K061440

JUN 27 2006

Section 807.87 (h) A 510(k) Summary as described in Section 807.92 or a 510(k) statement as described in 807.93

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

Date summary was prepared:

May 2006

Submitter's Name:

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

Contact Person:

Daniel L. Bennett
Quality Manager
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Email:dbennett@dotdecimal.com

Device Name:

p.d

Classification Name:

90 MUJ
21 CFR892.5050
Class II

Predicate Device(s):

Computerized Medical Systems Inc. (CMS) Xio Radiation Treatment Planning System, K032762

Intended Use:

.decimal created a software translator to be used with a Radiation Therapy Treatment Planning Systems (TPS). The software takes the TPS design of a compensating filter used for radiation therapy which contains steep, narrow, and unmachinable areas and

then smoothes them out into a machinable surface. The customer will use the software in-house before sending the file to .decimal to be manufactured. Each filter must be verified as being correct by the customer prior to use on a patient.

Summary of Technological Characteristics:

The technological characteristics of p.d are listed below and attached in section 11 of this document:

PD-11 p.d Software Validation
DMR-04 p.d Device Master Record

Summary of Clinical Testing:

Please see Section 12 of this document for the summary of clinical testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 27 2006

Mr. Daniel L. Bennett
Quality Manager
.Decimal, Inc.
121 Central Park Place
SANFORD FL 32771

Re: K061440
Trade/Device Name: p.d
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: May 16, 2006
Received: May 24, 2006

Dear Mr. Bennett:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0120

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known) K061440

Device Name: p.d

Indication for Use: The p.d software takes a Treatment Planning System design of a compensating filter used for radiation therapy which contains steep, narrow, and unmachinable areas and then smoothes them out into a machinable surface. The customer will use the software in-house before sending the file to .decimal to be manufactured. Each filter must be QA'd by the customer before use on a patient.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061440