

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, Inc.
% Ms. Kimberly Rupp
Quality & Regulatory Affairs Manager
121 Central Park Place
SANFORD FL 32771

October 16, 2013

Re: K132236
Trade/Device Name: .decimal Proton aperture
Regulation Number: 21 CFR 21 CFR 892.5710
Regulation Name: Radiation therapy beam-shaping block
Regulatory Class: Class II
Product Code: IXI
Dated: July 17, 2013
Received: July 18, 2013

Dear Ms. Rupp:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132236

Device Name: .decimal Proton Aperture

Indications for Use:

.decimal's Aperture manufacturing service manufactures the ring and solid core apertures for intensity modulation of external beam proton radiation therapy. The apertures are designed by the customer's treatment planning system to block radiation from hitting critical structures and healthy tissue while guiding the radiation to the targeted area.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael O'Hara

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) ___K132236___