K030175

APR 17 2003

CAPINTEC, INC.

January 15, 2003

RE: Summary of Safety and Effectiveness Information for the Capintec 2 Basic

Manufacturing and Service Center
Capintec, Inc.
540 Alpha Drive
Pittsburgh, PA 15238
Phone 412-963-1988
FAX 412-963-0610

Corporate Office
Capintec, Inc.
6 Arrow Road
Ramsey, NJ 07446
Phone 201-825-9500
FAX 201-825-1336

Establishment Registration Number 2518443

Contact information
Mary Anne Dell, M.S.
VP and General Manager
Phone 412-963-1099
FAX 412-963-0610
Email madell@capintec.com

Trade name or common name
2 Basic

Type of Submission
Traditional 510(k)

Classification of Device
Class II, Accessory to Linear Accelerator, Radiology Panel

Intended Use
The 2 Basic is intended to be used by trained medical physicist to measure the radiation output from radiation therapy machines for verification of patient treatment plan, quality assurance, or beam characteristics. It is not intended to function as a primary calibration device. The 2 Basic can be used in direct surface contact with patients or in a phantom material.

K034175

Product Description: The Capintec 2 Basic system consists of 2 diode detectors permanently attached to a precision electrometer and application software. The detectors are solid state silicon diodes with a hemispherical shape optimized for direct patient contact. They provide high sensitivity, excellent linearity, and uniform output vs. gantry angle. The diodes are completely water resistant and enclosed in biocompatible molded epoxy. The high precision electrometer measures the current from the detector and converts the value into a displayed dose and provides automatic zero compensation. Application software controls the system and stores measurement data for each detector, and associated beam parameters such as energy, MU, and patient demographic data. Data can be stored on the PC or printed for hard copy record. Customer must supply a UL recognized PC to be used with application software.

Predicate Device: Predicate Devices submitted by Theta Systems, Inc. Model PDM/2 Patient Dose Monitor 510(k) Number K912249 and Isorad Integral Buildup Photon Diodes 510(k) Number K912250. The 2 Basic uses the Equidose Diode Detector Design submitted by MasTek DEM, Inc. 510(k) Number K980826

The 2 Basic meets the following Safety Standards
Medical Electrical Equipment, Part 1 General Requirements – UL2601-1:2nd
Medical Electrical Equipment, Part 1 General Requirements – IEC60601-1:
Collateral standard: Electromagnetic Compatibility-IEC 60601-1-2
Medical Electrical Equipment, Part 1 General Requirements for Safety
Medical Electrical Equipment, Part 1 General Requirements-Can/CSA C22.2 No.606101-M90
Medical Electrical Systems-IEC 606601-1-1:1993+A1
IEC 60601-2-9 Patient Contact Dosimeters Used in Radiation Therapy with Electrically Connected Radiation Detectors.

The risk analysis, safety testing and verification and validation testing has addressed patient contact hazards, software hazards, and operator hazards and concluded that the unit is safe and fully meets the intended use and stated specifications of the product.

540 Alpha Drive • Pittsburgh, PA 15238 U.S.A. • (412) 963-1988 FAX (412) 963-0610

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2003

Ms. Mary Anne Dell
Vice President and General Manager
Capintec, Inc.
540 Alpha Drive
PITTSBURG PA 15241

Re: K030175
Trade/Device Name: 2 Basic
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: January 15, 2003
Received: January 17, 2003

Dear Ms. Dell

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 (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); 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Appendix 2

Indications for Use Form

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510(k) Number K030175

Device Name: 2 Basic

Indications For Use: The 2 Basic is a solid state diode detector system coupled with a precision electrometer and PC for radiation measurement, data storage and display. It is intended to be used by trained medical physicists for the measurement of radiation output from radiation therapy treatment machines. The 2 Basic can be used with direct patient contact for entrance skin measurements, or in air, water, or other suitable phantoms materials for beam output measurements.

Measurement data is used to verify and document the beam characteristics of radiation therapy treatment machines for quality assurance programs and to very therapeutic doses delivered to patients during treatments.

(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)

(Optional Format 1-2-96)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030175