EXHIBIT #7

APR 24 1998

K980402

CAPINTEC, INC.

510(k) SUMMARY

Submission Date: January 30, 1998

Pursuant to the requirements of Section 510(k) of the Food, Drug, and Cosmetic Act, notification is made of the intention of Capintec, Inc. to manufacture and market an electrometer used for output measurements of therapeutic x-ray machines, teletherapy units, or radioactive sources.

Capintec is divided into two physical locations as follows:

Corporate Headquarters
Capintec, Inc.
6 Arrow Road
Ramsey, New Jersey 07446
Phone 201-825-9500
FAX 201-825-1336

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

Contact Person: Mary Anne Dell
Contact Site: Manufacturing Facility

Classification Name: Electrometer
Classification Number: IYE (892.5050) (accessory item to linear accelerator)
Common or Usual Name: Electrometer
Proprietary Name: Capintec Model 292 Electrometer
Establishment Registration Number: 2518843
Regulatory Class: II

Description: The 292 is a precise and accurate software controlled low impedance electrometer with four measurement ranges, adjustable ± bias voltage which can act as a dose or dose rate meter.

Substantial equivalence: The model 292 is a microprocessor based upgrade of the model 192 electrometer. Both units perform exactly the same function, measure current with high precision over a select range of interest, and convert the measured current to radiological units with appropriate conversion factors. Both units were developed for use with the same ionization chambers, and same application. The model 192 uses analog circuitry for measurement and calibration, while the 292 has replaced the analog circuitry with microprocessor based technology to provide enhanced performance specifications and better data manipulation. The 192 is a pre-amendment device which was first manufactured and distributed in 1973, and is still sold today.

Intended Use: The Capintec 292 electrometer is intended to be used by trained medical physicists or qualified radiation therapy technologists to perform quality assurance checks and measurements on the output from therapeutic linear accelerators or teletherapy units. With the addition of a Capintec CRC dose calibrator chamber, the 292 may also be used by trained medical physicists or qualified technologists to measure radioactive sources used for therapeutic or diagnostic treatment.

Test Results: The same NIST calibrated ionization chamber was used with both the 192 and 292 electrometers, and measurements were made under a variety of accelerator and orthovoltage machine settings. Test results from both electrometers show excellent agreement to the limits of the reproducibility of the individual x-ray machines. In addition, the software algorithms were verified against manual calculations and agreement was 100%.

After the addition of a CRC dose calibrator chamber to the 292, the same NIST radioactive sources were measured on the 292 and a CRC 15R dose calibrator. Results agreed to within 1%.

Capintec has released several 292 units to selected radiation oncology facilitates for clinical testing and evaluation and provided testing procedures to each site. Acceptance criteria is 100% success in function and intended use. Suggestions received for improvement in the software or hardware from these "beta test sites" will be evaluated, tested, and incorporated when appropriate. Any problems discovered during this process will be corrected prior to release to production for commercial shipment.

Conclusion: The 292 functions as intended and is substantially equivalent in performance and intended use to the 192 electrometer for measurement of output from therapy x-ray machines and equivalent to the CRC15R dose calibrator in performance and intended use for the measurement of radioactive sources used in therapy or diagnostic applications. The 292 provides significantly improved performance specifications and better data manipulation compared to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 24 1998

Mary Anne Dell, M.S.
General Manager and Radiation Physicist
Capintec, Inc.
540 Alpha Drive
Pittsburgh, PA 15238

Re: K980402
Capintec Model 292 Electrometer
Dated: January 30, 1998
Received: February 2, 1998
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Ms. Dell:

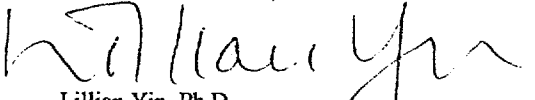
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K980402

Device Name: CAPINTEC MODEL 292 ELECTROMETER

Indications For Use:

THE CAPINTEC 292 ELECTROMETER IS INTENDED TO BE USED BY TRAINED MEDICAL PHYSICISTS OR QUALIFIED RADIATION THERAPY TECHNOLOGISTS TO PERFORM QUALITY ASSURANCE CHECKS AND MEASUREMENTS ON THE OUTPUT FROM THERAPEUTIC X-RAY MACHINES OR TELETHERAPY UNITS.

WITH THE ADDITION OF AN OPTIONAL CAPINTEC CRC DOSE CALIBRATOR CHAMBER, THE 292 MAY ALSO BE USED BY TRAINED MEDICAL PHYSICISTS OR QUALIFIED TECHNOLOGISTS TO MEASURE RADIOACTIVE SOURCES USED FOR THERAPEUTIC OR DIAGNOSTIC TREATMENT.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K980402

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

(Optional Format 1-2-96)